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1–5–05 Wednesday
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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 983

[Docket No. FV02–983–1 FR]

Pistachios Grown in California; Delay of the Effective Date for Aflatoxin, Size and Quality Requirements

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule; delay of effective date.

SUMMARY: This document delays the effective date from February 1, 2005, to August 1, 2005, for aflatoxin, size and quality requirements established under Marketing Order No. 983 (order). The order regulates the handling of pistachios produced in California. Sections 983.38 through 983.45 of the order establish maximum aflatoxin along with minimum size and quality requirements for California pistachios. The Administrative Committee for Pistachios, which is responsible for locally administering the order, recommended the delay in the effective date. Postponing the effective date of the regulations will provide the industry and the newly established administrative committee with additional preparation time needed to meet the aflatoxin, size and quality requirements of the order. Also, the postponed effective date would correspond with the beginning of the 2005 crop year.

DATES: The effective date of §§ 983.38 through 983.45 of 7 CFR part 983 published at 69 FR 17844 is delayed until August 12, 2005.

FOR FURTHER INFORMATION CONTACT: Melissa Schmaedick, Marketing Specialist, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, P.O. Box 1035, Moab, Utah 84532; telephone: (435) 259–7988, Fax: (435) 259–4945; or Rose Aguayo, Marketing Specialist, California Marketing Field Office, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 2202 Monterey Street, suite 102B, Fresno, California 93721; telephone: (559) 487–5901, Fax: (559) 487–5906.

Small businesses may request information on complying with this regulation by contacting Jay Guerber, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., STOP 0237, Washington, DC 20250–0237; telephone: (202) 720–2491, Fax: (202) 720–8938, or e-mail: *Jay.Guerber@usda.gov.*

SUPPLEMENTARY INFORMATION: This document delays the effective date from February 1, 2005, to August 1, 2005, for aflatoxin, size and quality provisions established under Marketing Order No. 983 (order). The order, which became effective in April 2004, regulates the handling of pistachios produced in California. Sections 983.38 through 983.45 of the order establish maximum aflatoxin along with minimum size and quality requirements for California pistachios, and were scheduled to become effective on August 1, 2004.

The Administrative Committee for Pistachios (Committee) recommended the delay in the effective date at a December 8, 2004, meeting. The Committee voted unanimously that postponing the effective date will provide the industry and the Committee with additional time to establish rules, regulations, and program procedures needed to implement the aflatoxin, size and quality requirements of the order. Rules, regulations and program procedures are recommended by the Committee, which is responsible for locally administering the order, for approval by the Secretary. Postponing the effective date of the order's regulatory provisions will allow the new Committee time to become more established and actively participate in implementing the order.

Also, the postponed effective date would correspond with the beginning of the 2005 crop year. Given that the California pistachio marketing order is a newly established regulatory program, the Agricultural Marketing Service deems that the coordination of program reporting and recordkeeping requirements with the beginning of the program's fiscal and crop year as important to successful implementation of the order.

Thus, the effective date of §§ 983.38 through 983.45 should be delayed until August 1, 2005. This delay will provide sufficient time for the Committee to recommend any rules and regulations deemed necessary.

List of Subjects in 7 CFR Part 983

Marketing agreements, Pistachios, Reporting and recordkeeping requirements.

Authority: 7 U.S.C. 601–674.

Dated: December 29, 2004.

A. J. Yates,

Administrator, Agricultural Marketing Service.

[FR Doc. 05–182 Filed 1–4–05; 8:45 am]

BILLING CODE 3410–02–M

DEPARTMENT OF HOMELAND SECURITY

8 CFR Part 241

[ICE No. 2317–04]

RIN 1653–AA41

DEPARTMENT OF JUSTICE

8 CFR Parts 1240 and 1241

[EOIR No. 146F; AG Order No. 2746–2004]

RIN 1125–AA50

Execution of Removal Orders; Countries to Which Aliens May Be Removed

AGENCY: United States Immigration and Customs Enforcement, Department of Homeland Security; Executive Office for Immigration Review, Department of Justice.

ACTION: Final rules.

SUMMARY: The Secretary of Homeland Security and the Attorney General publish these final rules to amend their respective agencies' regulations pertaining to removal of aliens.

With the Department of Homeland Security final rule, the Secretary of Homeland Security adopts as final, without substantial change, the proposed regulations published at 69 FR 42910 (July 19, 2004). The Department of Homeland Security amends its

regulations to clarify that acceptance by a country is not required under specific provisions of section 241(b) of the Immigration and Nationality Act in order to remove an alien to that country, and that a "country" for the purpose of removal is not premised on the existence or functionality of a government in that country. This rule further clarifies the countries to which an alien may be removed and the situations in which the Secretary of Homeland Security will remove an alien to an alternative or additional country. Additionally, this rule provides technical changes as a result of amendments to the Immigration and Nationality Act by the Homeland Security Act of 2002.

With the Department of Justice final rule, the Attorney General adopts as final, without substantial change, the proposed regulations at 69 FR 42911 (July 19, 2004). The Department of Justice clarifies the procedure for an alien to designate the country to which he or she would prefer to be removed, provides that the immigration judge shall inform any alien making such a designation that he or she may be removed to another country under section 241(b) of the Immigration and Nationality Act in the discretion of the Secretary of Homeland Security in effecting the foreign policy of the United States, and clarifies the effect of an identification of a country for removal in an immigration judge's order of removal from the United States. This rule clarifies that acceptance by a country is not a factor to be considered by the immigration judge in identifying a country or countries of removal in the administrative order of removal. The Department of Justice also makes technical changes to eliminate unnecessary provisions and update references to reflect the enactment of the Homeland Security Act of 2002.

DATES: These final rules are effective February 4, 2005.

FOR FURTHER INFORMATION CONTACT: If you have questions regarding the Department of Homeland Security's final rule, call: Mark Lenox, U.S. Immigration and Customs Enforcement, Department of Homeland Security, 801 I Street, NW., Suite 800, Washington, DC 20536, telephone (202) 616–9166 (not a toll-free call).

If you have questions regarding the Department of Justice's final rule, call: Mary Beth Keller, General Counsel, Executive Office for Immigration Review, 5107 Leesburg Pike, Suite 2600, Falls Church, Virginia 22041, telephone (703) 305–0470 (not a toll-free call).

SUPPLEMENTARY INFORMATION:

Department of Homeland Security

PART 241—Apprehension and Detention of Aliens Ordered Removed.

Department of Justice

PART 1240—Proceedings to Determine Removability of Aliens in the United States.

PART 1241—Apprehension and Detention of Aliens Ordered Removed.

On July 19, 2004, the Department of Homeland Security (DHS) and the Department of Justice (Justice) jointly published proposed rules with request for comments entitled "Execution of Removal Orders; Countries to Which Aliens May Be Removed" (69 FR 42901). In response to the proposed rulemaking, DHS received a total of 18 separate timely submissions and Justice received a total of 23 separate timely submissions. The commenters included various nongovernmental organizations (NGOs), private attorneys, and other interested individuals. Many of the submissions were duplicates sent to both DHS and Justice that either used or otherwise substantially adopted one set of comments submitted collectively by a group of NGOs. The majority of these comments did not differentiate between the authority of DHS or Justice. Accordingly, to the extent that these rules address two independent sources of authority in this area, the comments are addressed by the appropriate agency with authority over the area raised by the commenter. Additionally, because many of the comments submitted to both DHS and Justice are similar and endorse the submissions of other commenters, the Secretary and the Attorney General address the responses by topic rather than by referencing each specific commenter and comment.

DHS and Justice hereby incorporate the Supplementary Information contained in the Notice of Proposed Rulemaking, 69 FR 42901, 42902–09, and reiterate that the Secretary and the Attorney General have undertaken to publish these changes in their respective regulations in a single document as a convenience to the public. The Secretary and the Attorney General are each acting independently and within their respective statutory delegations of authority in separately amending the rules of their respective Departments as set forth in these final rules. The rules of DHS and Justice will continue to separately implement the provisions of the Immigration and Nationality Act (Act) within their respective jurisdictions.

A. The Purpose of the Final Rule

Section 241(b)(1) and (2) of the Act, 8 U.S.C. 1231(b)(1) and (2), provides the process for determining the countries to which an alien [1] may be removed after a hearing before an immigration judge, the issuance of a final order finding that the alien is removable from the United States and not eligible for relief from removal, and disposition of any administrative and judicial appeals.

Section 241(b)(1) of the Act, 8 U.S.C. 1231(b)(1), relates to arriving aliens [1] whom DHS has placed in removal proceedings, a relatively small category because most arriving aliens are subject to expedited removal under section 235 of the Act, 8 U.S.C. 1225. It should be noted that the authority to initiate expedited removal proceedings in certain circumstances has recently been expanded. *See* Notice Designating Aliens for Expedited Removal, 69 FR 48877 (August 11, 2004) (authorizing expedited removal proceedings for aliens present in the United States without having been admitted or paroled, who are encountered within 100 miles of the border, and who cannot establish that they have been physically present in the United States continuously for the preceding fourteen days); Notice Designating Aliens Subject to Expedited Removal Under Section 235(b)(1)(A)(iii) of the Immigration and Nationality Act, 67 FR 68924 (November 13, 2002) (authorizing expedited removal proceedings for certain aliens who arrive in the United States by sea, who are not admitted or paroled, and who have not been continuously

[1] The rules and this **SUPPLEMENTARY INFORMATION** use two distinct terms: the term "alien" is broader than the term "respondent," which includes aliens only while they are in removal proceedings. Accordingly, the Department of Homeland Security rule uses the term "alien," the Department of Justice rule uses the term "respondent," and the **SUPPLEMENTARY INFORMATION** uses the term that is applicable in the specific context. The Act generally uses the term "alien" and is not as discrete as the regulations.

physically present in the United States for the preceding two years). Section 241(b)(1) of the Act provides a two-step process to determine the country of removal for an arriving alien: (1) The country from which the alien boarded a conveyance to the United States; or (2) an alternative country, such as the country of citizenship or birth.

Section 241(b)(2) of the Act, 8 U.S.C. 1231(b)(2), applies in the far more common circumstance of the removal of other (*i.e.*, non-arriving) aliens. Section 241(b)(2) of the Act provides a three-step process to determine the country of removal for these aliens: (1) The country designated by the alien; (2) an alternative country of which the alien is a subject, national, or citizen, with certain conditions; and (3) an additional country, such as the country from which the alien boarded a conveyance to the United States or the country of the alien's residence or birth.

Sections 241(b)(1) and (2) of the Act use the terms "country" and "accept" without any statutory definition. Some subparagraphs within section 241(b)(2) of the Act state that the alien is to be removed to a "country" that will "accept" the alien, while other provisions do not state that a "country" must "accept" the alien. The United States courts of appeals have differed on the meaning and effect of these terms. *Compare Jama* v. *INS*, 329 F.3d 630 (8th Cir. 2003), *cert. granted*, 124 S.Ct. 1407 (2004) (No. 03–674), with *Ali* v. *Ashcroft*, 346 F.3d 873 (9th Cir. 2003), *petition for reh'g pending* (No. 03–35096, 9th Cir.). These rules implement the provisions of the Act and amend the regulations of DHS and Justice in response to this intercircuit conflict.

B. Discussion of Comments

The following paragraphs will address each substantive issue raised in comments received by DHS and Justice. This discussion will not describe in detail the provisions outlined in the rules, but rather will address only those provisions relevant to the comments. Commenters frequently addressed identical issues in their comments, and these issues have been consolidated for the response. This discussion has been organized into sections based upon the themes of comments for the convenience of the reader.

1. Promulgation of the Rules

Many commenters questioned the authority of the Secretary and the Attorney General to promulgate these final rules. Commenters questioned whether the rules had separation of power implications and whether the rules were ultra vires in light of the litigation pending around the country regarding the interpretation of section 241 of the Act, 8 U.S.C. 1231, and the language of the statute. *Compare Jama*, 329 F.3d 630 (8th Cir. 2003), with *Ali*, 346 F.3d 873 (9th Cir. 2003). In these comments, the commenters invoke the oft-quoted statement of *Marbury* v. *Madison*, 1 Cranch (5 U.S.) 137 (1803), that it is "emphatically the province and duty of the judicial department to say what the law is."

These comments fail to appreciate the nature of rulemaking within the structure of the federal law. Accordingly, the Attorney General and the Secretary must reiterate basic principles of separation of powers and administrative law that govern rulemakings. The three Branches of government operate within defined spheres, but those spheres sometimes overlap. Congress enacts statutes, and delegates to the Executive Branch the authority to make rules that interpret and fill in the administrative details of those statutes. The interpretation of the statutes in these rules are given due deference by the courts when cases present questions of statutory interpretation. *INS* v. *Aguirre-Aguirre*, 526 U.S. 415, 423–25 (1999); *Chevron U.S.A. Inc.* v. *Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842–45 (1983). The invocation of the judicial power, however, does not stay the processes of government; Congress may amend the statute at any time. Similarly, the Executive Branch may amend the regulations under the statute at any time. Not infrequently, these amendments result in different disposition of the cases pending before the courts. *See, e.g., Bell* v. *Wolfish*, 441 U.S. 520, 549–52 (1979) (amendment of Bureau of Prisons regulations while constitutional challenge to prior regulations pending in Supreme Court); *see also Smiley* v. *Citibank (South Dakota), N.A.*, 517 U.S. 735 (1996) (amendment to the regulations interpreting "interest" as used in the National Bank Act while issue of what constituted interest was in litigation); *cf. Sanks* v. *Georgia*, 401 U.S. 144 (1971) (amendment to state statute while constitutional challenge to prior statute pending in Supreme Court). In fact, in *Smiley*, the Court specifically stated: "That it was litigation that disclosed the need for the regulation is irrelevant." *Smiley, 517 U.S. at 741*. As these and a number of other cases make clear, exercise of authority granted to make rules pending litigation is both an acceptable and a long-standing practice.

The commenters suggest that the Executive's amendment is an interference with the authority of the courts. However, as the District of Columbia Circuit has pointed out,

> intent is irrelevant: no authority supports the proposition that a rule is arbitrary and capricious merely because it abrogates a circuit court decision. Quite to the contrary, "regulations promulgated to clarify disputed interpretations of a regulation are to be encouraged. Tidying-up a conflict in the circuits with a clarifying regulation permits a nationally uniform rule without the need for the Supreme Court to essay the meaning of every debatable regulation." *Pope* v. *Shalala*, 998 F.2d 473, 486 (7th Cir. 1993) (citation and internal quotation marks omitted).

National Mining Association v. *Department of Labor*, 292 F.3d 849 (D.C. Cir. 2002). With this in mind, the Attorney General and the Secretary of Homeland Security have undertaken to resolve the conflict through regulation.

Additionally, as noted in the proposed rules, the statute does not define the terms "country" and "acceptance." Given the exclusive province of the Executive in that vast external realm of determining when a "country" has "accepted" its proffer of an alien, the Attorney General and the Secretary, as the respective delegates of the President, are providing the interpretation that conforms with the foreign policy of the United States. These regulations are, thus, wholly within their authority to promulgate.

One commenter stated that it "makes little sense for the government to expend significant staff time and expense to promulgate regulations that could need retraction or extensive overhauling in a matter of months, depending upon the Supreme Court's determination." The Secretary and the Attorney General appreciate the commenters' suggestion but have determined that promulgation of these rules is necessary at this time.

Accordingly, the Secretary and the Attorney General promulgate the regulations as proposed, with minor changes as noted below.

2. Definition of the Term "Country"

Some commenters questioned the interpretation of the Secretary and the Attorney General of section 241(b) of the Act, 8 U.S.C. 1231(b), and articulated their position that the term "country" as used in that section is premised on the existence or functionality of a government in that country based on "longstanding judicial interpretations." In support of their argument, the commenters rely on three cases that are far from dispositive of the issue. Further, the difference in terminology used within section 241(b)(2) of the Act and Supreme Court precedent support

the interpretation of the Secretary and Attorney General.

First, the commenters cite three cases in support of their contention that "longstanding judicial interpretations" of "country" require the existence or functionality of a government. In all three cases cited by the commenters, the courts found that the United States could deport the aliens to the proposed country of removal, but whether "country" requires the existence or functionality of a government was not specifically at issue in any of the cases. In *Chuen* v. *Esperdy*, 285 F.2d 353 (2d Cir. 1960), the Second Circuit addressed whether "Hong Kong, a colony of the United Kingdom," was a country for purposes of the removal statute. In a per curiam opinion of two paragraphs finding in favor of the government, the court concluded "we think that any place possessing a government with authority to accept an alien deported from the United States can qualify as a "country" under the statute." *Id.* That issue is not in dispute; a place possessing a government with authority to accept an alien deported from the United States "can" qualify as a country. However, the converse does not flow from this conclusion, *i.e.*, that a place not possessing a government with authority to accept an alien deported from the United States cannot qualify as a country for purposes of section 241(b) of the Act. One conclusion simply does not flow from the other as a matter of logic. In fact, the court in *Chuen* was not faced with, nor did it address, the latter question. Accordingly, *Chuen* does not support the commenters' position.

Similarly, *Delany* v. *Moraitis*, 136 F.2d 129 (4th Cir. 1943), finding in favor of the government that an alien (a Greek citizen) could be deported to the custody of the Greek government in exile in England, does not support the proposition that "country" under section 241(b) of the Act requires the existence or functionality of a government. In *Delany*, it was not possible to deport the alien to Greece because it was under German control at the time. *Id.* at 130. The court framed the issue in *Delany* as follows: "The question presented by the appeal, therefore, is whether, under the statute, the [alien] must be allowed to remain in this country, where he has no right to remain under our laws, or whether the statute will be complied with if he be returned to the political dominion and control of the country from which he came. We think the latter is the case." *Id.* Commenters, in citing *Delany*, focus on the following statement in support of their proposition—"a man's 'country' is more than the territory in which its people live. The term is used generally to indicate the state, the organization of social life which exercises sovereign power in behalf of the people." *Id.* at 130. The fact that a country is "more than" the territory in which its people live—especially considering the unique factual circumstance of the case involving a government in exile recognized by the United States—does not exclude that a country is "at least" the territory in which its people live. As such, *Delany* does not support the proposition that "country" under 241(b) of the Act requires the existence or functionality of a government; in fact, as with *Chuen*, *Delany* simply did not address the specific issue of whether the term "country" in the removal provision requires the existence or functionality of a government. Accordingly, *Delany* does not support the commenters' position. It should be noted that the predecessor to section 241(b)(2)(F) of the Act was enacted post-*Delany* to allow for removal to governments in exile and that the Board of Immigration Appeals (Board) in *Matter of Linnas*, 19 I&N Dec. 302, 305 (BIA 1985), found that *Delany* was no longer effective law for the proposition that "country" can be construed to encompass a government in exile.

Finally, contrary to the commenters' suggestion, *Rogers* v. *Sheng*, 280 F.2d 663, 664–65 (D.C. Cir. 1960), finding in favor of the government that Formosa was a country for purposes of removal because it had a government that had "undisputed control of the island," is also not dispositive of the current issue. Formosa had been ceded by China to Japan in 1895. *Id.* at 664. The alien argued that Formosa was neither a country nor part of any country. *Id.* at 663. The court described the status of Formosa as follows: "Following World War II, Japan surrendered all claims of sovereignty over Formosa. But in the view of our State Department, no agreement has "purported to transfer the sovereignty of Formosa to (the Republic of) China." At the present time, we accept the exercise of Chinese authority over Formosa, and recognize the Government of the Republic of China * * * as the legal Government of China." *Id.* With this background in mind, the commenters' reliance on the fact that the court found that Formosa was a country because there was "a government on Formosa which has undisputed control of the island," *id.*, and therefore that the existence or functionality of a government is a requirement under section 241(b) of the Act, is misplaced. As with *Chuen* and *Delany*, the court in *Rogers* did not address the precise question of whether the term "country" under the predecessor to section 241(b) of the Act required the existence or functionality of a government. The court simply addressed the question of whether, as espoused by the government, Formosa was a country under the predecessor to section 241(b) of the Act based on the facts of the case, and the court ruled in favor of the government. Accordingly, the commenters' assertion that these three cases are "longstanding judicial interpretations" demonstrating that the term "country" requires the existence or functionality of a government is incorrect. While the cases were decided decades ago (one in 1943, and two in 1960) and they are "longstanding" in that sense, the remainder of the commenters" proposition, *i.e.*, that these cases demonstrate that the term "country" requires the existence or functionality of a government, does not follow from these cases. In fact, the cases did not directly address the issue of whether the term "country" as used in section 241(b) of the Act requires existence or functionality of a government. As such, the commenters' statement that the regulations are *ultra vires* because they contravene established precedent is simply incorrect.

Second, the specific language chosen by Congress within section 241(b) of the Act demonstrates that "country" does not require the existence or functionality of a government. It is settled that "[w]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *INS* v. *Cardozo-Fonseca*, 480 U.S. 421, 432 (1987) (quoting *Russello* v. *United States*, 464 U.S. 16, 23 (1983)). A review of section 241(b) of the Act demonstrates that Congress included and excluded particular language, not only within the same statute, but within the same subsection. Specifically, section 241(b)(2) of the Act contains references to both "country" and to the "government of the country," the latter term being used in the provisions discussing acceptance. Accordingly, the text of section 241(b)(2) of the Act itself supports the fact that "country" refers to a geographic region, without regard to the existence of functionality of a government. If Congress had intended the term "country" to also encompass an existing or functioning government, it would have been unnecessary for

Congress to have also used "government of the country" within the same subsection as "country." The fact that Congress deliberately chose both specific terms within such close proximity demonstrates that each term has a separate and distinct meaning, *i.e.*, the term "country" does not depend on the existence or functionality of a government, but the term "government of the country," used in the provision addressing acceptance, does encompass a "government." Furthermore, the position of the Secretary and Attorney General is supported by the Supreme Court's decision in *Smith* v. *United States*, 507 U.S. 197 (1993). While construing the Federal Tort Claims Act (FTCA) in *Smith*, the Court noted that the "commonsense meaning" of the term "country" is "'[a] region or tract of land.'" *Id.* at 201. Indeed, the Court held in that case that Antarctica is a "country" within the meaning of the FTCA "even though it has no recognized government." *Id.* The Court in Smith did acknowledge "that this is not the only possible interpretation of the term, and it is therefore appropriate to examine other parts of the statute before making a final determination." *Id.* As stated above, examining the other parts of section 241(b) of the Act mandates the conclusion that "country" does not depend on the existence or functionality of a government; if it did, other provisions within the same subsection would be rendered meaningless, a result to be avoided in statutory construction. *See, e.g., Dole Food Co.* v. *Patrickson*, 538 U.S. 468, 477 (2002) ("'a statute must, if possible, be construed in such fashion that every word has some operative effect'") (quoting *United States* v. *Nordic Village, Inc.*, 503 U.S. 30, 36 (1992)); *TRW, Inc.* v. *Andrews*, 534 U.S. 19, 30 (2001) ("[w]e are "reluctant to treat statutory terms as surplusage in any setting'") (quoting *Duncan* v. *Walker*, 533 U.S. 167, 174 (2001)).

For these reasons, the Secretary and Attorney General reject the commenters' suggestion that the term "country" in section 241(b)(2) of the Act requires the existence or functionality of a government. Accordingly, the regulations in this area are being promulgated as proposed.

3. Acceptance Under Section 241(b)(2) of the Act, 8 U.S.C. 1231(b)(2)

Several commenters generally contended that section 241(b)(2) of the Act, 8 U.S.C. 1231(b)(2), requires acceptance by the government of a country in all circumstances, and that, absent acceptance, the Executive Branch's authority is legally circumscribed. As discussed in more detail below, the so-called "acceptance requirement" is not a requirement that precludes the Executive Branch from exercising its authority; in fact, there is no general "acceptance requirement" that precludes action as a legal matter, with the exception contained in section 241(b)(2)(E)(iv) of the Act, where the acceptance itself provides the only connection between the alien and the removal country at issue. Instead of labeling the general acceptance language in section 241(b)(2) of the Act as a general "acceptance requirement," it is more appropriately labeled the "acceptance exception," in that parts of section 241(b)(2) of the Act release the Secretary of Homeland Security from the mandatory language of "shall remove" if certain circumstances are not present, one of those circumstances being acceptance by the government of a country. In this regard, there is a difference between a legal requirement that precludes the Executive Branch from exercising its authority generally, which is what the commenters' proposed interpretation would create, versus a consideration that enables the Executive Branch to carry out its obligations under the Act, while continuing to balance the foreign policy considerations of its actions. Additionally, the question of whether removal should be effectuated absent acceptance by the government of the removal country is a separate inquiry; that question has no bearing on whether the Secretary of Homeland Security is authorized to do so.

In construing the Act, the Supreme Court repeatedly has held itself "bound to assume that the legislative purpose is expressed by the meaning of the words used." *INS* v. *Cardozo-Fonseca*, 480 U.S. 421, 431 (1987) (internal quotations omitted). That approach is consistent with the Court's more general admonition that "[t]he plain meaning of legislation should be conclusive, except in the 'rare cases [in which] the literal application of a statute will produce a result demonstrably at odds with the intentions of its drafters.'" *United States* v. *Ron Pair Enters. Inc.*, 489 U.S. 235, 242 (1989) (alteration in original); *see also Connecticut Nat'l Bank* v. *Germain*, 503 U.S. 249, 253–54 (1992) ("[A] legislature says in a statute what it means and means in a statute what it says there."). As set forth below, except for section 241(b)(2)(E)(vii) of the Act, the language of section 241(b)(2) of the Act does not require, as a legal prerequisite, that acceptance be obtained before removal of an alien.

First, section 241(b)(2)(A)–(C) of the Act, which is generally the first step in the country-of-removal inquiry, addresses removal to a country designated by the alien. In pertinent part, those provisions state that the Secretary of Homeland Security "shall remove" an alien to the country designated by the alien (section 241(b)(2)(A) of the Act), but that the Secretary "may disregard a designation" if "the government of the country is not willing to accept the alien into the country" (section 241(b)(2)(C)(iii) of the Act) or if the Secretary "decides that removing the alien to the country is prejudicial to the United States" (section 241(b)(2)(C)(iv) of the Act). It is important to note that within this provision, Congress employed both the mandatory term "shall" and the permissive term "may." The use of both these words within the same subsection is highly instructive. *See, e.g., United States* v. *Rodgers*, 461 U.S. 677, 706 (1983) ("The word 'may,' when used in a statute, usually implies some degree of discretion."); *Lopez* v. *Davis*, 531 U.S. 230, 241 (2001) (attaching significance to the fact that "Congress' use of the permissive 'may' in [18 U.S.C.] 3621(e)(2)(B) contrasts with the legislators' use of a mandatory 'shall' in the very same section"); *Anderson* v. *Yungkau*, 329 U.S. 482, 485 (1947) ("[W]hen the same [Federal Rule of Civil Procedure] uses both 'may' and 'shall,' the normal inference is that each is used in its usual sense—the one being permissive, the other mandatory."). Accordingly, the statute mandates that the Secretary "shall remove" an alien to the country designated, but also provides that the Secretary "may" disregard the designated country of removal if the government of the country is not willing to accept the alien. Nowhere does it require that the Secretary must, as a legal matter, disregard that designation. Far from containing an "acceptance requirement," section 241(b)(2)(C)(iii) of the Act contains an "acceptance exception" to removal, enabling the Secretary to disregard the designation made by an alien when the government of the country chosen by the alien is not willing to accept the alien, thereby providing the Executive Branch with discretion to act in a manner consistent with its foreign policy. Accordingly, contrary to the commenters' assertion, the first step of the country-of-removal inquiry does not support the conclusion that acceptance is a legal requirement for removal.

Second, section 241(b)(2)(D) of the Act, the second step in the country-of-removal inquiry, also does not, as a legal matter, preclude removal without

acceptance. In pertinent part, that provision states that the Secretary "shall remove" the alien to a country of which the alien is a subject, national, or citizen, "unless the government of the country * * * is not willing to accept the alien." As with section 241(b)(2)(C), that provision does not bar removal without acceptance; it requires removal to any country of which the alien is a subject, national, or citizen, but provides an exception when such a country fails to provide acceptance. Accordingly, section 241(b)(2)(D)(ii) of the Act also does not contain a legal impediment to removal; instead, like the language in section 241(b)(2)(C)(iii), it releases the Secretary from the mandatory language of "shall remove" and preserves the discretion of the Secretary of Homeland Security to act.

Finally, section 241(b)(2)(E) of the Act, the third step in the country-of-removal inquiry, does not support the commenters' position that acceptance by a country is a legal requirement to removal generally. Contrary to the commenters' assertions, neither the structure, history, nor title of section 241(b)(2)(E) of the Act supports the proposition that acceptance is a requirement. Section 241(b)(2)(E) of the Act states that the Secretary "shall remove" the alien to any of seven specified countries or categories of countries. The first six of these are countries with some prior connection to the alien and are defined without any reference to acceptance, including, for example, "[t]he country in which the alien was born," *see* section 241(b)(2)(E)(iv) of the Act. The final provision, on the other hand, states: "If impracticable, inadvisable, or impossible to remove the alien to each country described in a previous clause of this subparagraph, another country whose government *will accept* the alien into that country," *see* section 241(b)(2)(E)(vii) of the Act (emphasis added). It is in this last clause, and only in this last clause, that section 241(b)(2) of the Act contains what is appropriately labeled an "acceptance requirement." Specifically, the wording of this last clause ("another country *whose government will accept* the alien into that country") stands in stark contrast to any of the other so-called acceptance provisions discussed above. Additionally, the fact that the only reference to acceptance within section 241(b)(2)(E) of the Act is contained in clause (vii) and clearly absent from the other six clauses demonstrates that there is no general acceptance requirement within section 241(b)(2)(E) of the Act. *See Cardozo-Fonseca*, 480 U.S. at 432 (quoting *Russello* v. *United States*, 464 U.S. 16, 23 (1983)) ("'Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.'"). Not only did Congress include and exclude reference to acceptance within the same statute, it did so within the same subparagraphs of section 241(b)(2)(E) of the Act. Accordingly, the language of section 241(b)(2)(E) of the Act only requires acceptance as a legal prerequisite to removal in clause (vii); it does not require acceptance as a legal prerequisite to removal in clauses (i)–(vi). Additionally, it should be noted that what constitutes acceptance for purposes of the Act is a determination made by the Secretary of Homeland Security.

The commenters' contention that the history of section 241(b)(2)(E) of the Act supports a broad imposition of the acceptance requirement throughout clauses (i)–(vi) of section 241(b)(2)(E) of the Act, where no reference to acceptance exists, is also erroneous. Several commenters state that because sections 241(b)(2)(C)(iii), 241(b)(2)(D)(ii), and 241(b)(2)(E)(vii) of the Act require acceptance, and that because section 241(b)(2)(E) of the Act is an integral part of 241(b) of the Act, "only the most mechanical and contrived reading would assert that the requirement does not apply with equal force" to sections 241(b)(2)(E)(i)–(vi) of the Act. However, as already discussed above, sections 241(b)(2)(C)(iii) and (D)(ii) do not contain an "acceptance requirement," but an "acceptance exception'; the only subsection within section 241(b)(2) of the Act that contains an acceptance requirement is 241(b)(2)(E)(vii) of the Act. There is nothing "contrived or mechanical" about reading an acceptance requirement only within that subsection. In fact, far from being "contrived or mechanical," it is what the statute mandates, since Congress included specific words within one subsection but excluded them within the others.

Certain commenters suggest that the undeniably progressive nature of the provisions set forth in section 241 of the Act provides an "indication" that acceptance is required within all subsections of section 241(b)(2)(E) because it would "twist the removal process" if acceptance would be required from a country with the closest connection to the alien, *i.e.*, the country of which the alien is a subject, national, or citizen, but not from countries with more attenuated connections to the alien. The Secretary of Homeland Security and the Attorney General again reiterate that, contrary to the commenters' assertion, acceptance is not generally required within section 241(b)(2) of the Act. For the reasons already discussed, there is only one acceptance requirement within section 241(b)(2) of the Act, and it is found at section 241(b)(2)(E)(vii) of the Act. Accordingly, the progressive nature of section 241(b)(2) of the Act, in terms of providing steps for determining the country of removal, has no bearing on acceptance.

Some commenters also proposed that the heading of section 241(b)(2)(E) of the Act indicates that acceptance is required in all circumstances. Commenters state that the change of the heading from "other countries" to "additional removal countries" indicates congressional intent that the countries captured by section 241(b)(2)(E) of the Act be different from the previous countries. However, the title of the section—Additional Removal Countries—is not accurately described as imposing an acceptance requirement not otherwise contained in the text of the provision. Commenters' statement correctly alludes to the proposition that the "title of a statute and the heading of a section" are "tools available for the resolution of doubt about the meaning of a statute." *Almendarez-Torres* v. *United States*, 523 U.S. 224, 234 (1998); *but see INS* v. *St. Cyr*, 533 U.S. 289, 308–309 (2001) (noting that "title alone is not controlling"); *INS* v. *National Center for Immigrants' Rights, Inc.*, 502 U.S. 183, 189 (1991). However, contrary to the commenters' proposition, the fact that headings can be "tools available for resolution of doubt" is not instructive in this case where there is no need to resolve any doubt. The change in the heading from "other" to "additional" cannot overcome the fact that clauses (i) through (vi) of section 241(b)(2)(E) of the Act do not contain any mention of acceptance. There is simply no doubt to resolve in this case.

Finally, some commenters also suggested that section 241(b)(2)(E) of the Act generally requires acceptance by all receiving countries because to find otherwise would lead to "unmanageable" and "absurd" results in that an alien could be removed to the "country from which the alien was admitted to the United States," under section 241(b)(2)(E)(i) of the Act, without acceptance by the government of that country, even if the country was simply a border country through which the alien was traveling or the country was simply host to a major airline. In

this regard, these commenters stated that "[t]he statute did not grant unfettered discretion to the DHS to remove an alien when the agency deemed it possible to do so, and the agency does not have the power to read this authority into the statute." In fact, the commenters are mistaken. Section 241(b)(2) of the Act simply provides a checklist of sorts outlining the countries to which an alien may be removed. Section 241(b)(2) of the Act, however, does not provide the authority for DHS to remove an alien once that alien is ordered removed; the authority is " 'a fundamental sovereign attribute exercised by the Government's political departments largely immune from judicial control.' " *Fiallo* v. *Bell*, 430 U.S. 787, 792 (1977) (quoting *Shaughnessy* v. *United States ex. rel. Mezei*, 345 U.S. 206, 210 (1953)). Commenters are confusing two different concepts, *i.e.*, whether particular action is appropriate, as opposed to whether particular action is authorized. There is a difference between the legal authority to act and the discretion to act. The Secretary of Homeland Security is authorized to remove an alien pursuant to sections 241(b)(2)(E)(i)–(vi) of the Act, regardless of any acceptance by the government of the foreign country. Whether it is wise or practical to do so is simply a separate inquiry, not at all related to whether there is authority to do so. As stated in the Notice of Proposed Rulemaking, "the general practice of the Executive Branch is not to attempt to remove an individual under the Act to a country whose government refuses to accept him." 69 FR at 42904. This general practice is based upon an acknowledgement that it is not generally practical to remove aliens to a country whose government refuses to accept him. However, the practice is based on considerations of foreign policy, nothing more.

Accordingly, the Secretary of Homeland Security and the Attorney General find it unnecessary to amend the proposed rules based on these comments.

4. Acceptance, Judicial Precedent, and Ratification by Congress

Several commenters suggest that there is historical precedent from both the federal courts and the Board of Immigration Appeals (the Board) requiring acceptance. These commenters suggest that Congress "ratified" this acceptance requirement in adopting the current version of section 241 of the Act, 8 U.S.C. 1231. Neither the decisions of the federal courts or the Board support the position that acceptance is a requirement under current section 241(b)(2) of the Act, nor has Congress ratified such interpretation.

The federal court cases cited by some commenters do not support the proposition that these courts have interpreted the removal statute to require acceptance as a legal prerequisite. In fact, most of the cases cited have not specifically considered the issue of whether acceptance was a legal prerequisite. In *United States ex rel. Hudak* v. *Uhl*, 20 F.Supp. 928 (N.D.N.Y. 1937), for example, the court stated that "[i]t will be presumed in every case of deportation that the United States immigration authorities have obtained the consent of the native sovereignty to receive the deported alien." *Id.* at 930. There was no clear discussion by the court whether its "presumption" was based on a legal prerequisite in the removal provision versus the practical considerations regarding what would occur if an alien is taken to a foreign sovereign and that sovereign refuses to receive the alien. As such, *Hudak* cannot be said to support the commenters' proposition that acceptance is a legal prerequisite to removal. In *Chi Sheng Liu* v. *Holton*, 297 F.2d 740 (9th Cir. 1962), the court noted that the appellant contended that the Act required acceptance before he could be deported. *Id.* at 743. The court then considered that a letter from the Consul General of the country was sufficient evidence of acceptance. *Id.* at 744. Because there was an indication of acceptance from the government of the proposed country of removal, there was no need for the court to consider the question of whether that acceptance was a legal prerequisite to removal. Similarly, United States ex rel. *Lee Ming Hon* v. *Shaughnessy*, 142 F.Supp 468 (S.D.N.Y. 1956), is a two-paragraph decision, the focus of which is whether a particular document is sufficient proof that the government of the proposed country of removal provided acceptance. There is no discussion regarding whether acceptance is a legal requirement to removal, as opposed to a practical obstacle to removal. Accordingly, these cases do not stand for the proposition that acceptance is a legal requirement to removal. The common thread among the cases involves the practical difficulties in removal where acceptance is lacking, a fact the Executive Branch acknowledged in its Notice of Proposed Rulemaking. *See, e.g.*, 69 FR at 42904.

In *United States ex rel. Tom Man* v. *Murff*, 264 F.2d 926 (2d Cir. 1959), the court did state "we think that deportation * * * is subject to the condition expressed in the seventh subdivision [the predecessor to section 241(b)(2)(E) of the Act]: *i.e.*, that the 'country' shall be 'willing to accept' him 'into its territory.' " *Id.* at 928; *see also Amanullah & Wahidullah* v. *Cobb*, 862 F.2d 362 (1st Cir. 1988) (Pettine, J.) (relying on *Tom Man* for the proposition that acceptance is a requirement and noting that there was communication from the proposed country of removal that the aliens would not be accepted); *Lee Wei Fang* v. *Kennedy*, 317 F.2d 180 (D.C. Cir. 1963), *cert. denied*, 375 U.S. 833 (1963) (citing *Tom Man* for the proposition that acceptance is a requirement, yet not elaborating whether the requirement was legal or practical, and then focusing on what constituted a country). However, aside from the quoted statement itself, there is no elaboration by the court discussing the reason why it "thought" that deportation was subject to acceptance. *Tom Man*, and the cases citing it, did not engage in full analysis of the question whether acceptance is a legal prerequisite to removal.

Similarly, the decisions of the Board cited by the commenters do not support their position that acceptance is a legal prerequisite to removal. In *Matter of Anunciacion*, 12 I&N Dec. 815 (BIA 1968), the Board stated that the question "whether or not a specified country will accept the alien as a deportee is one of comity concerning solely the United States and the country in question." *Id.* at 817. Accordingly, *Matter of Anunciacion* cannot fairly be described as supporting the position that acceptance is a legal, as opposed to practical, prerequisite to removal. Additionally, commenters rely on *Matter of Linnas*, 19 I&N Dec. 302 (BIA 1985); however, reliance on this case is also misplaced. In *Matter of Linnas*, the main question before the Board was whether the offices of the Republic of Estonia in New York City constituted a country for purposes of removal and whether the alien could therefore be removed to those offices. The Board answered the question in the negative. *Id.* at 307. In determining whether the offices in New York City constituted a country, the Board cited *Tom Man*, as the case arose in that circuit, and found that the language of the removal section "expressly requires, or has been construed to require, that the 'government' of a country selected under any of the three steps must indicate it is willing to accept a deported alien into its 'territory.' " *Id.* However, this statement by the Board was made in the context of deciding what constituted a country for purposes of removal, and the Board was relying

on *Tom Man*, as circuit precedent, in making this statement. The Board did not address the fact that determining what constitutes a country for purposes of removal is one inquiry; the other inquiry being whether acceptance by the government of that country is a legal prerequisite to removal. Accordingly, *Matter of Linnas* is not instructive on whether acceptance is a legal prerequisite to removal because that issue was not before the Board.

It is with this background regarding the existing case law that some commenters assert that Congress has ratified an acceptance requirement into section 241(b)(2) of the Act. The commenters classify the cases as being "long-standing" and having a "consistent construction" of the predecessors to section 241(b)(2) of the Act. However, as already described, there is no consistent construction that acceptance is a legal prerequisite to removal under section 241(b)(2) of the Act, except for section 241(b)(2)(E)(vii) of the Act, which does contain an acceptance requirement. Accordingly, there was no arguable settled precedent for Congress to ratify.

Accordingly, the commenters are incorrect in their assertion that Congress has ratified an acceptance requirement into the entirety of section 241(b)(2) of the Act, even where the text of the section is clear that no such acceptance is legally required. Therefore, the Secretary and the Attorney General are adopting the proposed rules in this area unchanged.

5. Lack of General Acceptance Requirement and Effect on Other Provisions of the Act

Some commenters suggest that the proposed rules would render parts of section 241(b)(2) of the Act, 8 U.S.C. 1231(b)(2), superfluous because the rule allows the Department of Homeland Security to remove an alien under section 241(a)(2)(E)(i)–(vi) of the Act to a country which, for example, would be prohibited under section 241(b)(2)(D) of the Act. The commenters' characterization is incorrect as there is no general "prohibition" on removal within section 241(b)(2) of the Act. As discussed at length above, the acceptance provisions within section 241(b)(2) of the Act do not prohibit removal; they simply release the Secretary from the requirement to take action under certain circumstances. The authority to choose not to effectuate a removal under certain circumstances, i.e., the discretion granted to the Secretary, cannot accurately be labeled a "prohibition" as these commenters suggest. Accordingly, parts of section 241(b)(2) of the Act are not rendered superfluous.

Likewise, the claim by certain commenters that section 241(a)(7)(A) of the Act, 8 U.S.C. 1231(a)(7)(A), would be rendered superfluous under these rules is incorrect. In the words of the commenters, "[i]f a receiving country's refusal to accept a deportee could so easily be overridden, this provision, too, effectively would be useless." There is nothing "useless" or superfluous about this section. Section 241(a)(7)(A) of the Act provides that an alien ordered removed is not eligible for employment authorization unless the Secretary of Homeland Security makes a "specific finding that the alien cannot be removed due to the refusal of all countries designated by the alien or under this section to receive the alien." If the Secretary makes a "specific finding" that the alien cannot be removed as a practical matter because of lack of acceptance, an alien may obtain employment authorization as appropriate. That is all the section provides, and it does so even though the Secretary is legally authorized to remove aliens under section 241(b)(2) of the Act, except for section 241(b)(2)(E)(vii) of the Act, without the proposed removal country's acceptance. Therefore, this section is not rendered superfluous because it continues to operate notwithstanding these rules.

Some commenters cite to the provisions relating to removal of alien terrorists in section 507(b)(2)(C) of the Act, 8 U.S.C. 1537(b)(2)(C), in the section where they are addressing superfluous provisions, yet they appear to be arguing that section 507(b)(2)(C) of the Act somehow instructs the reading of section 241(b)(2) of the Act without any further elaboration. It is unclear whether commenters are arguing that the alien terrorist removal provisions would be rendered superfluous, or whether the alien terrorist provisions mandate that an acceptance requirement be read into section 241(b)(2) of the Act where none is specifically contained. In any event, either proposition is incorrect. Congress specifically enacted separate provisions to be invoked as appropriate in dealing with alien terrorists. These provisions, detailed in sections 501 through 507 of the Act, include the establishment of a special removal court to handle alien terrorist cases, and create a framework for handling those cases. Accordingly, the provisions relating to removal of alien terrorists contained in sections 501 through 507 of the Act, 8 U.S.C. 1531–1537, are independent of the other provisions dealing with non-terrorist aliens and are not instructive regarding the general removal provisions and certainly do not in any way support the contention that section 241(b)(2) of the Act legally requires acceptance by the proposed country of removal before removal can be effectuated, except as otherwise provided by Congress in section 241(b)(2)(E)(vii) of the Act.

Some commenters also seem to suggest that section 243(d) of the Act, 8 U.S.C. 1253(d), which permits the Secretary of State to discontinue the issuance of visas to citizens, subjects, nationals, and residents of a country if the government of that country refuses to accept their return, is rendered superfluous. This is incorrect, as nothing in these rules affects the Secretary of State's legal authority to discontinue the issuance of visas for individuals of certain countries if those countries do not affirmatively accept their citizens, subjects, nationals, or residents when asked to do so by the United States. The Secretary of State may continue to take such action as he or she deems appropriate under this section notwithstanding the interpretations in these rules. Section 243(d) of the Act simply provides a potential consequence when a foreign government refuses to accept its nationals, citizens, etc. The fact that the Secretary of Homeland Security may choose to remove an alien to a foreign country without acceptance by the government of that country because the Secretary has determined that it is in the foreign policy interests of the United States does not negate the import of section 243(d) in authorizing the Secretary of State to take appropriate action against that country by discontinuing issuance of visas. What sometimes cannot be obtained through diplomacy in terms of obtaining the consent of the government of a foreign country to accept its nationals may sometimes be obtained when some adverse consequence attaches to the actions of the government of the foreign country. As a result, the Secretary of Homeland Security rejects the commenters' claim that the proposed regulations render portions of the Act superfluous.

6. Office of Legal Counsel Opinion

Some commenters focus on an opinion issued by the Office of Legal Counsel (OLC) of the Department of Justice that they contend supports the position that acceptance by the government of a country is a legal prerequisite to removal. *See* Memorandum Opinion for the Deputy Attorney General: *Re: Limitations on the Detention Authority of the Immigration and Naturalization Service* (OLC Feb.

20, 2003) *http://www.usdoj.gov/olc/INSDetention.htm*. That opinion addressed, *inter alia*, the circumstances under which a removable alien may permissibly be detained for more than 90 days during the pendency of the removal process. *See id.* at 15–24. In explaining why the removal process may sometimes take longer than 90 days, the opinion described step three of the sequential process as follows:

> If the country of the alien's citizenship or nationality declines to accept the alien, the Attorney General is instructed to attempt to remove the alien to one of six listed countries, including the country in which the alien was born and the country from which the alien was admitted to the United States. *See* INA § 241(b)(2)(E)(i)–(vi). Each of those countries, of course, would have to be separately negotiated with by the United States, and would also have to be given an appropriate amount of time—presumably 30 days—to decide whether to accept or reject the alien. Finally, if none of the six listed countries is willing to accept the alien, or if the Attorney General decides that it would be "inadvisable" to send the alien to any of the listed countries that is willing to accept him, the Attorney General is instructed to remove the alien to any country of the Attorney General's choice whose government is willing to accept the alien. *See* INA § 241(b)(2)(E)(vii).

Id. at 21 n.11. Importantly, the OLC opinion did not address the specific issue of whether acceptance by the government of a country was a legal prerequisite to removal under section 241(b)(2) of the Act or merely a pragmatic consideration. In fact, the section of the opinion quoted by the commenters is contained in a footnote to the opinion, where the text of the opinion is focusing on the length of time negotiating with different governments may take. As was stated in the Notice of Proposed Rulemaking, "the general practice of the Executive Branch is not to attempt to remove an individual under the Act to a country whose government refuses to accept him." 69 FR at 42904. Accordingly, the OLC opinion was simply relying on what was the standard practice of the Executive Branch as it related to length of time it might take to negotiate with foreign governments; it was not espousing a legal position that acceptance by a government is required under section 241(b)(2) of the Act. In this rule, it is the Attorney General who is construing the legal interpretation of the Act on this particular issue (an issue which was not the focus of the OLC opinion). The Attorney General is vested with the authority to issue interpretations of the Act, and his determinations are controlling, as provided in section 103(a)(1) of the Act, 8 U.S.C. 1103(a)(1).

7. Agency Operating Instructions

Some commenters cite section 243.1(c)(1) of the Immigration and Naturalization Service Operations Instructions for the following statement: "deportation cannot be effected until travel documentation has been obtained." Based on this statement in the operating instructions, commenters contend that acceptance is generally required under section 241(b)(2) of the Act. However, agency operating instructions provide guidance to its employees and do not have the force and effect of law. *See, e.g., Haitian Refugee Center* v. *Baker*, 953 F.2d 1498, 1512 (11th Cir.), *cert. denied*, 502 U.S. 1122 (1992); *Perales* v. *Casillas*, 903 F.2d 1043, 1051 (5th Cir. 1990) (quoting *Dong Sik Kwon* v. *INS*, 646 F.2d 909, 918–19 (5th Cir. 1989)); see also United States v. Caceres, 440 U.S. 741 (1979) (noting that Internal Revenue Service Manual did not create enforceable rights warranting suppression of evidence obtained in violation of Manual). The operations instructions contain guidance for line officers; they are not indicative of agency authority generally. Accordingly, commenters' reliance on this 10-word phrase within the operating instructions dealing with travel documentation does not support the proposition that acceptance is a legal requirement under section 241(b)(2) of the Act. Indeed, as the Secretary of Homeland Security has already recognized, "the general practice of the Executive Branch is not to attempt to remove an individual under the Act to a country whose government refuses to accept him." 69 FR 42904. Since it is not the general practice of the Executive Branch to do so, and since acceptance can be demonstrated by providing travel documentation, this operating instruction is not inconsistent with the fact that acceptance is not a legal requirement to removal, but a practical one. Additionally, this 10-word phrase within the operating instruction does not create an enforceable right that does not otherwise exist in the statute itself. Therefore, the agency operating instructions do not support the commenters' position that acceptance is generally required.

8. Removal of Aliens to Countries Without Functioning Foreign Governments

Certain commenters suggested that human rights concerns preclude the United States from returning aliens to countries without functioning governments, as could occur under the proposed rules. This proposition by commenters would eviscerate the specific provisions within the Act and the regulations that provide for protection under certain circumstances and would create a separate protection provision flowing solely from customary international law.

The Act and regulations provide various mechanisms whereby aliens can seek protection from removal. Specifically, an alien present in the United States may apply for asylum if he or she establishes a well-founded fear of persecution on account of race, religion, nationality, membership in a particular social group, or political opinion, see sections 101(a)(42) and 208 of the Act, 8 U.S.C. 1101(a)(42), 1158. Similarly, an alien may apply for withholding of deportation to a particular country under section 241(b)(3)(A) of the Act, 8 U.S.C. 1231(b)(3)(A), if he or she establishes that it is more likely than not that he or she will be persecuted on account of race, religion, nationality, membership in a particular social group, or political opinion. Additionally, the regulations implementing the Convention Against Torture and Other Cruel, Inhuman, or Degrading Treatment or Punishment (Convention Against Torture), provide protection, in the form of withholding of removal or deferral of removal, if an alien is more likely than not to be tortured if removed to the proposed country of removal. 8 CFR 208.16(c)(3), 208.17(a); *see* Convention Against Torture, S. Treaty Doc. No. 100–20 (1988), 23 I.L.M. 1027 (1984), approved by the United States Senate Oct. 28, 1990, 136 Cong. Rec. 36625 (1990). Except for deferral of removal under the Convention Against Torture under 8 CFR 208.17(a), however, these provisions also exclude aliens from seeking protection under certain circumstances. For example, section 208(b)(2) of the Act lists exceptions for aliens seeking asylum; section 241(b)(3)(b) of the Act lists exceptions for aliens seeking withholding of removal; and 8 CFR 208.16(d)(2) lists exceptions for aliens seeking withholding of removal under the Convention Against Torture.

Additionally, section 244 of the Act, 8 U.S.C. 1254a, provides temporary protected status for nationals of a foreign state if the Secretary of Homeland Security "finds that there is an ongoing armed conflict within the state" and returning aliens to the state "would pose a serious threat to their personal safety," or "there exist extraordinary and temporary conditions in the foreign state that prevent aliens who are nationals of the state from returning to the state in safety, unless

the [Secretary of Homeland Security] finds that permitting the aliens to remain temporarily in the United State is contrary to the national interest of the United States." However, section 244(c)(2) of the Act also excludes certain aliens from temporary protected status.

These provisions demonstrate that Congress provided for protection from removal in specific circumstances and, even when protection is available, excluded certain aliens from obtaining such protection. The commenters' general assertions that international law prohibits removal of aliens to a country without a functioning government, notwithstanding an alien's inability to qualify for protection under any or the provisions of the Act or regulations mentioned above, are misplaced because it would create obligations for the United States that are not cognizable in domestic courts. "Several times, indeed, the Senate has expressly declined to give the federal courts the task of interpreting and applying international human rights law, as when its ratification of the International Covenant on Civil and Political Rights declared that the substantive provisions of the document were not self-executing. These reasons argue for great caution in adapting the law of nations to private rights." *Sosa* v. *Alvarez-Machain*, 542 U.S.__124 S.Ct. 2739,, 2763–64 (No. 03–339, June 28, 2004) (citing 138 Cong. Rec. 8071 (1992)). For example, article 3 of the Convention Against Torture, is often relied upon for the requirement that the United States may not remove an individual to a country where it is more likely than not that the individual will be tortured. However, the Convention Against Torture is not self-executing, as the United States Senate made clear in its reservations, understandings, declarations, and provisos contained in its resolution of ratification of the Convention Against Torture. The Senate required separate implementing legislation and regulations. Regulations implementing the Convention were adopted pursuant to a congressional directive in section 2242 of the Foreign Affairs Reform and Restructuring Act of 1998, Pub. L. 105–277, 112 Stat. 2681–761, 2681–822. See 64 FR 8478, 8488 (February 19, 1999). Thus, the protection afforded by the Convention Against Torture, cognizable in domestic courts, is contained in the implementing legislation and regulations. General reference to international law does not create more "law" in this area than was otherwise specifically domestically authorized and implemented.

Accordingly, statutory and regulatory provisions provide protection to aliens as appropriate; customary international law cannot be said to provide additional rights cognizable in domestic courts than are already provided under domestic law. Therefore, the Secretary and the Attorney General will not modify the proposed regulations in response to this comment.

9. Foreign Policy Considerations

Some commenters suggest that the proposed rule raises serious foreign policy concerns because nothing in the rule prohibits DHS from removing aliens to a country over the country's objection. In so doing, these commenters reference the norm of customary international law of sovereign equality. The commenters fail to recognize, however, that the rule does not need to address, nor is it the place to address, foreign policy considerations such as sovereign equality. As stated in the Notice of Proposed Rulemaking, the "general practice of the Executive Branch is not to attempt to remove an individual under the Act to a country whose government refuses to accept him." 69 FR at 42904. The commenters, while acknowledging this statement in the Notice of Proposed Rulemaking, indicate that nothing in the Notice specifically prohibits the Executive Branch from doing so. Commenters are correct that nothing in the rule prohibits the Executive Branch from doing so because nothing in the Act prohibits the Executive Branch from doing so, and foreign policy considerations, which are entrusted to the Executive Branch, do not compel reading such a prohibition into the Act.

The Executive Branch is vested with the discretion to act in the foreign policy interests of the United States. As the Supreme Court has stressed repeatedly, the right of the Executive Branch to remove aliens "stems not alone from legislative power but is inherent in the executive power to control the foreign affairs of the nation." *United States ex rel. Knauff* v. *Shaughnessy*, 338 U.S. 537, 542 (1950). The "power to expel or exclude aliens" is "a fundamental sovereign attribute exercised by the Government's political departments." *Fiallo* v. *Bell*, 430 U.S. 787, 792 (1977). As stated in the Notice of Proposed Rulemaking, "[t]hese considerations apply with special force to immigration issues arising under the Act involving foreign countries that are either hostile, dysfunctional, or lack the capacity to exercise their sovereign authority. In particular, in exercising authority to remove aliens under the Act, the Executive Branch has the responsibility to assess," and is in the best position to assess, the foreign policy implications of its actions. 69 FR at 42906. Therefore, sovereign equality is an issue for the Executive Branch to determine; it does not create a private right of action nor does it suggest, much less compel, that the authority of the Executive Branch to effect removals to a particular country over that country's objection is in any way affected as a matter of domestic law cognizable in domestic courts.

10. Identifying Country of Removal at Removal Hearing for Protection Requests

Some commenters state that an alien has a due process right to know the country to which he or she will be removed during the removal hearing. These commenters note that choosing the country of removal has due process implications to the extent that the proposed country or countries of removal may affect an alien's decision to apply for asylum, withholding of removal under section 241(b)(3) of the Act, 8 U.S.C. 1231(b)(3), and protection under the Convention Against Torture. Accordingly, these commenters request that the proposed rule be modified to "protect the rights of asylum applicants and those fearing persecution."

The Secretary and Attorney General find it unnecessary to amend the proposed rule in response to this comment. In this context, it is important to differentiate between asylum, withholding of removal under section 241(b)(3) of the Act, and protection under the Convention Against Torture in discussing what protection is available to aliens. Under section 101(a)(42) of the Act, 8 U.S.C. 1101(a)(42), an alien may apply for asylum if he or she has been persecuted, or has a well-founded fear of persecution, from his or her country of nationality or the country where he or she last habitually resided. An alien in the United States may apply for asylum regardless of whether removal proceedings are pending and regardless of the country or countries designated for removal. By contrast, an alien may apply for withholding of removal under section 241(b)(3) of the Act or protection under the Convention Against Torture under 8 CFR 208.16(c)(2), 208.17(a) to prevent removal only to a specific country or countries. Accordingly, the proposed country of removal does not in any way affect an alien's ability to apply for asylum. Therefore, in discussing protection claims in the next few paragraphs, the Secretary of Homeland Security and the Attorney General will be referring to withholding of removal

under 241(b)(3) of the Act and protection under the Convention Against Torture, as these are specific to the proposed country of removal, but will not be referring to asylum since it is not dependent upon the proposed country of removal.

In terms of arriving aliens who are covered under section 241(b)(1) of the Act, each potential country of removal can be identified during the removal hearing, except for section 241(b)(1)(C)(iv) of the Act, where the alien may be removed to "[a] country with a government that will accept the alien into the country's territory." Similarly, for aliens covered under section 241(b)(2) of the Act, each potential country of removal can be identified during the removal hearing, except for section 241(b)(2)(E)(vii) of the Act, where the alien may be removed to "another country whose government will accept the alien into that country." Thus, an alien will have the opportunity to apply for protection as appropriate from any of the countries that are identified as potential countries of removal under section 241(b)(1) or (b)(2) of the Act. In this respect, the Secretary and Attorney General are aware of the cases cited by the commenters wherein the potential countries of removal were not all specifically named and where the aliens were not afforded the opportunity to apply for protection as appropriate from those countries. *See, Kossov* v. *INS*, 132 F.3d 405 (7th Cir. 1998); *Kuhai* v. *INS*, 199 F.3d 909 (7th Cir. 1999); *but see Andriasian* v. *INS*, 180 F.3d 1033, 1041 (9th Cir. 1999) (wherein the agency agreed that alien was entitled to remand where potential country of removal was not designated until the end of the removal hearing). It is important to note, however, that there are cases where protection claims from more than one country are identified and considered at the removal hearing. *See, e.g., Ambartsoumian* v. *Ashcroft*, 388 F.3d 85 (3rd Cir. 2004). As discussed in the Notice of Proposed Rulemaking, all parties in the removal proceeding share responsibility for ensuring that the record identifies the countries to which the alien may be removed where removal is premised upon some previous connection to that country. 69 FR at 42908. Indeed, 8 CFR 1240.10(f), as amended by this rule, requires that immigration judges identify for the record the countries to which an alien may be removed. Accordingly, except for removals pursuant to sections 241(b)(1)(C)(iv) or 241(b)(2)(E)(vii) of the Act, an alien will know at the time of the removal hearing all of the potential countries of removal and may apply for protection from the country or countries as appropriate. Any protection claims will then be addressed as part of the removal hearing, which itself provides the process that is due.

The Secretary does acknowledge that identification of a removal country under sections 241(b)(1)(C)(iv) or 241(b)(2)(E)(vii) of the Act, where removal will be to a country with no connection to the alien other than a determination by the Secretary of Homeland Security that the country is willing to accept the alien, will likely not occur until after the removal proceeding is concluded. Importantly, the vast majority of removals are to countries with which the alien has some connection and for which the alien would have had ample opportunity to apply for protection as necessary. To the extent that removal will occur under section 241(b)(1)(C)(iv) or 241(b)(2)(E)(vii) of the Act, the Executive Branch will identify the particular country and then assess whether the government of the proposed country of removal is willing to accept the alien. In the exercise of its functions as it relates to removal under either of these sections, the Executive Branch, through the Secretary of Homeland Security and the Secretary of State, is aware of the relevant law as it relates to the protection of aliens being removed to any particular country. *Cf* 22 CFR. 95.3 (implementing the Convention Against Torture in extradition cases and providing that allegations relating to torture will be reviewed by appropriate "policy and legal offices"). In appropriate circumstances, DHS may agree to join motions to reopen that would otherwise be barred by time and number limitations. *See* 8 CFR 1003.2(c)(3)(iii), 1003.23(b)(4)(iv).

11. Modification of Certain Regulations

Certain commenters suggested that existing regulations are not consistent with the approach taken in these rules. The commenters correctly note that with these rules, DHS is amending its regulations to reflect its interpretation of the Act. As a result of these amendments, DHS's regulations will become uniform and consistent with its interpretation of the Act.

Commenters also suggested that the language of 8 CFR 241.4(g)(2) and (3) are in conflict with the interpretation of the Act, as set forth in these regulations. As currently written, 8 CFR 241.4(g)(2) directs the local United States Immigration and Customs Enforcement Detention and Removal Office of the Department of Homeland Security responsible for an alien's case to attempt to secure travel documents for an alien, and to elevate the case to headquarters in the event that the local office is unable to secure such documents. Section 241.4(g)(3) discusses how the status of travel documents should be considered as part of a custody determination. The fact that regulations, in the section dealing with travel documents, state that the agency should attempt to obtain travel documents, and that availability of travel documents is a relevant factor in the custody determination, is not inconsistent with these rules. Because the Executive Branch does not generally "attempt to remove an individual under the Act to a country whose government refuses to accept him," 69 FR at 42904, there is nothing inconsistent about regulations where the district director is instructed to "undertake appropriate steps to secure travel documents." Nothing in the two regulations cited by the commenters prohibit the Secretary of Homeland Security from effectuating a removal absent those travel documents; they simply incorporate the standing practice that removals will not generally occur if the government of the proposed country of removal refuses to accept the alien. To the extent that issuance of a travel document is but one of many methods employed by the Secretary of Homeland Security to determine that the country does not refuse to accept the alien, the two regulations are nothing more than a realization of the practical aspects of removal. Accordingly, in this context, commenters again mistake the difference between the practical aspects of removal and the legal authority by which to effectuate those removals.

12. Miscellaneous Comments

The Departments were also asked by one commenter what the phrase "zone of interest" meant as used in the preamble to the proposed regulations. *See* 69 FR at 42906. This phrase is discussed in detail in footnote 2 of the preamble to the proposed regulation, and the Secretary and Attorney General decline to address further the meaning of the phrase at this time.

An additional commenter suggested that these regulations were part of the DHS effort to streamline expedited removal. These rules only address the countries to which an alien may be removed after the alien has been ordered removed; they do not affect the expedited removal procedures. The Secretary does note, however, that the authority to initiated expedited removal proceedings has recently been expanded. *See* Notice Designating Aliens for Expedited Removal, 69 FR 48877 (August 11, 2004) (authorizing expedited removal proceedings for

aliens present in the United States without having been admitted or paroled, who are encountered within 100 miles of the border, and who cannot establish that they have been physically present in the United States continuously for the preceding fourteen days); Notice Designating Aliens Subject to Expedited Removal Under Section 235(b)(1)(A)(iii) of the Immigration and Nationality Act, 67 FR 68924 (November 13, 2002) (authorizing expedited removal proceedings for certain aliens who arrive in the United States by sea, who are not admitted or paroled, and who have not been continuously physically present in the United States for the preceding two years).

Some commenters generally alleged that some of the factual background provided in the Notice of Proposed Rulemaking was irrelevant. The Secretary of Homeland Security and the Attorney General disagree that the factual background was irrelevant, as it was provided to assist the public in understanding the purpose and scope of this rule.

One commenter argued that the statutory limitations on motions to reopen in section 240(c)(6)(C)(ii) of the Act reflect Congress's intent to give legal effect to an immigration judge's designation of a country for removal. Accordingly, the commenter argues that the restrictions on motions to reopen do not permit removal of an alien to a third county not named by the immigration judge. The commenter further argues that at a minimum, Justice should modify 8 CFR 1003.2 and 1003.23 to account for changes in the country of intended removal. Justice disagrees with this commenter and declines to accept the proposed changes. Contrary to the commenter's claim, current immigration law provides the United States with the authority to remove aliens to countries other than those designated by an immigration judge. For aliens who have not made a formal entry into the United States, the alien may be removed to any country that satisfies the criteria listed in section 241(b)(1) of the Act, and for all other aliens, the alien may be removed to any country that satisfies the criteria listed in sections 241(b)(2)(C), (D), and (E) of the Act, without approval from an immigration judge. See also 8 CFR 1240.10(g) (recodified in 8 CFR 1240.12(d)). Additionally, for those aliens who wish to raise new issues regarding the designated country of removal, current law already provides a mechanism for reopening their cases. When appropriate, DHS may agree to waive the time and numerical limits on an alien's right to file a motion to reopen, 8 CFR 1003.2(c)(3)(iii), 1003.23(b)(4)(iv), or the immigration judge or the Board of Immigration Appeals may reopen the case sua sponte, 8 CFR 1003.2(a), 1003.23(b)(1).

One commenter addressed a portion of the Justice regulation relating to 8 CFR 1241.8, suggesting that the word "may" should be changed to "shall" in order to more accurately reflect the existing requirement in the cross-referenced section at 8 CFR 241.8. However, the Department of Justice has decided to defer making any revisions to section 1241.8, pending further consideration, and accordingly this rule makes no change in the existing language of 8 CFR 1241.8 at this time.

Similarly, DHS and Justice have decided to defer making revisions to 8 CFR 236.1 and 1236.1, pending further consideration, and accordingly this rule makes no change in the existing language of 8 CFR 236.1 and 1236.1 at this time.

Finally, Justice received several miscellaneous comments from one commenter who supported sending illegal immigrant lawbreakers back to a country of the immigration judge's choosing immediately, asserted that the United States has too many illegal immigrants (which causes taxes to go up), and that it is time we seal our borders. As discussed above, the Department declines to expand upon the authority provided by Congress in sections 241(b)(1) and (2) of the Act to allow an immigration judge to send an alien back to a country of the judge's choosing. The Department of Justice, DHS, and other agencies of the United States government vigorously enforce American immigration laws against illegal immigration, and these rules are only one aspect of the effort to ensure that the United States is able to effectuate the removal of aliens who are deportable or inadmissible. The Department of Justice believes that the remaining proposals suggested by this commenter fall outside the scope of this rule and will not be addressed.

C. Joint and Independent Notice of Rulemaking

The Secretary of Homeland Security hereby amends regulations of the Department of Homeland Security to clarify the authority for removal of aliens to specific countries in the exercise of discretion under section 241 of the Act. The Secretary is exercising his authority under sections 103 and 241 of the Act (8 U.S.C. 1103, 1231). The Attorney General hereby amends the regulations of the Department of Justice to clarify the authority and procedures before immigration judges in designating countries of removal in the record of proceedings, to clarify the scope of immigration judge orders of removal from the United States, and to provide further guidance in interpreting the Act. The Attorney General is exercising his authority under section 103(a)(1) and (g) of the Act, and his authority under 28 U.S.C. 503, 509–510.

Administrative Matters

Regulatory Flexibility Act

The Secretary and the Attorney General, in accordance with 5 U.S.C. 605(b), have reviewed their respective rules and, by approving them, certify that these rules do not have a significant economic impact on a substantial number of small entities. The rules affect only individual aliens and government agencies.

Unfunded Mandates Reform Act of 1995

These rules will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

Neither of these rules is a major rule as defined by section 251 of the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 804. Neither rule will result in an annual effect on the economy of $100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Executive Order 12866

These rules have been drafted and reviewed in accordance with Executive Order 12866, section 1(b), Principles of Regulation. The Departments have determined that their respective rules are significant regulatory actions under section 3(f) of Executive Order 12866, Regulatory Planning and Review. Accordingly, these rules have been submitted to the Office of Management and Budget for review.

There are no additional costs to the Department of Justice in the implementation of the rule other than the minimal amount of time required for immigration judges to explain the possibility that an alien may be removed to a country other than designated.

Similarly, there are no additional costs of the Department of Homeland Security other than in the small number of cases in which execution of an order of removal will be to a country other than as previously designated, in which officials of DHS will be required to ensure compliance with United States law and international obligations. There are no costs to individuals.

The benefits of the rule lie in the clarification of the law and the elimination of delay in effecting a small number of removal orders, but these benefits are not quantifiable. In some cases, the individual alien will already be in the custody of DHS and, therefore, reducing the time required to execute an order of removal will reduce the costs of detaining that alien.

Executive Order 13132

These rules will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of Executive Order 13132, the respective Departments have determined that these rules do not have sufficient federalism implications to warrant a federalism summary impact statement.

Executive Order 12988

These rules meet the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform.

Paperwork Reduction Act of 1995

These rules do not impose any new reporting or recordkeeping requirements under the Paperwork Reduction Act.

List of Subjects

8 CFR Part 241

Administrative practice and procedure, Aliens, Immigration.

8 CFR Part 1240

Administrative practice and procedure, Aliens.

8 CFR Part 1241

Administrative practice and procedure, Aliens, Immigration.

Department of Homeland Security

8 CFR Chapter I

Authority and Issuance

■ Accordingly, for the reasons stated in the joint preamble and pursuant to the authority vested in me as the Secretary of Homeland Security, chapter I of title 8 of the Code of Federal Regulations is amended as follows:

PART 241—APPREHENSION AND DETENTION OF ALIENS ORDERED REMOVED

■ 1. The authority citation for part 241 continues to read as follows:

Authority: 5 U.S.C. 301, 552, 552a; 8 U.S.C. 1103, 1182, 1223, 1224, 1225, 1226, 1227, 1231, 1251, 1253, 1255, 1330, 1362; 18 U.S.C. 4002, 4013(c)(4); 8 CFR part 2.

■ 2. Section 241.1 is revised to read as follows:

§ 241.1 Final order of removal.

An order of removal becomes final in accordance with 8 CFR 1241.1.

■ 3. Section 241.3 is amended by adding a new paragraph (d), to read as follows:

§ 241.3 Detention of aliens during removal period.

* * * * *

(d) *Information regarding detainees.* Disclosure of information relating to detainees shall be governed by the provisions of 8 CFR 236.3.

§ 241.4 [Amended]

■ 4. Section 241.4(k)(1)(i) is amended by removing the phrase "because no country currently will accept the alien," and by removing the phrase "removal of the alien prior to expiration of the removal period" in the first sentence.

■ 5. Section 241.5 is amended by revising paragraph (c)(1), to read as follows:

§ 241.5 Conditions of release after removal period.

* * * * *

(c) * * *

(1) The alien cannot be removed in a timely manner; or

* * * * *

§ 241.13 [Amended]

■ 6. Section 241.13 is amended by:

■ a. Removing the phrase "to the country to which the alien was ordered removed and there is no third country willing to accept the alien" in the first sentence of paragraph (d)(1); and by

■ b. Adding the term "and" immediately before the phrase "the views of the Department of State" and by removing the phrase ", and the receiving country's willingness to accept the alien into its territory" in the first sentence of paragraph (f).

■ 7. Section 241.15 is revised to read as follows:

§ 241.15 Countries to which aliens may be removed.

(a) *Country.* For the purposes of section 241(b) of the Act (8 U.S.C. 1231(b)), the Secretary retains discretion to remove an alien to any country described in section 241(b) of the Act (8 U.S.C. 1231(b)), without regard to the nature or existence of a government.

(b) *Acceptance.* For the purposes of section 241(b) of the Act (8 U.S.C. 1231(b)), the Secretary retains discretion to determine the effect, if any, of acceptance or lack thereof, when an acceptance by a country is required, and what constitutes sufficient acceptance.

(c) *Absence or lack of response.* The absence of or lack of response from a de jure or functioning government (whether recognized by the United States, or otherwise) or a body acting as a de jure or functioning government in the receiving country does not preclude the removal of an alien to a receiving country.

(d) *Prior commitment.* No commitment of acceptance by the receiving country is required prior to designation of the receiving country, before travel arrangements are made, or before the alien is transported to the receiving country.

(e) *Specific provisions regarding acceptance.* Where the Department cannot remove an alien under section 241(b)(2)(A)–(D) of the Act, acceptance is not required to remove an alien to a receiving country pursuant to section 241(b)(2)(E)(i)–(vi) of the Act. Where the Department cannot remove an arriving alien under section 241(b)(1)(A) or (B) of the Act, acceptance is not required to remove an alien to a receiving country pursuant to section 241(b)(1)(C)(i)–(iii) of the Act.

(f) *Interest of the United States controlling.* The Secretary or his designee may designate a country previously identified in section 241(b)(2)(A)–(D) of the Act when selecting a removal country under section 241(b)(2)(E) of the Act (and may designate a country previously identified in section 241(b)(1)(A) or (B) of the Act when selecting an alternative removal country under subsection 241(b)(1)(C) of the Act) if the Secretary or his designee determines that such designation is in the best interests of the United States.

(g) *Limitation on construction.* Nothing in this section shall be construed to create any substantive or procedural right or benefit that is legally enforceable by any party against the United States or its agencies or officers or any other person.

■ 8. Section 241.25(b) is revised to read as follows:

§ 241.25 Deportation.

* * * * *

(b) *Place to which deported.* Any alien (other than an alien crewmember or an alien who boarded an aircraft or vessel in foreign contiguous territory or an adjacent island) who is ordered excluded shall be deported to the country where the alien boarded the vessel or aircraft on which the alien arrived in the United States. Otherwise, the Secretary may, as a matter of discretion, deport the alien to the country of which the alien is a subject, citizen, or national; the country where the alien was born; the country where the alien has a residence; or any other country.

* * * * *

■ 9 Section 241.31 is revised to read as follows:

§ 241.31 Final order of deportation.

An order of deportation becomes final in accordance with 8 CFR 1241.31.

§ 241.33 [Amended]

■ 10. Section 241.33 is amended by:

■ a. Revising the last sentence in paragraph (a) introductory text, to read "An order of deportation becomes final in accordance with 8 CFR 1241.31."; and by

■ b. Removing paragraphs (a)(1), (2), (3), and (4).

Dated: December 28, 2004.

Tom Ridge,

Secretary.

Department of Justice

8 CFR Chapter V

Authority and Issuance

■ Accordingly, for the reasons stated in the joint preamble and pursuant to the authority vested in me as the Attorney General of the United States, chapter V of title 8 of the Code of Federal Regulations is amended as follows:

PART 1240—PROCEEDINGS TO DETERMINE REMOVABILITY OF ALIENS IN THE UNITED STATES

■ 1. The authority citation for part 1240 is revised to read as follows:

Authority: 8 U.S.C. 1103, 1182, 1186a, 1224, 1225, 1226, 1227, 1229, 1229a, 1229b, 1229c, 1253, 1255, and 1362.

■ 2. Section 1240.10 is amended by:

■ a. Revising paragraph (f); and by

■ b. Removing paragraph (g).

The revision reads as follows:

§ 1240.10 Hearing.

* * * * *

(f) *Country of removal.* With respect to an arriving alien covered by section 241(b)(1) of the Act, the country, or countries in the alternative, to which the alien may be removed will be determined pursuant to section 241(b)(1) of the Act. In any other case, the immigration judge shall notify the respondent that if he or she is finally ordered removed, the country of removal will in the first instance be the country designated by the respondent, except as otherwise provided under section 241(b)(2) of the Act, and shall afford him or her an opportunity then and there to make such designation. The immigration judge shall also identify for the record a country, or countries in the alternative, to which the alien's removal may be made pursuant to section 241(b)(2) of the Act if the country of the alien's designation will not accept him or her into its territory, or fails to furnish timely notice of acceptance, or if the alien declines to designate a country. In considering alternative countries of removal, acceptance or the existence of a functioning government is not required with respect to an alternative country described in section 241(b)(1)(C)(i)–(iii) of the Act or a removal country described in section 241(b)(2)(E)(i)–(iv) of the Act. *See* 8 CFR 241.15.

■ 3. Section 1240.12 is amended by revising paragraph (c) and adding a new paragraph (d), to read as follows:

§ 1240.12 Decision of the immigration judge.

* * * * *

(c) *Order of the immigration judge.* The order of the immigration judge shall direct the respondent's removal from the United States, or the termination of the proceedings, or other such disposition of the case as may be appropriate. The immigration judge is authorized to issue orders in the alternative or in combination as he or she may deem necessary.

(d) *Removal.* When a respondent is ordered removed from the United States, the immigration judge shall identify a country, or countries in the alternative, to which the alien's removal may in the first instance be made, pursuant to the provisions of section 241(b) of the Act. In the event that the Department of Homeland Security is unable to remove the alien to the specified or alternative country or countries, the order of the immigration judge does not limit the authority of the Department of Homeland Security to remove the alien to any other country as permitted by section 241(b) of the Act.

PART 1241—APPREHENSION AND DETENTION OF ALIENS ORDERED REMOVED

■ 4. The authority citation for part 1241 is revised to read as follows:

Authority: 5 U.S.C. 301, 552, 552a; 8 U.S.C. 1103, 1182, 1223, 1224, 1225, 1226, 1227, 1231, 1251, 1253, 1255, 1330, 1362; 18 U.S.C. 4002, 4013(c)(4).

§§ 1241.3, 1241.4, 1241.5, 1241.9, 1241.10, 1241.11, 1241.12, and 1241.13 [Removed]

■ 5. Sections 1241.3, 1241.4, 1241.5, 1241.9, 1241.10, 1241.11, 1241.12, and 1241.13 are removed.

■ 6. Section 1241.2 is revised to read as follows:

§ 1241.2 Warrant of removal; detention of aliens during removal period.

For the regulations of the Department of Homeland Security with respect to the detention and removal of aliens who are subject to a final order of removal, see 8 CFR part 241.

■ 7. Section 1241.6 is amended by revising paragraphs (a) and (b), to read as follows:

§ 1241.6 Administrative stay of removal.

(a) An alien under a final order of deportation or removal may seek a stay of deportation or removal from the Department of Homeland Security as provided in 8 CFR 241.6.

(b) A denial of a stay by the Department of Homeland Security shall not preclude an immigration judge or the Board from granting a stay in connection with a previously filed motion to reopen or a motion to reconsider as provided in 8 CFR part 1003.

* * * * *

§ 1241.7 [Amended]

■ 8. Section 1241.7 is amended by removing the first sentence.

■ 9. Section 1241.14 is amended by revising paragraph (a), and removing and reserving paragraphs (b), (c), and (d), to read as follows:

§ 1241.14 Continued detention of removable aliens on account of special circumstances.

(a) *Scope.* This section provides for the review of determinations by the Department of Homeland Security to continue the detention of particular removable aliens found to be specially dangerous. See 8 CFR 241.14.

(1) *Applicability.* This section applies to the review of the continued detention of removable aliens because the Department of Homeland Security has determined that release of the alien would pose a special danger to the

public, where there is no significant likelihood of removal in the reasonably foreseeable future. This section does not apply to aliens who are not subject to the special review provisions under 8 CFR 241.13.

(2) *Jurisdiction.* The immigration judges and the Board have jurisdiction with respect to determinations as to whether release of an alien would pose a special danger to the public, as provided in paragraphs (f) through (k) of this section.

* * * * *

■ 10. Section 1241.15 is revised to read as follows:

§ 1241.15 Lack of jurisdiction to review other country of removal.

The immigration judges and the Board of Immigration Appeals have no jurisdiction to review any determination by officers of the Department of Homeland Security under 8 CFR 241.15.

■ 11. Section 1241.20 is revised to read as follows:

§ 1241.20 Aliens ordered excluded.

For the regulations of the Department of Homeland Security pertaining to the detention and deportation of excluded aliens, see 8 CFR 241.20 through 241.25.

§§ 1241.21, 1241.22, 1241.23, 1241.24, and 1241.25 [Removed]

■ 12. Sections 1241.21 through 1241.25 are removed.

■ 13. Section 1241.30 is revised to read as follows:

§ 1241.30 Aliens ordered deported.

For the regulations of the Department of Homeland Security pertaining to the detention and deportation of aliens ordered deported, see 8 CFR 241.30 through 241.33.

Dated: December 28, 2004.

James B. Comey,

Acting Attorney General.

[FR Doc. 05–125 Filed 1–4–05; 8:45 am]

BILLING CODE 4410–10–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. NM297; Special Conditions No. 25–279–SC]

Special Conditions: Raytheon Model 4000 Horizon; Side-Facing Single-Occupant Seats

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for the Raytheon Model 4000 Horizon airplane. This airplane will have a novel or unusual design feature associated with side-facing single-occupant seats. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: The effective date of these special conditions is December 22, 2004. Send your comments on or before February 22, 2005.

ADDRESSES: Comments on these special conditions may be mailed in duplicate to: Federal Aviation Administration, Transport Airplane Directorate, Attn: Rules Docket (ANM–113), Docket No. NM297, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; or delivered in duplicate to the Transport Airplane Directorate at the above address. Comments must be marked: Docket No. NM297. Comments may be inspected in the Rules Docket weekdays, except Federal holidays, between 7:30 a.m. and 4 p.m.

FOR FURTHER INFORMATION CONTACT: John A. Shelden, FAA, Airframe/Cabin Safety Branch, ANM–115, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2785, facsimile (425) 227–1232.

SUPPLEMENTARY INFORMATION: The substance of these special conditions has been subject to the notice and comment period in several prior instances and has been derived without substantive change from those previously issued. For this reason, and because a delay would significantly affect the certification of the airplane, which is imminent, the FAA has determined that prior public notice and comment are unnecessary and impracticable, and good cause exists for adopting these special conditions upon issuance. We are requesting comments to allow interested persons to submit views that may not have been submitted in response to the prior opportunities for comment.

Comments Invited

We invite interested persons to participate in this rulemaking by submitting written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data. We ask that you send us two copies of written comments.

We will file in the docket all comments we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning these special conditions. The docket is available for public inspection before and after the comment closing date. If you wish to review the docket in person, go to the address in the **ADDRESSES** section of this preamble between 7:30 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

We will consider all comments we receive on or before the closing date for comments. We will consider comments filed late if it is possible to do so without incurring expense or delay. We may change these special conditions in light of the comments we receive.

If you want the FAA to acknowledge receipt of your comments on these special conditions, include with your comments a pre-addressed, stamped postcard on which the docket number appears. We will stamp the date on the postcard and mail it back to you.

Background

On August 1, 1996, Raytheon Aircraft Company, 9709 E. Central, Wichita, KS 67201, applied for a type certificate for their new Model 4000 Horizon airplane and reapplied on May 31, 2001. The Model 4000 Horizon is a twin-engine, pressurized executive jet airplane with standard seating provisions for 10 passenger/crew and allowance for baggage and optional equipment. This airplane will have a maximum takeoff weight of 36,000 pounds and will have two aft-mounted Pratt & Whitney PW 308A engines.

Type Certification Basis

Under the provisions of 14 CFR 21.17, the Raytheon Aircraft Company must show that the Model 4000 Horizon airplane meets the applicable provisions of part 25, effective February 1, 1965, as amended by amendment 25–1 through amendment 25–101.

If the Administrator finds that the applicable airworthiness regulations (*i.e.*, 14 CFR part 25) do not contain adequate or appropriate safety standards for the Raytheon Model 4000 Horizon airplane because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

In addition to the applicable airworthiness regulations and special conditions, the Raytheon Model 4000

Horizon must comply with the fuel vent and exhaust emission requirements of part 34, effective September 10, 1990, as amended by any amendment in effect on the date of certification, and the noise certification requirements of part 36, effective December 1, 1969, as amended by any amendment in effect on the date of certification, and the FAA must issue a finding of regulatory adequacy pursuant to § 611 of Public Law 92–574, the "Noise Control Act of 1972."

Special conditions, as defined in § 11.19, are issued in accordance with § 11.38 and become part of the type certification basis in accordance with § 21.17.

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same novel or unusual design feature, the special conditions would also apply to the other model under the provisions of § 21.101.

Novel or Unusual Design Features

The Raytheon Model 4000 offers interior arrangements, which include single-occupant side-facing seat installations. One arrangement includes an aft LH toilet installation, which will be approved for occupancy during taxi, takeoff, and landing. The belted toilet seat is a single-occupant side-facing seating system located directly behind the LH aft pocket door partition. It consists of a toilet assembly, toilet cabinet, forward partition, contact pad, and restraint system (lap belt).

Section 25.785(b) requires that "each seat * * * at each station designated as occupiable during takeoff and landing must be designed so that a person making proper use of these facilities will not suffer serious injury in an emergency landing as a result of the inertia forces specified in §§ 25.561 and 25.562." Additionally, § 25.562 requires dynamic testing of all seats occupied during takeoff and landing. Side-facing seats, however, are considered a novel design for transport category airplanes that include amendment 25–64 in the certification basis, and were not considered when those airworthiness standards were established. Hence, the existing regulations do not provide adequate or appropriate safety standards for occupants of side-facing seats. In order to provide a level of safety that is equivalent to that afforded occupants of forward and aft-facing seats, additional airworthiness standards, in the form of special conditions, are necessary.

Discussion

The following special conditions are considered to provide occupants of single occupancy side-facing seats a level of safety that is equivalent to that afforded occupants of forward and aft-facing seats. These special conditions supplement part 25 and, more specifically, they supplement §§ 25.785 and 25.562.

Applicability

As discussed above, these special conditions are applicable to the Raytheon Model 4000 Horizon. Should Raytheon Aircraft Company apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, the special conditions would apply to that model as well under the provisions of § 21.101.

Conclusion

This action affects only certain novel or unusual design features on the Raytheon Model 4000 Horizon airplane. It is not a rule of general applicability, and it affects only the applicant who applied to the FAA for approval of these features on the airplane.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

■ The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

■ Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for the Raytheon Model 4000 Horizon airplane.

In addition to the airworthiness standards of §§ 25.562 and 25.785, the minimum acceptable standards for dynamic certification of Raytheon Model 4000 Horizon single-occupant side-facing seats are as follows:

Additional Injury Criteria

(a) *Existing Criteria:* All injury protection criteria of § 25.562(c)(1) through (c)(6) apply to the occupant of a side-facing seat. Head Injury Criterion (HIC) assessments are required only for head contact with the seat and/or adjacent structures.

(b) *Body-to-Wall/Furnishing Contact:* The seat must be installed aft of a structure, such as an interior wall or furnishing, that will support the pelvis, upper arm, chest, and head of an occupant seated next to the structure. A conservative representation of the structure and its stiffness must be included in the tests. It is recommended, but not required, that the contact surface of this structure be covered with at least two inches of energy-absorbing protective padding (foam or equivalent), such as Ensolite.

(c) *Thoracic Trauma:* The Thoracic Trauma Index (TTI) injury criterion must be substantiated by dynamic test or by rational analysis, based on a previous test or tests of a similar seat installation. Testing must be conducted with a Side Impact Dummy (SID), as defined in 49 CFR part 572, Subpart F, or its equivalent. TTI must be less than 85, as defined in 49 CFR part 572, Subpart F. TTI data must be processed as defined in Federal Motor Vehicle Safety Standard (FMVSS) part 571.214, section S6.13.5.

(d) *Pelvis:* Pelvic lateral acceleration must be shown by dynamic test or by rational analysis based on previous test(s) of a similar seat installation to not exceed 130g. Pelvic acceleration data must be processed as defined in FMVSS part 571.214, section S6.13.5.

(e) *Shoulder Strap Loads:* Where upper torso straps (shoulder straps) are used for occupants, tension loads in individual straps must not exceed 1,750 pounds. If dual straps are used for restraining the upper torso, the total strap tension loads must not exceed 2,000 pounds.

Additional Test Requirements

The above performance measures must not be exceeded during the following dynamic tests:

(a) Conduct a longitudinal test per § 25.562(b)(2) with a SID, undeformed floor, no yaw, and with all lateral structural supports (armrests/walls).

Pass/fail injury assessments: TTI and pelvic acceleration.

(b) Conduct a longitudinal test per § 25.562(b)(2) with the Hybrid II ATD, deformed floor, 10 degrees yaw, and with all lateral structural supports (armrests/walls).

Pass/fail injury assessments: HIC, upper torso restraint load, restraint system retention and pelvic acceleration.

(c) Conduct a vertical test per § 25.562(b)(1) with a Hybrid II ATD with existing pass/fail criteria.

Issued in Renton, Washington, on December 22, 2004.

Kevin Mullin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–122 Filed 1–4–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 92–ANE–15–AD; Amendment 39–13916; AD 2004–26–04]

RIN 2120–AA64

Airworthiness Directives; Pratt & Whitney JT8D–200 Series Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding existing airworthiness directive (AD) 99–22–14 for Pratt & Whitney (PW) JT8D–200 series turbofan engines. That AD currently requires removing low pressure turbine (LPT)-to-exhaust case bolts and nuts and replacement with improved LPT-to-exhaust case bolts and nuts on JT8D–209, –217, –217A, –217C, and –219 engines. That AD also requires installation of improved high pressure turbine (HPT) containment hardware on JT8D–217C, and –219 engines. This AD requires installation of improved HPT containment hardware on JT8D–209, –217, –217A, –217C, and –219 engines. This AD results from four reports of uncontained HPT failures of JT8D–200 series engines, since AD 99–22–14 was issued. We are issuing this AD to prevent uncontained HPT events resulting from HPT shaft fractures.

DATES: This AD becomes effective February 9, 2005. The Director of the Federal Register approved the incorporation by reference of certain publications listed in the regulations as of February 9, 2005. The Director of the Federal Register previously approved the incorporation by reference of certain other publications as listed in the regulations as of December 28, 1999 (64 FR 58328, October 29, 1999).

ADDRESSES: You can get the service information identified in this AD from Pratt & Whitney, 400 Main St., East Hartford, CT 06108; telephone (860) 565–7700; fax (860) 565–1605.

You may examine the AD docket at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA. You may examine the service information, at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

FOR FURTHER INFORMATION CONTACT: Keith Lardie, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803–5299; telephone (781) 238–7189; fax (781) 238–7199.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) was published in the **Federal Register** on July 15, 2004 (69 FR 42356). That action proposed to require installation of improved HPT containment hardware on JT8D–209, –217, –217A, –217C, and –219 engines in accordance with Pratt & Whitney Alert Service Bulletin (ASB) No. JT8D A6346, dated September 10, 1998, or Revision 1, dated April 23, 1999, or Revision 2, dated December 1, 1999, or Revision 3, dated May 21, 2004. We published the proposed AD in the **Federal Register** on July 15, 2004 (69 FR 42356).

Examining the AD Docket

You may examine the AD Docket (including any comments and service information), by appointment, between 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays. See **ADDRESSES** for the location.

Comments

We provided the public the opportunity to participate in the development of this AD. We have considered the one comment received. The commenter supports the proposal.

Conclusion

We have carefully reviewed the available data, including the comment received, and determined that air safety and the public interest require adopting the AD as proposed.

Costs of Compliance

There are about 2,345 PW JT8D–200 series turbofan engines of the affected design in the worldwide fleet. We estimate that 1,143 engines are installed on airplanes of U.S. registry, and that 280 engines will be affected by this AD. We estimate that 80% of the –217C and –219 engines already have the improved HPT containment hardware installed. We also estimate that no additional labor costs will be incurred when these parts are installed during engine shop visit. Required parts will cost about $19,991 per engine. Based on these figures, we estimate the total cost of the AD to U.S. operators to be $5,597,480.

Authority for this Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in subtitle VII, part A, subpart III, Section 44701, "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a "significant regulatory action" under Executive Order 12866;

(2) Is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a summary of the costs to comply with this AD and placed it in the AD Docket. You may get a copy of this summary by sending a request to us at the address listed under **ADDRESSES.** Include "AD Docket No. 92–ANE–15–AD" in your request.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the Federal Aviation Administration amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Amendment 39–11392 (64 FR 58328, October 29, 1999) and by adding a new airworthiness directive (AD), Amendment 39–13916, to read as follows:

2004–26–04 Pratt & Whitney: Amendment 39–13916. Docket No. 92–ANE–15–AD. Supersedes AD 99–22–14, Amendment 39–11392.

Effective Date

(a) This AD becomes effective February 9, 2005.

Affected ADs

(b) This AD supersedes AD 99–22–14, Amendment 39–11392.

Applicability

(c) This AD applies to Pratt & Whitney (PW) JT8D–209, –217, –217A, –217C, and –219 turbofan engines. These engines are installed on, but not limited to, Boeing 727 series and McDonnell Douglas MD–80 series airplanes.

Unsafe Condition

(d) This AD results from four reports of uncontained high pressure turbine (HPT) failures of JT8D–200 series engines, since AD 99–22–14 was issued. We are issuing this AD to prevent uncontained HPT events resulting from HPT shaft fractures.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified unless the actions have already been done.

(f) Install the improved HPT containment hardware. Use the applicable compliance schedule in Table 1 of this AD, and paragraphs 1. through 3.G. of the Accomplishment Instructions of PW Alert Service Bulletin (ASB) No. JT8D A6346, dated September 10, 1998, or Revision 1, dated April 23, 1999, or Revision 2, dated December 1, 1999, or Revision 3, dated May 21, 2004.

TABLE 1.—COMPLIANCE SCHEDULE

For engine models:	Install improved HPT containment hardware:
JT8D–217C and –219	At the next engine shop visit after the effective date of this AD, but no later than December 31, 2004.
JT8D–209, –217, and –217A	At the next engine shop visit after the effective date of this AD, but no later than December 31, 2007.

Definition

(g) For the purpose of this AD, an engine shop visit is defined as engine maintenance that involves the separation of the J and K flanges.

Alternative Methods of Compliance

(h) The Manager, Engine Certification Office, has the authority to approve alternative methods of compliance for this AD if requested using the procedures found in 14 CFR 39.19.

Material Incorporated by Reference

(i) You must use the Pratt & Whitney Alert Service Bulletins listed in Table 2 of this AD to perform the installations required by this AD. The Director of the Federal Register approved the incorporation by reference of ASB No. A6346, Revision 2 and Revision 3, listed in Table 2 of this AD in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The Director of the Federal Register previously approved the incorporation by reference of ASB No. JT8D A6346, dated September 10, 1998, and ASB No. JT8D A6346 Revision 1, dated April 23, 1999, as of December 28, 1999 (64 FR 58328, October 29, 1999). You can get copies from Pratt & Whitney, 400 Main St., East Hartford, CT 06108; telephone (860) 565–7700; fax (860) 565–1605. You can review copies at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. Table 2 follows:

TABLE 2.—INCORPORATION BY REFERENCE

Alert service Bulletin No.	Page number(s) shown on the page	Revision level shown on the page	Date shown on the page
JT8D A6346	ALL	Original	September 10, 1998.
Total Pages: 23			
JT8D A6346	1,2	1	April 23, 1999.
	3	Original	September 10, 1998.
	4	1	April 23, 1999.
	5,6	Original	September 10, 1998.
	7–25	1	April 23, 1999.
Total Pages: 25			
JT8D A6346	1,2	2	December 1, 1999.
	3	Original	September 10, 1998.
	4,5	2	December 1, 1999.
	6	Original	September 10, 1998.
	7	1	April 23, 1999.
	8	2	December 1, 1999.
	9–13	1	April 23, 1999.
	14	2	December 1, 1999.
	15–21	1	April 23, 1999.
	22	2	December 1, 1999.
	23–25	1	April 23, 1999.
Total Pages: 25			
JT8D A6346	ALL	3	May 21, 2004.
Total Pages: 22			

Related Information

(j) None.

Issued in Burlington, Massachusetts, on December 20, 2004.

Francis A. Favara,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 05–84 Filed 1–4–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–19200; Directorate Identifier 2003–NM–195–AD; Amendment 39–13927; AD 2005–01–03]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 747–100, –100B, –100B SUD, –200B, –200C, –200F, and –300 Series Airplanes; and Model 747SP and 747SR Series Airplanes; Equipped With Pratt & Whitney JT9D–3 and –7 (Except –70) Series Engines or General Electric CF6–50 Series Engines With Modified JT9D–7 Inboard Struts

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Boeing airplanes listed above. This AD requires repetitive detailed inspections of the midspar web of the inboard and/or outboard struts for cracking, disbonding, or buckling; repetitive detailed inspections of the midspar stiffeners for any crack or fracture; related investigative actions; and corrective actions, if necessary. This AD is prompted by reports of cracking in the midspar web. We are issuing this AD to detect and correct cracking in the midspar assembly, which could result in the loss of the midspar assembly load path, and could, combined with the loss of the nacelle station 180 bulkhead load path, lead to the separation of the engine from the airplane.

DATES: This AD becomes effective February 9, 2005.

The incorporation by reference of a certain publication listed in the AD is approved by the Director of the Federal Register as of February 9, 2005.

ADDRESSES: For service information identified in this AD, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207. You can examine this information at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

You can examine the contents of this AD docket on the Internet at *http://dms.dot.gov,* or in person at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., room PL–401, on the plaza level of the Nassif Building, Washington, DC. This docket number is FAA–2004–19200; the directorate identifier for this docket is 2003–NM–195–AD.

FOR FURTHER INFORMATION CONTACT: Candice Gerretsen, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 917–6428; fax (425) 917–6590.

Examining the Docket

The AD docket contains the proposed AD, comments, and any final disposition. You can examine the AD docket on the Internet at *http://dms.dot.gov,* or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the DOT street address stated in the **ADDRESSES** section.

SUPPLEMENTARY INFORMATION: The FAA proposed to amend 14 CFR Part 39 with an AD for certain Boeing Model 747–100, –100B, –100B SUD, –200B, –200C, –200F, and –300 series airplanes; and Model 747SP and 747SR series airplanes; equipped with Pratt & Whitney JT9D–3 and –7 (except –70) series engines or General Electric CF6–50 series engines with modified JT9D–7 inboard struts. That action, published in the **Federal Register** on September 29, 2004 (69 FR 58101), proposed to require repetitive detailed inspections of the midspar web of the inboard and/or outboard struts for cracking, disbonding, or buckling; repetitive detailed inspections of the midspar stiffeners for any crack or fracture; related investigative actions; and corrective actions, if necessary.

Comments

We provided the public the opportunity to participate in the development of this AD. We have considered the comment that has been submitted on the proposed AD. The commenter, the manufacturer, supports the proposed AD.

Conclusion

We have carefully reviewed the available data, including the comment that has been submitted, and determined that air safety and the public interest require adopting the AD as proposed.

Costs of Compliance

There are about 228 airplanes of the affected design worldwide and 78 airplanes of U.S. registry. The actions will take about 6 to 13 work hours per airplane, at an average labor rate of $65 per work hour. Based on these figures, the estimated cost of the AD for U.S. operators is between $30,420 and $65,910, or between $390 and $845 per airplane, per inspection cycle.

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, "General requirements." Under that section, the FAA is charged with promoting safety flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this AD.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the regulation:

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and
3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. We prepared a regulatory evaluation of the estimated costs to comply with this AD. See the

ADDRESSES section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2005–01–03 Boeing: Amendment 39–13927. Docket No. FAA–2004–19200; Directorate Identifier 2003–NM–195–AD.

Effective Date

(a) This AD becomes effective February 9, 2005.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Boeing Model 747–100, –100B, –100B SUD, –200B, –200C, –200F, and –300 series airplanes; and Model 747SP and 747SR series airplanes; certificated in any category; equipped with Pratt & Whitney JT9D–3, and –7 (except –70) series engines or General Electric CF6–50 series engines with modified JT9D–7 inboard struts; as listed in Boeing Alert Service Bulletin 747–54A2219, dated September 4, 2003.

Unsafe Condition

(d) This AD was prompted by reports of cracking in the midspar web. We are issuing this AD to detect and correct cracking in the midspar assembly, which could result in the loss of the midspar assembly load path, and could, combined with the loss of the nacelle station 180 bulkhead load path, lead to the separation of the engine from the airplane.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Compliance Times

(f) Within 18 months after the effective date of this AD, do the actions in paragraphs (g) and (h) of this AD, as applicable. Repeat the actions thereafter at intervals not to exceed 1,200 flight cycles.

Inboard Strut Midspar Inspection

(g) For Group 1 and 2 airplanes specified in paragraph 1.A.1. of Boeing Alert Service Bulletin 747–54A2219, dated September 4, 2003: Perform a detailed inspection of the midspar web of the inboard struts for cracking, disbonding, or buckling; a detailed inspection of the midspar stiffeners for any crack or fracture; related investigative actions; and any applicable corrective actions; in accordance with "Part 1" of the Work Instructions of Boeing Alert Service Bulletin 747–54A2219, dated September 4, 2003; except as required by paragraph (i) of this AD. Perform any related investigative actions and any applicable corrective actions before further flight.

Outboard Strut Midspar Inspection

(h) For Group 1 airplanes specified in paragraph 1.A.1. of Boeing Alert Service Bulletin 747–54A2219, dated September 4, 2003: Perform a detailed inspection of the midspar web of the outboard struts for cracking, disbonding, or buckling; a detailed inspection of the midspar stiffeners for any crack or fracture; related investigative actions; and any applicable corrective actions; in accordance with "Part 2" of the Work Instructions of Boeing Alert Service Bulletin 747–54A2219, dated September 4, 2003; except as required by paragraph (i) of this AD. Perform any related investigative actions and any applicable corrective actions before further flight.

Contact the FAA/Designated Engineering Representative (DER)

(i) Where Boeing Alert Service Bulletin 747–54A2219, dated September 4, 2003, specifies to contact Boeing for appropriate action: Before further flight, repair per a method approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA; or per data meeting the type certification basis of the airplane approved by a Boeing Company DER who has been authorized by the Manager, Seattle ACO, to make such findings. For a repair method to be approved, the approval must specifically reference this AD.

Alternative Methods of Compliance (AMOCs)

(j)(1) The Manager, Seattle ACO, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD, if it is approved by a Boeing Company DER who has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the approval must specifically refer to this AD.

Material Incorporated by Reference

(k) You must use Boeing Alert Service Bulletin 747–54A2219, dated September 4, 2003, to perform the actions that are required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approves the incorporation by reference of this document in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. For copies of the service information, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207. For information on the availability of this material at the National Archives and Records Administration (NARA), call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

You may view the AD docket at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., room PL–401, Nassif Building, Washington, DC.

Issued in Renton, Washington, on December 27, 2004.

Kevin M. Mullin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–105 Filed 1–4–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2004–NE–19–AD; Amendment 39–13917; AD 2004–26–05]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce plc RB211–524 Series Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding an existing airworthiness directive (AD) for certain Rolls-Royce plc (RR) RB211–524 series turbofan engines. That AD currently requires initial and repetitive borescope insepctions of the head section and meterpanel assembly of the combustion liner, and replacement, if necessary, with serviceable parts. In addition, that AD allows an optional installation of a front combustion liner with a strengthened head section as a terminating action to the inspection requirements. This AD requires initial and repetitive borescope inspections of the head section and meterpanel assembly of the combustion liner, and replacement if necessary with serviceable parts. This AD also requires reduction of the inspection intervals of certain RB211–524 engine models that have not been repaired to RR Field Repair Scheme FRS5367/B, and a mandatory terminating action to be completed by a certain date. This AD results from five events that are directly attributed to combustor head breakup and meterpanel failure which were found at overhaul inspection. At least one of these events resulted in a combustion case burn-through. We are issuing this AD to prevent engine combustion liner deterioration, which

can result in combustion liner breakup, case burn-through, and engine fire.

DATES: This AD becomes effective February 9, 2005. The incorporation by reference of RR ASB RB.211–72–AB482, Revision 9, dated July 28, 2003; Rolls-Royce Service Bulletins (SB's) RB.211–72–9764, Revision 3, dated January 16, 1998, RB.211–72–9670, Original Issue, dated August 27, 1993; and RB.211–72–9764 Supplement 1, dated January 16, 1998; are approved by the Director of the Federal Register as of February 9, 2005.

ADDRESSES: You can get the service information identified in this AD from Rolls-Royce plc, P.O. Box 31, Derby, DE24–8BJ, United Kingdom; telephone: 011–44–1332–242424; fax 011–44–1332–249936.

You may examine the AD docket at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA. You may examine the service information, at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or to to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

FOR FURTHER INFORMATION CONTACT: Ian Dargin, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803–5299; telephone (781) 238–7178; fax (781) 238–7199.

SUPPLEMENTARY INFORMATION: The FAA proposed to amend 14 CFR part 39 with a proposed AD. The proposed AD applies to RR RB211–524 series turbofan engines. We published the proposed AD in the **Federal Register** on May 18, 2004 (69 FR 28094). That action proposed to require initial and repetitive borescope inspections of the head section and meterpanel assembly of the combustion liner and replacement if necessary, with serviceable parts. That action also proposed a reduction of the inspection intervals of certain RB211–524 engine models that have not been repaired to RR Field Repair Scheme FRS53667/B, and a mandatory terminating action to be completed by a certain date.

Examining the AD Docket

You may examine the AD Docket (including any comments and service information), by appointment, between 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays. *See* **ADDRESSES** for the location.

Comments

We provided the public the opportunity to participate in the development of this AD. We received no comments on the proposal or on the determination of the cost to the public. However, we corrected RR Service Bulletin (SB) No. RB.211–71–9670 in Compliance paragraph (q) of this AD to RR SB No. RB.211.–72–9670.

Conclusion

We have carefully reviewed the available data and determined that air safety and the public interest require adopting the AD with the change described previously. We have determined that the change will neither increase the economic burden on any operator nor increase the scope of the AD.

Costs of Compliance

There are about 537 RB211–524 series turbofan engines of the affected design in the worldwide fleet. We estimate that 18 engines installed on airplanes of U.S. registry will be affected by this AD. We also estimate that it will take approximately 2.0 work hours per engine to perform the actions, and that the average labor rate is $65 per work hour. Required parts will cost about $228,389 per engine. Based on these figures, we estimate that total cost of the AD to U.S. operators to be $4,113,342.

Authority for this Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a "significant regulatory action" under Executive Order 12866;

(2) Is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a summary of the costs to comply with this AD and placed it in the AD Docket. You may get a copy of this summary by sending a request to us at the address listed under **ADDRESSES**. Include "AD Docket No. 2004–NE–19–AD" in your request.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the Federal Aviation Administration amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Amendment 39–9978 (62 FR 16475, April 7, 1997) and by adding a new airworthiness directive, Amendment 39–13917, to read as follows:

2004–26–05 Rolls-Royce plc: Amendment 39–13917. Docket No. 2004–NE–19–AD. Supersedes AD 97–07–04, Amendment 39–9978.

Effective Date

(a) This AD becomes effective February 9, 2005.

Affected ADs

(b) This AD supersedes AD 97–07–04, Amendment 39–9978.

Applicability

(c) This AD applies to Rolls-Royce plc (RR) engine models RB211–524B–02, –524B2, –524B3, –524B4, –524C2, and –524D4 series engines incorporating RR Service Bulletin (SB) No. RB.211–72–7221 or RR SB No. RB.211–72–7998 with front combustion liner

assembly, part number (P/N) UL16885, UL29916, UL27107, UL28972, or UL28974 installed but not incorporating RR SB No. RB.211–72–9670 or RR SB No. RB.211–72–9764, and engine models RB211–524G and –524H series engines with front combustion liner assembly P/N UL27659, UL23992, or UL22988 but not incorporating RR SB No. RB.211–72–9764. These engines are installed on, but not limited to, Boeing 747 and Lockheed L1011 series airplanes.

Unsafe Condition

(d) This AD results from five events that are directly attributed to combustor head breakup and meterpanel failure which were found at overhaul inspection. At least one of these events resulted in a combustion case burn-through. The actions specified in this AD are intended to prevent engine combustion liner deterioration, which can result in combustion liner breakup, case burn-through, and engine fire.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified unless the actions have already been done. Engine inspections previously made to RR Service Bulletin No. RB.211–72–B482, Revision 8, can be credited for counting cycles since last inspection.

Inspections of Combustion Liner Head Sections—Not Previously Repaired

(f) Borescope-inspect combustion liner head sections that have not been previously repaired. Use paragraphs 3.A.(1) through 3.A.(5) of the Accomplishment Instructions of RR Alert Service Bulletin (ASB) No. RB.211–72–AB482, Revision 9, dated July 28, 2003, and the compliance thresholds in Table 1 of this AD.

TABLE 1.—COMBUSTOR HEAD SECTION—NOT PREVIOUSLY REPAIRED

Engine series	Initial inspection (cycles since-new (CSN))	Repetitive inspection (cycles-since-last-inspection (CSLI))	Parts exceeding initial inspection cycles (cycles-in-service (CIS))
(1) RB211–524C2, –524D4, –524G, and –524H.	Within 1,400 to 1,600 CSN	Within 200 CSLI	Within 100 CIS after the effective date of this AD.
(2) RB211–524B–02, –524B, –524B3, and –524B4.	Within 3,000 to 3,200 CSN	Within 200 CSLI	Within 200 CIS after the effective date of this AD.

Inspections of Combustion Head Sections—Previously Repaired Using RR Field Repair Scheme FRS5367/B

(g) Borescope-inspect combustion liner head sections previously repaired using RR Field Repair Scheme FRS5367/B. Use paragraphs 3.A.(1) through 3.A.(5) of the Accomplishment Instructions of RR ASB No. RB.211–72–AB482, Revision 9, dated July 28, 2003, and the compliance thresholds in Table 2 of this AD.

TABLE 2.—COMBUSTOR HEAD SECTION—PREVIOUSLY REPAIRED USING RR FIELD REPAIR SCHEME FRS5367/B

Engine series	Initial inspection (cycles-since-last-repair (CSLR))	Repetitive inspection (cycles-since-last-inspection (CSLI))	Parts exceeding initial inspection cycles (cycles-in-service (CIS))
(1) RB211–524C2, –524D4, –524G, and –524H.	Within 1,800 to 2,200 CSLR	Within 400 CSLI	Within 200 CIS after the effective date of this AD.
(2) RB211–524B–02, –524B2, –524B3, and –524B4.	Within 3,000 to 3,200 CSLR	Within 400 CSLI	Within 200 CIS after the effective date of this AD.

Inspections of Combustion Head Sections That Have Been Repaired But Did Not Use RR Field Repair Scheme FRS5367/B

(h) Borescope-inspect combustion liner sections that have been repaired using a method other than RR Field Repair Scheme FRS5367/B. Use paragraphs 3.A.(1) through 3.A.(5) of the Accomplishment Instructions of RR ASB No. RB.211–72–AB482, Revision 9, dated July 28, 2003, and the compliance thresholds in Table 3 of this AD.

TABLE 3.—COMBUSTOR HEAD SECTION—REPAIRED, BUT DID NOT USE RR FIELD REPAIR SCHEME FRS5367/B

Engine series	Initial inspection cycles (cycles-since-last-repair (CSLR))	Repetitive inspection cycles (cycles-since-last-inspection (CSLI))	Parts exceeding initial inspection cycles (cycles-in-service (CIS))
(1) RB211–524C2, –524D4, –524G, and –524H.	Within 500 to 700 CSLR	Within 200 CSLI	Within 100 CIS after the effective date of this AD.
(2) RB211–524B–02, –524B2, –524B3, and –524B4.	Within 2,000 to 2,200 CSLR	Within 200 CSLI	Within 200 CIS after the effective date of this AD.

Note 1: For an installed front combustion liner that is subject to RR ASB No. RB.211–72–AB482, Revision 9, dated July 28, 2003: If the operator can confirm with the relevant overhaul base or repair vendor that the nicrobraze repair RR Field Repair Scheme FRS5367 has been applied to all 18 struts, then this is equivalent to compliance with RR Field Repair Scheme FRS5367/B.

Note 2: Head sections repaired by replacement of all 18 struts using RR Field Repair Scheme FRS6548 are considered as equivalent to fitting a new head section for inspection purposes.

Inspections of Meterpanel Assemblies—Not Repaired

(i) Borescope-inspect meterpanel assemblies, incorporating Service Bulletin (SB) No. RB.211–72–7998, that have not been previously repaired. Using Paragraphs 3.B.(1) through 3.B.(7) of the Accomplishment Instructions of RR ASB No. RB.211–72–AB482, Revisions 9, dated July 28, 2003, and the compliance thresholds in Table 4 of this AD.

TABLE 4.—METERPANEL ASSEMBLY—NOT REPAIRED

Engine series	Initial inspection cycles-since-new (CSN)	Repetitive inspection cycles (cycles-since-last-inspection (CSLI))	Parts exceeding initial inspection cycles (cycles-in-service (CIS))
(1) RB211–524D4, –524G, and –524H.	Within 1,000 to 1,200 CSN	Within 400 CSLI	Within 50 CIS after the effective date of this AD.
(2) RB211–524D4, –524G, and –524H that have not used RB211–524H ratings at any time.	Within 1,800 to 2,000 CSN	Within 400 CSLI	Within 50 CIS after the effective date of this AD.

Inspections of Meterpanel Assemblies—Repaired

(j) Borescope-inspect meterpanel assemblies, incorporating Service Bulletin (SB) No. RB.211–72–7998, that have been previously repaired. Use paragraphs 3.B.(1) through 3.B.(7) of the Accomplishment Instructions of RR ASB No. RB.211–72–AB482, Revision 9, dated July 28, 2003, and the compliance thresholds in Table 5 of this AD.

TABLE 5.—METERPANEL ASSEMBLY—REPAIRED

Engine series	Initial inspection cycles (cycles-since-last-repair (CSLR))	Repetitive inspection cycles (cycles-since-last-inspection (CSLI))	Parts exceeding initial inspection cycles (cycles-in-service (CIS))
(1) RB211–524D4, –524G, and –524H.	Within 500 to 700 CSLR	Within 400 CSLI	Within 50 CIS after the effective date of this AD.

Note 3: There is no requirement to inspect meter panels for combustors to a pre-RR SB No. RB.211–72–7998 standard.

Reject Parts

(k) Replace parts that exceed the acceptance criteria. Information about the acceptance criteria can be found in the Aircraft Maintenance Manual, 72–00–00, Inspection/Check.

Mandatory Terminating Action

(l) Replace any front combustion liner assembly that has a P/N listed in paragraph (c) of this AD at the next shop visit or within 10,000 CSN but no later than December 31, 2012.

(m) Replacement of the front combustion liner assembly with a front combustion liner assembly that incorporates the modifications in RR SB No. RB.211–72–9670 or RR SB No. RB.211–72–9764 in the RB211–524B02, –524B2, –524B3, –524B4, –524C2 and –524D4 engines constitutes terminating action to the repetitive inspections in paragraphs (f), (g), (h), (i), and (j), of this AD.

(n) Replacement of the front combustion liner assembly with a front combustion liner assembly that incorporates the modifications in RR SB No. RB.211–72–9764 in the RB211–524G and –524H engines constitutes terminating action to the repetitive inspections in paragraphs (f), (g), (h), (i), and (j) of this AD.

Definition of Shop Visit

(o) For the purpose of this AD, a shop visit is defined as any time that the 04 module is removed for refurbishment or overhaul.

Alternative Methods of Compliance

(p) The Manager, Engine Certification Office, has the authority to approve alternative methods of compliance for this AD if requested using the procedures found in 14 CFR 39.19.

Material Incorporated by Reference

(q) You must use the Rolls-Royce plc (RR) Alert Service Bulletin (ASB) and Service Bulletins (SB's) listed in Table 6 of this AD to do the inspections and replacements required by this AD. The Director of the Federal Register approved the incorporation by reference of RR ASB No. RB.211–72–AB482, Revision 9, dated July 28, 2003; SB's No. RB.211–72–9764, Revision 3, dated January 16, 1998, No. RB.211–72–9670, Original Issue, dated August 27, 1993; and SB No. RB.211–72–9764 Supplement, Revision 1, dated January 16, 1998; in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You can get copies at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030; or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. Table 6 follows:

TABLE 6.—INCORPORATION BY REFERENCE

Service bulletin	Page number(s) shown on the page	Revision level shown on the page	Date shown on the page
RB.211–72–AB482,	All	9	July 28, 2003.
Total Pages: 12			
RB.211–72–9670,	All	Original	Aug. 27, 1993.
Total Pages: 49			
RB.211–72–9764	1	3	Jan. 16, 1998.
	2	Original	Aug. 20, 1993.
	3, 4	3	Jan. 16, 1998.
	5	1	Aug. 25, 1995.
	6	3	Jan. 16, 1998.
	7–10	Original	Aug. 20, 1993.
	11	3	Jan. 16, 1998.
	12–30	Original	Aug. 20, 1993.
Total Pages: 30			
RB.211–72–9764 Supplement	1	1	Jan. 16, 1998.
Total Pages: 1			

Related Information

(r) Civil Aviation Authority airworthiness directive AD G–2003–0011, dated October 1, 2003, (previously 005–07–95, dated November 15, 2001), also addresses the subject of this AD. Aircraft Maintenance Manual 72–00–00 also addresses the subject of this AD.

Issued in Burlington, Massachusetts, on December 20, 2004.

Francis A. Favara,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 05–85 Filed 1–4–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–19496; Directorate Identifier 2003–NM–181–AD; Amendment 39–13920; AD 2004–26–08]

RIN 2120–AA64

Airworthiness Directives; Bombardier Model CL–215–6B11 (CL215T Variant) and CL–215–6B11 (CL415 Variant) Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Bombardier Model CL–215–6B11 (CL215T variant) and CL–215–6B11 (CL415 variant) series airplanes. This AD requires replacing the mounting pad studs of the auxiliary feather pump with new, longer studs, and installing a pressure relief valve. This AD is prompted by a few incidents of external oil leaks from the oil pump of the power control unit due to a malfunction of the pressure regulating valve. We are issuing this AD to prevent fracturing of the pump body, which could result in loss of engine oil, and consequent inability to maintain engine oil pressure and to feather the propeller.

DATES: This AD becomes effective February 9, 2005.

The incorporation by reference of certain publications listed in the AD is approved by the Director of the Federal Register as of February 9, 2005.

ADDRESSES: For service information identified in this AD, contact Bombardier, Inc., Canadair, Aerospace Group, P.O. Box 6087, Station Centreville, Montreal, Quebec H3C 3G9, Canada. You can examine this information at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

You can examine the contents of this AD docket on the Internet at *http://dms.dot.gov*, or in person at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., Room PL–401, on the plaza level of the Nassif Building, Washington, DC. This docket number is FAA–2004–19496; the directorate identifier for this docket is 2003–NM–181–AD.

FOR FURTHER INFORMATION CONTACT: Richard Fiesel, Aerospace Engineer, Airframe and Propulsion Branch, ANE–171, FAA, New York Aircraft Certification Office, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone (516) 228–7304; fax (516) 794–5531.

Examining the Docket

The AD docket contains the proposed AD, comments, and any final disposition. You can examine the AD docket on the Internet at *http://dms.dot.gov*, or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the DOT street address stated in the **ADDRESSES** section.

SUPPLEMENTARY INFORMATION: The FAA proposed to amend 14 CFR part 39 with an AD for certain Bombardier Model CL–215–6B11 (CL215T variant) and CL–215–6B11 (CL415 variant) series airplanes. That action, published in the **Federal Register** on November 3, 2004 (69 FR 63968), proposed to require replacing the mounting pad studs of the auxiliary feather pump with new, longer studs, and installing a pressure relief valve.

Comments

We provided the public the opportunity to participate in the development of this AD. No comments have been submitted on the proposed AD or on the determination of the cost to the public.

Conclusion

We have carefully reviewed the available data and determined that air safety and the public interest require adopting the AD as proposed.

Costs of Compliance

The following table provides the estimated costs for U.S. operators to comply with this AD.

ESTIMATED COSTS

Action	Work hours	Average labor rate per hour	Parts	Cost per airplane	Number of U.S.-registered airplanes	Fleet cost
Replacement	2	$65	Free	$130	3	$390
Installation	4	65	Free	260	3	780

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in subtitle VII, part A, subpart III, section 44701, "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between

the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a "significant regulatory action" under Executive Order 12866;

(2) Is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2004–26–08 Bombardier, Inc. (Formerly Canadair): Amendment 39–13920. Docket No. FAA–2004–19496; Directorate Identifier 2003–NM–181–AD.

Effective Date

(a) This AD becomes effective February 9, 2005.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Bombardier Model CL–215–6B11 (CL215T variant) series airplanes, having serial numbers (S/N) 1056 through 1125 inclusive, and Model CL–215–6B11 (CL415 variant) series airplanes having S/Ns 2001 through 2053 inclusive; certificated in any category.

Unsafe Condition

(d) This AD was prompted by a few incidents of external oil leaks from the oil pump of the power control unit due to a malfunction of the pressure regulating valve. We are issuing this AD to prevent fracturing of the pump body, which could result in loss of engine oil, and consequent inability to maintain engine oil pressure and to feather the propeller.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Replacement

(f) Within 12 months after the effective date of this AD, replace the mounting pad studs of the auxiliary feather pump with new, longer studs, and install a pressure relief valve; in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 215–3108, dated March 28, 2001 (for Model CL–215–6B11 (CL215T variant) series airplanes); or Bombardier Service Bulletin 215–4234, dated March 28, 2001 (for Model CL–215–6B11 (CL415 variant) series airplanes); as applicable.

Note 1: Bombardier Service Bulletin 215–3108 and Bombardier Service Bulletin 215–4234 refer to Pratt & Whitney Canada Service Bulletin PW100–72–21636, Revision 2, dated June 26, 2002, as an additional source of service information for accomplishing the replacement of the mounting pad studs.

No Reporting

(g) Although the service bulletin refers to a reporting requirement in paragraph 2.B, that reporting is not required by this AD.

Alternative Methods of Compliance (AMOCs)

(h) The Manager, New York Aircraft Certification Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19.

Related Information

(i) Canadian airworthiness directive CF–2002–14, dated February 13, 2002, also addresses the subject of this AD.

Material Incorporated by Reference

(j) You must use Bombardier Service Bulletin 215–3108, dated March 28, 2001; or Bombardier Service Bulletin 215–4234, dated March 28, 2001; as applicable; to perform the actions that are required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approves the incorporation by reference of these documents in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. For copies of the service information, contact Bombardier, Inc., Canadair, Aerospace Group, P.O. Box 6087, Station Centre-ville, Montreal, Quebec H3C 3G9, Canada. For information on the availability of this material at the National Archives and Records Administration (NARA), call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

You may view the AD docket at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., Room PL–401, Nassif Building, Washington, DC.

Issued in Renton, Washington, on December 20, 2004.

Kevin M. Mullin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–101 Filed 1–4–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2003–NM–135–AD; Amendment 39–13925; AD 2005–01–01]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A319 and A320–200 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD), applicable to certain Airbus Model A319 and A320–200 series airplanes, that currently requires repetitive inspections to detect loose, missing, or discrepant rivets in specified areas of the door frames of the overwing emergency exits; measurement of the grip length of all rivets in the specified areas; and corrective action if necessary, which terminates the repetitive inspections. This new amendment also requires an inspection for correct dimensions of the interior countersinks of the rivet holes, and related corrective action. The actions specified by this AD are intended to prevent loose, missing, or discrepant rivets, which could lead to reduced structural integrity of the door frames of the overwing emergency exits. This action is intended to address the identified unsafe condition.

DATES: Effective February 9, 2005.

The incorporation by reference of certain service information, as listed in the regulations, is approved by the Director of the Federal Register as of February 9, 2005.

The incorporation by reference of certain other service information, as listed in the regulations, was approved previously by the Director of the Federal Register as of April 5, 2002 (67 FR 9392, March 1, 2002).

ADDRESSES: The service information referenced in this AD may be obtained from Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW.,

Renton, Washington; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2125; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) by superseding AD 2002–04–10, amendment 39–12667 (67 FR 9392, March 1, 2002), which is applicable to certain Airbus Model A319 and A320–200 series airplanes, was published in the **Federal Register** on April 7, 2004 (69 FR 18304). The action proposed to retain the existing requirements for repetitive inspections for loose, missing, or discrepant rivets in specified areas of the door frames of the overwing emergency exits; and measurement of the grip length of all rivets in the specified areas; and corrective action if necessary, which terminates the repetitive inspections. The proposed AD also proposed to add an inspection for correct dimensions of the interior countersinks of the rivet holes, and related corrective action.

Comments

We provided the public the opportunity to participate in the development of this AD. We have considered the comments that have been submitted on the proposed AD. The commenters support the proposed AD.

Conclusion

We have carefully reviewed the available data, including the comments that have been submitted, and determined that air safety and the public interest require adopting the AD as proposed.

Cost Impact

This AD affects about 168 airplanes of U.S. registry.

The inspections required by AD 2002–04–10 take about 1 work hour per airplane, at an average labor rate of $65 per work hour. Based on these figures, the cost impact of those inspections is estimated to be $65 per airplane, per inspection cycle.

The new inspection required by this AD takes about 1 work hour per airplane, at an average labor rate of $65 per work hour. Based on these figures, the cost impact of the new inspection on U.S. operators is estimated to be $10,920, or $65 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the requirements of this AD, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Impact

The regulations adopted herein will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this action (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. Section 39.13 is amended by removing amendment 39–12667 (67 FR 9392, March 1, 2002), and by adding a new airworthiness directive (AD), amendment 39–13925, to read as follows:

2005–01–01 Airbus: Amendment 39–13925. Docket 2003–NM–135–AD. Supersedes AD 2002–04–10, Amendment 39–12667.

Applicability: Model A319 series airplanes and A320–200 series airplanes; certificated in any category; as listed in Airbus Service Bulletin A320–53–1147, dated September 22, 2000; Revision 02, dated December 3, 2002; or Revision 03, dated August 5, 2003.

Compliance: Required as indicated, unless accomplished previously.

To prevent loose, missing, or discrepant rivets in specified areas of the door frames of the overwing emergency exits, which could lead to reduced structural integrity of the door frames, accomplish the following:

Restatement of Requirements of AD 2002–04–10

Repetitive Inspections

(a) Within 3,500 flight cycles after April 5, 2002 (the effective date of AD 2002–04–10, amendment 39–12667): Conduct a detailed inspection of the specified areas of the door frames of the overwing emergency exits for loose, missing, or discrepant rivets, in accordance with Part B and Figure 5 of the Accomplishment Instructions of Airbus Service Bulletin A320–53–1147, dated September 22, 2000; Revision 02, dated December 3, 2002; or Revision 03, dated August 5, 2003. If no loose, missing, or discrepant rivets are found, repeat the inspection at intervals not to exceed 3,500 flight cycles until the requirements of paragraph (d) have been accomplished. As of the effective date of this AD, only Revision 02 or Revision 03 of the service bulletin may be used.

Note 1: For the purposes of this AD, a detailed inspection is defined as: "An intensive visual examination of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required."

Corrective Action

(b) If the inspection required by paragraph (a) of this AD reveals that there are loose, missing, or discrepant rivets: Prior to further flight, accomplish the requirements of either paragraph (b)(1) or (b)(2) of this AD, in accordance with Part C and Figure 5 of the Accomplishment Instructions of Airbus Service Bulletin A320–53–1147, dated September 22, 2000; Revision 02, dated December 3, 2002; or Revision 03, dated August 5, 2003. As of the effective date of this AD, only Revision 02 or Revision 03 of the service bulletin may be used.

(1) Measure the grip length of all rivets in the specified areas in which the loose, missing, or discrepant rivets were detected and perform corrective action (*e.g.*, inspecting rivet holes for cracks, opening up rivet holes, repairing cracks at rivet holes, and installing new rivets) as applicable, per the service bulletin; except as specified in paragraph (c) of this AD. Repeat the detailed visual inspection required by paragraph (a) of this AD at intervals not to exceed 3,500 flight cycles until the requirements of paragraph (d) of this AD have been accomplished.

(2) Measure the grip length of all rivets in all specified areas and perform corrective action (*e.g.*, inspecting rivet holes for cracks, opening up rivet holes, repairing cracks at rivet holes, and installing new rivets) as applicable, per the service bulletin; except as specified in paragraph (c) of this AD.

(c) If Airbus Service Bulletin A320–53–1147, dated September 22, 2000; Revision 02, dated December 3, 2002; or Revision 03, dated August 5, 2003; recommends contacting the manufacturer for instructions concerning certain repairs, perform those repairs in accordance with a method approved by the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, or by the Direction Générale de l'Aviation Civile or its delegated agent.

Terminating Action

(d) Prior to the accumulation of 24,000 total flight cycles or within 3,500 flight cycles after April 5, 2002, whichever occurs later: Accomplish the requirements of paragraph (b)(2) of this AD, which constitutes terminating action for the requirements specified in paragraphs (a) and (b) of this AD.

New Requirements of This AD

Inspection of Interior Countersinks/ Corrective Action

(e) Prior to the accumulation of 24,000 total flight cycles or within 3,500 flight cycles after the effective date of this AD, whichever occurs later: Do a detailed inspection for correct dimensions of the interior countersinks of the rivet holes of the door frames of the overwing emergency exits; and any related corrective action; per the Accomplishment Instructions of Airbus Service Bulletin A320–53–1147, Revision 02, including Appendix 01, dated December 3, 2002; or Revision 03, including Appendix 01, dated August 5, 2003. Do any related corrective action within 1,000 flight cycles after doing the inspection.

Alternative Methods of Compliance

(f)(1) In accordance with 14 CFR 39.19, the Manager, International Branch, ANM–116, is authorized to approve alternative methods of compliance for this AD.

(2) Alternative methods of compliance, approved previously per AD 2002–04–10, amendment 39–12667, are approved as alternative methods of compliance with paragraphs (a) and (b) of this AD.

Note 2: The subject of this AD is addressed in French airworthiness directive 2003–147(B) R1, dated May 14, 2003.

Incorporation by Reference

(g) Unless otherwise specified in this AD, the actions must be done in accordance with Airbus Service Bulletin A320–53–1147, dated September 22, 2000; Airbus Service Bulletin A320–53–1147, Revision 02, including Appendix 01, dated December 3, 2002; or Airbus Service Bulletin A320–53–1147, Revision 03, including Appendix 01, dated August 5, 2003.

(1) The incorporation by reference of Airbus Service Bulletin A320–53–1147, Revision 02, including Appendix 01, dated December 3, 2002; and Airbus Service Bulletin A320–53–1147, Revision 03, including Appendix 01, dated August 5, 2003, is approved by the Director of the Federal Register, in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(2) The incorporation by reference of Airbus Service Bulletin A320–53–1147, dated September 22, 2000, was approved previously by the Director of the Federal Register as of April 5, 2002 (67 FR 9392, March 1, 2002).

(3) Copies may be obtained from Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Effective Date

(h) This amendment becomes effective on February 9, 2005.

Issued in Renton, Washington, on December 27, 2004.

Kevin M. Mullin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–103 Filed 1–4–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–18557; Directorate Identifier 2003–NM–174–AD; Amendment 39–13926; AD 2005–01–02]

RIN 2120–AA64

Airworthiness Directives; Lockheed Model 1329 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Lockheed Model 1329 series airplanes. This AD requires repetitive inspections to detect crack damage in the front spar cap assembly of the lower vertical stabilizer; reworking the spar cap doublers if no crack damage is found during any inspection; and repairing if any crack damage is found during any inspection. This AD is prompted by reports of cracks in the front spar cap assembly of the lower vertical stabilizer at box beam station 24 on the aft side of the 25% chord line. We are issuing this AD to find and fix cracks in the front spar cap assembly of the lower vertical stabilizer, which could result in rapid crack propagation and failure of the front spar cap. Failure of the front spar cap could lead to loss of rudder control and consequent reduced controllability of the airplane.

DATES: This AD becomes effective February 9, 2005.

The incorporation by reference of certain publications listed in the AD is approved by the Director of the Federal Register as of February 9, 2005.

ADDRESSES: For service information identified in this AD, contact Lockheed Martin Aircraft & Logistics Center, 120 Orion Street, Greenville, South Carolina 29605. You can examine this information at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

You can examine the contents of this AD docket on the Internet at *http://dms.dot.gov*, or at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., room PL–401, on the plaza level of the Nassif Building, Washington, DC. This docket number is FAA–2004–18557; the directorate identifier for this docket is 2003–NM–174–AD.

FOR FURTHER INFORMATION CONTACT:

Technical information: Carl Gray, Aerospace Engineer, Airframe Branch, ACE–117A, FAA, Atlanta Aircraft Certification Office, One Crown Center, 1895 Phoenix Boulevard, suite 450, Atlanta, Georgia 30349; telephone (770) 703–6131; fax (770) 703–6097.

Plain language information: Marcia Walters, *marcia.walters@faa.gov.*

Examining the Docket

The AD docket contains the proposed AD, comments, and any final disposition. You can examine the AD docket on the Internet at *http://dms.dot.gov,* or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the DOT street address stated in the **ADDRESSES** section.

SUPPLEMENTARY INFORMATION: The FAA proposed to amend 14 CFR part 39 with an AD for certain Lockheed Model 1329 series airplanes. That action, published in the **Federal Register** on July 7, 2004 (69 FR 40821), proposed to require repetitive inspections to detect crack damage in the front spar cap assembly of the lower vertical stabilizer; reworking the spar cap doublers if no crack damage is found during any inspection; and repairing if any crack damage is found during any inspection.

Comments

We provided the public the opportunity to participate in the development of this AD. We have considered the comment that has been submitted on the proposed AD.

Request To Withdraw Proposed AD

One commenter contends that the FAA should not classify cracking of the front spar cap assembly of the lower vertical stabilizer as a safety issue. The commenter justifies this statement by saying that we have known about the cracking for over four years, and if it is a true safety issue, we would have addressed it either many years ago, or last year when Lockheed Service Bulletin 329–302, dated July 9, 2003 (for Model 1329–23A, –23D, and –23E series airplanes); and Lockheed Service Bulletin 329II–55–4, dated July 9, 2003 (for Model 1329–25 series airplanes) were published. While the commenter does not explicitly make a request, we infer from its statements that the commenter requests to withdraw the proposed AD. The commenter also asks the following questions:

1. What analysis has been done to show that cracking will not cause a problem until 301 flight hours?

2. Have we been lucky that cracking has not caused safety issues in the last four years?

3. How could cracking possibly affect the rudder? Would the entire tail depart from the aircraft?

We do not agree with the commenter. To withdraw this action would be inappropriate, since we have determined that an unsafe condition exists and that inspections must be conducted to ensure continued safety. We have provided answers to the commenter's questions below:

1. Lockheed Martin Engineering performed damage tolerance analysis (DTA) to establish the inspection intervals for cracking. Based on this data, it has recommended inspection intervals of 300 flight hours for airplanes that have accumulated fewer than 10,000 total flight hours and 150 flight hours for airplanes that have accumulated 10,000 or more total flight hours. We agree with its analysis and the inspection intervals it recommended in Lockheed Service Bulletin 329–302; and Lockheed Service Bulletin 329II–55–4.

2. We have determined that there have not been any serious accidents related to the unsafe condition addressed in this AD because of the small number of Lockheed Model 1329 series airplanes in the U.S. fleet and the low utilization of those airplanes. Also, some operators have already found Model 1329 series airplanes with cracking of the front spar cap assembly of the lower vertical stabilizer and have repaired those airplanes.

3. Cracks in the front spar cap assembly of the lower vertical stabilizer, if allowed to propagate, substantially reduce the structural load capability of the rudder spar. This condition could lead to spar failure. Failure of the rudder spar cap could lead to operational handling problems of the rudder, which could cause loss of control of the airplane.

Explanation of Changes Made to This AD

For clarification, we have revised the definition of a "detailed inspection" in this final rule.

We inadvertently misstated the compliance time for paragraph (g)(2) of this AD and have clarified it accordingly.

Conclusion

We have carefully reviewed the available data, including the comment that has been submitted, and determined that air safety and the public interest require adopting the AD with the changes described previously. We have determined that these changes will neither increase the economic burden on any operator nor increase the scope of the AD.

Costs of Compliance

This AD affects about 85 airplanes of U.S. registry and 98 airplanes worldwide. The required actions take about 1 work hour per airplane, at an average labor rate of $65 per work hour. No parts are required. Based on these figures, the estimated cost of the AD for U.S. operators is $5,525, or $65 per airplane.

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in title 49 of the United States Code. Subtitle I, section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in subtitle VII, part A, subpart III, section 44701, "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this AD.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a "significant regulatory action" under Executive Order 12866;

(2) Is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this AD. See the **ADDRESSES** section for

a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2005–01–02 Lockheed: Amendment 39–13926. Docket No. FAA–2004–18557; Directorate Identifier 2003–NM–174–AD.

Effective Date

(a) This AD becomes effective February 9, 2005.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Lockheed Model 1329–23A, –23D, and –23E series airplanes, serial numbers 5001 through 5162 inclusive, and Lockheed Model 1329–25 series airplanes, serial numbers 5201 through 5240 inclusive; certificated in any category.

Unsafe Condition

(d) This AD was prompted by reports of cracks in the front spar cap assembly of the lower vertical stabilizer at box beam station 24 on the aft side of the 25% chord line. We are issuing this AD to find and fix cracks in the front spar cap assembly of the lower vertical stabilizer, which could result in rapid crack propagation and failure of the front spar cap, leading to loss of rudder control and consequent reduced controllability of the airplane.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Service Bulletin References

(f) The term "service bulletin," as used in this AD, means the Accomplishment Instructions of the following service bulletins, as applicable:

(1) For Model 1329–23A, –23D, and –23E series airplanes: Lockheed Service Bulletin 329–302, dated July 9, 2003; and

(2) For Model 1329–25 series airplanes: Lockheed Service Bulletin 329II–55–4, dated July 9, 2003.

Initial and Repetitive Inspections

(g) Do a detailed inspection to detect any crack damage in the left and right radius detail of the spar cap doublers, at the applicable time specified in paragraph (g)(1) or (g)(2) of this AD, in accordance with the service bulletin.

Note 1: For the purposes of this AD, a detailed inspection is defined as: "An intensive examination of a specific item, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at an intensity deemed appropriate. Inspection aids such as mirror, magnifying lenses, etc., may be necessary. Surface cleaning and elaborate procedures may be required."

(1) For airplanes that have accumulated 10,000 or more total flight hours as of the effective date of this AD: Inspect within 150 flight hours after the effective date of this AD. Repeat the detailed inspection thereafter at intervals not to exceed 150 flight hours.

(2) For airplanes that have accumulated fewer than 10,000 total flight hours as of the effective date of this AD: Inspect within 300 flight hours after the effective date of this AD. Repeat the detailed inspection thereafter at intervals not to exceed 300 flight hours. At the time the airplane has accumulated 10,000 or more total flight hours, repeat the detailed inspection thereafter at intervals not to exceed 150 flight hours.

No Damage Detected

(h) If no crack damage is found during any inspection required by paragraph (g) of this AD, before further flight, rework the spar cap doublers by performing the actions in paragraphs (h)(1) and (h)(2) of this AD, in accordance with the service bulletin.

(1) Remove all burrs, sharp edges, and extraneous tool marks by smoothing the radius to an RMS 125 finish.

(2) Touch up finish to prevent corrosion.

Damage Detected: Corrective Action

(i) If any crack damage is found during any inspection required by paragraph (g) of this AD, and the service bulletin specifies to contact Lockheed Martin Technical Support Center for repair instructions: Before further flight, repair in accordance with a method approved by the Manager, Atlanta Aircraft Certification Office (ACO), FAA. For a repair method to be approved by the Manager, Atlanta ACO, as required by this paragraph, the Manager's approval letter must specifically refer to this AD.

Parts Installation

(j) As of the effective date of this AD, no person shall install a spar cap doubler, part number (P/N) JE15–2 L/R or P/N JE15–15 L/R, on any airplane unless it has been reworked as required by paragraph (h) of this AD.

Reporting Requirement

(k) Submit a report of the findings (both positive and negative) of any inspection required by paragraph (g)(1) or (g)(2) of this AD to the Manager, Atlanta ACO, FAA, Small Airplane Directorate, One Crown Center, 1895 Phoenix Boulevard, suite 450, Atlanta, Georgia 30349; fax (770) 703–6097; at the applicable time specified in paragraph (k)(1) or (k)(2) of this AD. (The report must include the inspection results, a description of any discrepancy found (*e.g.*, crack length and location), the airplane serial number, and the number of landings and flight hours on the airplane.) Information collection requirements contained in this AD have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*) and have been assigned OMB Control Number 2120–0056.

(1) For airplanes on which any inspection required by paragraph (g) of this AD is accomplished after the effective date of this AD: Submit the report within 30 days after performing those inspections.

(2) For airplanes on which any inspection required by paragraph (g) of this AD has been accomplished before the effective date of this AD: Submit the report within 30 days after the effective date of this AD.

Previously Accomplished Initial Inspections

(l) Initial inspections accomplished within 12 months prior to the effective date of this AD in accordance with the service bulletin are considered acceptable for compliance with the applicable actions specified in paragraph (g) of this AD.

Alternative Methods of Compliance (AMOCs)

(m) The Manager, Atlanta ACO, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19.

Material Incorporated by Reference

(n) You must use Lockheed Service Bulletin 329–302, dated July 9, 2003; or Lockheed Service Bulletin 329II–55–4, dated July 9, 2003; as applicable; to perform the actions that are required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approves the incorporation by reference of this document in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. For copies of the service information, contact Lockheed Martin Aircraft & Logistics Center, 120 Orion Street, Greenville, South Carolina 29605. For information on the availability of this material at the National Archives and Records Administration (NARA), call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

You may view the AD docket at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., Room PL–401, Nassif Building, Washington, DC.

Issued in Renton, Washington, on December 27, 2004.

Kevin M. Mullin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–104 Filed 1–4–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–18752; Directorate Identifier 2004–NM–107–AD; Amendment 39–13929; AD 2005–01–05]

RIN 2120–AA64

Airworthiness Directives; Empresa Brasileira de Aeronautica S.A. (EMBRAER) Model EMB–135 and EMB–145 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding an existing airworthiness directive (AD), which applies to certain EMBRAER Model EMB–135 and EMB–145 series airplanes. That AD currently requires replacing the nose landing gear wheel nuts and associated inner and outer seals, and reidentifying the landing gear strut. This new AD adds an airplane to the applicability and revises a part number for a replacement part. This AD is prompted by a report of an invalid part number for the new nose landing gear wheel nut. We are issuing this AD to prevent separation of the wheels from the nose landing gear due to the failure of the outer wheel bearings, and consequent loss of control of the airplane during takeoff and landing.

DATES: This AD becomes effective February 9, 2005.

On June 9, 2004 (69 FR 24940, May 5, 2004), the Director of the Federal Register approved the incorporation by reference of EMBRAER Service Bulletin 145–32–0068, Change 04, dated January 20, 2003; and EMBRAER Service Bulletin 145LEG–32–0006, Change 01, dated January 20, 2003.

ADDRESSES: For service information identified in this AD, contact Empresa Brasileira de Aeronautica S.A. (EMBRAER), P.O. Box 343—CEP 12.225, Sao Jose dos Campos—SP, Brazil.

You can examine this information at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

You can examine the contents of this AD docket on the Internet at *http://dms.dot.gov*, or at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW, room PL–401, on the plaza level of the Nassif Building, Washington, DC.

FOR FURTHER INFORMATION CONTACT:

Technical information: Todd Thompson, Aerospace Engineer; International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW, Renton, Washington 98055–4056; telephone (425) 227–1175; fax (425) 227–1149.

Plain language information: Marcia Walters, *marcia.walters@faa.gov.*

Examining the Docket

The AD docket contains the proposed AD, comments, and any final disposition. You can examine the AD docket on the Internet at *http://dms.dot.gov*, or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the DOT street address stated in the **ADDRESSES** section.

SUPPLEMENTARY INFORMATION: The FAA proposed to amend part 39 of the Federal Aviation Regulations (14 CFR Part 39) with an AD to supersede AD 2004–09–15, amendment 39–13604, (69 FR 24940, May 5, 2004). The existing AD applies to certain EMBRAER Model EMB–135 and EMB–145 series airplanes. The proposed AD was published in the **Federal Register** on August 4, 2004 (69 FR 47038), and continued to require replacing the nose landing gear wheel nuts and associated inner and outer seals, and reidentifying the landing gear strut. The proposed AD also added an airplane to the applicability and revised a part number for a replacement part.

Comments

We provided the public the opportunity to participate in the development of this AD. We have considered the comment that has been submitted on the proposed AD.

Request to Add an Alternative Method of Compliance (AMOC)

The commenter requests that a reference to replacement seal assembly part number (P/N) AEC–68–1498, which was approved as an AMOC for AD 2004–09–15, be included in the proposed AD. The commenter notes that P/N AEC–68–1498 has a parts manufacturer approval and is an FAA-approved replacement assembly for the P/N 68–1498 seal assembly. The commenter contends that P/N AEC–68–1498 should be included in the proposed AD as an approved seal assembly.

The FAA does not agree to include a reference to replacement seal assembly P/N AEC–68–1498 in this final rule. However, we do agree that AMOCs approved previously for AD 2004–09–15, amendment 39–13604, are acceptable as AMOCs for this final rule. We have revised paragraph (i) of this final rule to include the following statement: "AMOCs, approved previously in accordance with AD 2004–09–15, amendment 39–13604, are approved as AMOCs for this AD."

Conclusion

We have carefully reviewed the available data, including the comment that was submitted, and determined that air safety and the public interest require adopting the AD with the change described previously. We have determined that this change will neither increase the economic burden on any operator nor increase the scope of the AD.

Costs of Compliance

This AD affects about 365 airplanes of U.S. registry.

The actions that are required by AD 2004–09–15, and retained in this AD, take about 1 work hour per airplane, at an average labor rate of $65 per work hour. Required parts will be provided free of charge by the airplane manufacturer. Based on these figures, the estimated cost of the currently required actions for U.S. operators is $23,725, or $65 per airplane.

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, "General requirements." Under that section, the FAA is charged with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this AD.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States,

or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a "significant regulatory action" under Executive Order 12866;

(2) Is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing amendment 39–13604 (69 FR 24940, May 5, 2004), and by adding the following new airworthiness directive:

2005–01–05 Empresa Brasileira de Aeronautica S.A. (EMBRAER): Amendment 39–13929. Docket No. FAA–2004–18752; Directorate Identifier 2004–NM–107–AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective February 9, 2005.

Affected ADs

(b) This AD supersedes AD 2004–09–15, amendment 39–13604.

Applicability

(c) This AD applies to Model EMB–135 and EMB–145 series airplanes having serial numbers (S/N) 145003 through 145373 inclusive, 145375, 145377 through 145391 inclusive, and 145393 through 145408 inclusive; certificated in any category; equipped with nose landing gear struts, part number (P/N) 1170C0000–01 (including all modifications), P/N 1170C0000–02, or P/N 1170C0000–03.

Unsafe Condition

(d) This AD was prompted by a report of an invalid part number for the new nose landing gear wheel nut. We are issuing this AD to prevent separation of the wheels from the nose landing gear due to the failure of the outer wheel bearings, and consequent loss of control of the airplane during takeoff and landing.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Replacement and Reidentification

(f) At the applicable time specified in paragraph (f)(1) or (f)(2) of this AD, replace the nose landing gear wheel nuts, P/N 1170–0007, with new wheel nuts, P/N 1170–0082; replace the associated inner and outer seals, P/N 68–1157 or P/N 72–290, with new seals, P/N 68–1498; and reidentify the struts. Do the actions in accordance with the Accomplishment Instructions of EMBRAER Service Bulletin 145–32–0068, Change 04, dated January 20, 2003; or EMBRAER Service Bulletin 145LEG–32–0006, Change 01, dated January 20, 2003; as applicable.

(1) For Model EMB–135 and EMB–145 series airplanes having S/N 145003 through 145373 inclusive, 145377 through 145391 inclusive, and 145393 through 145408 inclusive: Within 12 months after June 9, 2004 (the effective date of AD 2004–09–15).

(2) For Model EMB–145 series airplane having S/N 145375: Within 12 months after the effective date of this AD.

(g) Actions accomplished before the effective date of this AD per the EMBRAER Service Bulletins listed in Table 1 of this AD are considered acceptable for compliance with the corresponding actions specified in this AD:

TABLE 1.—SERVICE BULLETINS CONSIDERED ACCEPTABLE FOR COMPLIANCE

EMBRAER service bulletin	Change level	Date
145–32–0068 ..	Original ..	May 4, 2001.
145–32–0068 ..	01	Jan. 14, 2002.
145–32–0068 ..	02	Apr. 16, 2002.
145–32–0068 ..	03	Nov. 25, 2002.
145LEG–32–0006.	Original ..	Nov. 26, 2002.

Parts Installation

(h) As of the effective date of this AD, no person may install nose landing gear wheel nuts, P/N 1170–0007, or the associated inner and outer seals, P/N 68–1157 or P/N 72–290, on any airplane.

Alternative Methods of Compliance (AMOC)

(i)(1) The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) AMOCS approved previously in accordance with AD 2004–09–15, amendment 39–13604, are approved as AMOCs for this AD.

Related Information

(j) Brazilian airworthiness directive 2002–03–01R2, effective April 22, 2003, also addresses the subject of this AD.

Material Incorporated by Reference

(k) You must use EMBRAER Service Bulletin 145–32–0068, Change 04, dated January 20, 2003; or EMBRAER Service Bulletin 145LEG–32–0006, Change 01, dated January 20, 2003; as applicable; to perform the actions that are required by this AD, unless the AD specifies otherwise. The Director of the Federal Register previously approved the incorporation by reference of these documents as of June 9, 2004 (69 FR 24940, May 5, 2004). For copies of the service information, contact Empresa Brasileira de Aeronautica S.A. (EMBRAER), P.O. Box 343—CEP 12.225, Sao Jose dos Campos—SP, Brazil. For information on the availability of this material at the National Archives and Records Administration (NARA), call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* You may view the AD docket at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., room PL–401, Nassif Building, Washington, DC.

Issued in Renton, Washington, on December 27, 2004.

Kevin M. Mullin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–164 Filed 1–4–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 30433; Amdt. No. 3112]

Standard Instrument Approach Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, addition of new obstacles, or changes in air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under

instrument flight rules at the affected airports.

DATES: This rule is effective January 5, 2005. The compliance date for each SIAP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of January 5, 2005.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination—

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591;

2. The FAA Regional Office of the region in which the affected airport is located;

3. The Flight Inspection Area Office which originated the SIAP; or,

4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

For Purchase—Individual SIAP copies may be obtained from:

1. FAA Public Inquiry Center (APA–200), FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591; or

2. The FAA Regional Office of the region in which the affected airport is located.

By Subscription—Copies of all SIAPs, mailed once every 2 weeks, are for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

FOR FURTHER INFORMATION CONTACT: Donald P. Pate, Flight Procedure Standards Branch (AMCAFS–420), Flight Technologies and Programs Division, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 (Mail Address: P.O. Box 25082, Oklahoma City, OK 73125), telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This amendment to part 97 of the Federal Aviation Regulations (14 CFR part 97) establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs). The complete regulatory description of each SIAP is contained in official FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and § 97.20 of the Federal Aviation Regulations (FAR). The applicable FAA Forms are identified as FAA Forms 8260–3, 8260–4, and 8260–5. Materials incorporated by reference are available for examination or purchase as stated above.

The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained in FAA form documents is unnecessary. The provisions of this amendment state the affected CFR (and FAR) sections, with the types and effective dates of the SIAPs. This amendment also identifies the airport, its location, the procedure identification and the amendment number.

The Rule

This amendment to part 97 is effective upon publication of each separate SIAP as contained in the transmittal. Some SIAP amendments may have been previously issued by the FAA in a National Flight Data Center (NFDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for some SIAP amendments may require making them effective in less than 30 days. For the remaining SIAPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs and safety in air commerce, I find that notice and public procedure before adopting these SIAPs are impracticable and contrary to the public interest and, where applicable, that good cause exists for making some SIAPs effective in less than 30 days.

Conclusion

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air traffic control, Airports, Incorporation by reference, and Navigation (Air).

Issued in Washington, DC, on December 3, 2004.

James J. Ballough,

Director, Flight Standards Service.

Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me, part 97 of the Federal Aviation Regulations (14 CFR part 97) is amended by establishing, amending, suspending, or revoking Standard Instrument Approach Procedures, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

** * * Effective 20 January 2005*

Lompoc, CA, Lompoc, VOR/DME–A, Amdt 5
Lompoc, CA, Lompoc, RNAV (GPS) RWY 25, Orig
Lompoc, CA, Lompoc, GPS RWY 25, Orig, CANCELLED
Washington, DC, Washington Dulles Intl, ILS OR LOC/DME RWY 19R, Amdt 23 and ILS RWY 19R (CAT II/III), Amdt 23
Washington, DC, Washington Dulles Intl, Converging ILS RWY 19R, Amdt 6
Washington, DC, Washington Dulles Intl, RNAV (GPS) RWY 19R, Amdt 1
Wichita, KS, Colonel James Jabara, RNAV (GPS) RWY 18, Orig
Wichita, KS, Colonel James Jabara, RNAV (GPS) RWY 36, Orig
Wichita, KS, Colonel James Jabara, GPS RWY 18, Orig-A, CANCELLED
Wichita, KS, Colonel James Jabara, GPS RWY 36, Orig, CANCELLED
Wichita, KS, Colonel James Jabara, VOR–A, Amdt 4
Wichita, KS, Colonel James Jabara, RNAV (GPS)–E, Orig

Covington, KY, Cincinnati/Northern Kentucky Intl, ILS OR LOC RWY 9, Amdt 17
Covington, KY, Cincinnati/Northern Kentucky Intl, ILS OR LOC RWY 27, Amdt 16
Oakdale, LA, Allen Parrish, RNAV (GPS) RWY 36, Orig
Gulfport, MS, Gulfport-Biloxi Intl, VOR/DME OR TACAN RWY 32, Amdt 4
Gulfport, MS, Gulfport-Biloxi Intl, VOR RWY 14, Amdt 22
Gulfport, MS, Gulfport-Biloxi Intl, VOR/DME OR TACAN RWY 14, Amdt 3
Gulfport, MS, Gulfport-Biloxi Intl, NDB RWY 14, Amdt 12
Gulfport, MS, Gulfport-Biloxi Intl, RADAR–1, Amdt 6
Gulfport, MS, Gulfport-Biloxi Intl, RNAV (GPS) RWY 14, Orig
Gulfport, MS, Gulfport-Biloxi Intl, RNAV (GPS) RWY 32, Orig
Gulfport, MS, Gulfport-Biloxi Intl, ILS OR LOC RWY 14, Amdt 14
Gulfport, MS, Gulfport-Biloxi Intl, GPS RWY 14, Orig, CANCELLED
Gulfport, MS, Gulfport-Biloxi Intl, GPS RWY 18, Orig, CANCELLED
Gulfport, MS, Gulfport-Biloxi Intl, GPS RWY 32, Orig, CANCELLED
Gulfport, MS, Gulfport-Biloxi Intl, GPS RWY 36, Orig, CANCELLED
Gulfport, MS, Gulfport-Biloxi Intl, VOR RWY 32, Amdt 21
Gulfport, MS, Gulfport-Biloxi Intl, RNAV (GPS) RWY 18, Orig
Gulfport, MS, Gulfport-Biloxi Intl, RNAV (GPS) RWY 36, Orig
Gulfport, MS, Gulfport-Biloxi Intl, ILS OR LOC/DME RWY 32, Amdt 4
Tunica, MS, Tunica Muni, ILS OR LOC RWY 35, Orig
Fargo, ND, Hector Intl, RNAV (GPS) RWY 18, Orig
Fargo, ND, Hector Intl, RNAV (GPS) RWY 36, Orig
Fargo, ND, Hector Intl, RNAV (GPS) RWY 17, Orig, CANCELLED
Fargo, ND, Hector Intl, RNAV (GPS) RWY 35, Orig-B, CANCELLED
Lexington, OR, Lexington, RNAV (GPS)–A, Orig
Lexington, OR, Lexington, RNAV (GPS) RWY 8, Orig

** * * Effective 17 February 2005*

Hayden, CO, Yampa Valley, RNAV (GPS) RWY 28, Orig-B
Hayden, CO, Yampa Valley, RNAV (GPS) Z RWY 10, Orig-B
Lamar, CO, Lamar Muni, RNAV (GPS) RWY 8, Orig-A
Lamar, CO, Lamar Muni, RNAV (GPS) RWY 18, Orig-A
Lamar, CO, Lamar Muni, RNAV (GPS) RWY 26, Orig-A
Lamar, CO, Lamar Muni, RNAV (GPS) RWY 36, Orig-A
Boise, ID, Boise Air Terminal (Gowen Field), RNAV (GPS) RWY 28R, Orig-A
Boise, ID, Boise Air Terminal (Gowen Field), RNAV (GPS) RWY 28L, Amdt 1A
Bozeman, MT, Gallatin Field, RNAV (GPS)-A, Orig-A
Akron, OH, Akron-Canton Regional, RNAV (GPS) RWY 14, Orig, CANCELLED
Akron, OH, Akron-Canton Regional, RNAV (GPS) RWY 32, Orig, CANCELLED
McAlester, OK, McAlester Regional, VOR–A, Amdt 13
Sioux Falls, SD, Joe Foss Field, RNAV (GPS) RWY 15, Orig-B

** * * Effective 17 March 2005*

Kotzebue, AK, Ralph Wien Memorial, RNAV (GPS) RWY 8, Orig
Kotzebue, AK, Ralph Wien Memorial, RNAV (GPS) RWY 26, Orig
Kotzebue, AK, Ralph Wien Memorial, ILS OR LOC/DME RWY 8, Orig
Kotzebue, AK, Ralph Wien Memorial, VOR RWY 8, Amdt 3A
Kotzebue, AK, Ralph Wien Memorial, VOR RWY 26, Amdt 3
Kotzebue, AK, Ralph Wien Memorial, VOR/DME RWY 8, Amdt 4
Kotzebue, AK, Ralph Wien Memorial, VOR/DME Z RWY 26, Orig
Kotzebue, AK, Ralph Wien Memorial, VOR/DME Y RWY 26, Orig
Kotzebue, AK, Ralph Wien Memorial, ILS/DME RWY 8, Amdt 5, CANCELLED
Kotzebue, AK, Ralph Wien Memorial, GPS RWY 8, Orig, CANCELLED
Kotzebue, AK, Ralph Wien Memorial, GPS RWY 26, Orig-A, CANCELLED
Kotzebue, AK. Ralph Wien Memorial, VOR/DME 2 RWY 26, Orig, CANCELLED
Kotzebue, AK, Ralph Wien Memorial, VOR/DME RWY 26, Amdt 1B, CANCELLED
San Jose, CA, Norman Y. Mineta San Jose Intl, RNAV (GPS) RWY 12R, Orig
San Jose, CA, Norman Y. Mineta San Jose Intl, GPS RWY 12R, Orig-A, CANCELLED
San Jose, CA, Norman Y. Mineta San Jose Intl, RNAV (GPS) RWY 30L, Orig
San Jose, CA, Norman Y. Mineta San Jose Intl, GPS RWY 30L, Orig-A, CANCELLED
Eastport, ME, Eastport Muni, RNAV (GPS) RWY 15, Orig
Eastport, ME, Eastport Muni, RNAV (GPS) RWY 33, Orig
Eastport, ME, Eastport Muni, NDB RWY 15, Amdt 1
Eastport, ME, Eastport Muni, NDB RWY 33, Amdt 1
Eastport, ME, Eastport Muni, GPS RWY 15, Orig-B, CANCELLED
Oshkosh, WI, Wittman Regional, RNAV (GPS) RWY 36, Amdt 1C
Casper, WY, Natrona County Intl, RNAV (GPS) RWY 21, Amdt 1
Casper, WY, Natrona County Intl, VOR/DME RWY 3, Amdt 4
Casper, WY, Natrona County Intl, VOR/DME OR TACAN RWY 21, Amdt 8

The FAA published an Amendment in Docket No. 30430, Amdt No. 3110 to Part 97 of the Federal Aviation Regulations (Vol 69, FR No. 229, page 69508; dated November 30, 2004) under section 97.33 effective 20 JAN 2005, which is hereby rescinded:

Deadhorse, AK, Deadhorse, LOC/DME BC RWY 22, Amdt 10

[FR Doc. 05–106 Filed 1–4–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

15 CFR Part 996

[Docket No: 040908256–4353–02]

RIN 0648–AS50

National Ocean Service; Quality Assurance and Certification Program for NOAA Hydrographic Products

AGENCY: National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Final rule.

SUMMARY: The National Oceanic and Atmospheric Administration (NOAA) has been mandated to develop and implement a quality assurance program that is equally available to all applicants, under which the Administrator may certify hydrographic products that satisfy standards promulgated by the Administrator. "Hydrographic products" are any publicly or commercially available products produced by a non-Federal entity that include or display hydrographic data. The Administrator will fulfill this mandate by establishing procedures by which hydrographic products are proposed for certification; by which standards and compliance tests are developed, adopted, and applied for those products; and by which certification may be awarded or denied. These procedures would be the mandated Quality Assurance Program. The implementation of the program would be the execution of those procedures for specific hydrographic products.

DATES: Effective Date: February 4, 2005.

ADDRESSES: Comments in writing should be submitted to Director, Office of Coast Survey, National Ocean Service, NOAA (N/CS), 1315 East West Highway, Silver Spring, MD 20910. Written comments may be faxed to (301) 713–4019. Comments by e-mail should be submitted to *HydrographicProducts@noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Mr. David B. Enabnit, Office of Coast Survey, NOAA (N/CSx2), 1315 East-West Highway, Silver Spring, MD, 20910, (voice phone) 301–713–2770 x132, (fax phone) 301–713–4019, (e-mail) *Dave.Enabnit@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion of Comments Received and Changes Made

On October 15, 2004, we published a notice of proposed rulemaking entitled, "Quality Assurance and Certification Program for NOAA Hydrographic Products" in the **Federal Register** (FR 69 FR 61172), and solicited comments. Eight sets of comments were received on this proposed rule and the policy statement that accompanied it. The substance of the comments and the resulting changes made to the regulation are summarized below. Most of the comments were made in the context of a single, specific hydrographic product. However, the Program has been established to accommodate the full range of potential products allowed by the law, which is extremely broad (see "Definitions" under the "Background" section below).

One set of comments stated that the Quality Assurance Program was an inappropriate activity for NOAA, and a number of reasons were listed. In response, NOAA cites the Hydrographic Services Improvement Act of 1998, as amended (codified as 33 U.S.C. 892b), which mandated the establishment of this program. Therefore, NOAA has no latitude in the matter. The comments further suggested that a substantial fee structure would be appropriate for the program. Again, NOAA refers to the enabling legislation that limits the fees NOAA may charge.

Comments were received that, in some instances, NOAA might adopt existing standards or compliance tests for purposes of the Quality Assurance Program. ISO 19379 and the RTCM standard for Electronic Chart Systems were two examples cited. NOAA recognizes this opportunity, and specifically refers to this possibility in paragraphs 2, 5, and 6 of the policy statement. New sections § 996.11(e) and § 996.12(e) have been added to the regulation, and subsequent subsections appropriately renumbered, to insure that this option is available when the program is implemented.

One set of comments stated that § 996.20, "Submission of a hydrographic product for certification," in which an applicant submits a hydrographic product to NOAA, was unnecessary and burdensome, and that applicants should submit products directly to the compliance testing body. Upon review, it was determined that the submission required by this section is only 4 items of administrative information and should impose little burden on an applicant. However, it serves an important purpose in allowing NOAA to advise applicants on the appropriate standard and version against which to certify; identifying approved compliance testing organizations that are available; and other matters that may aid the applicant or avoid the cost of an inappropriate test. This section of the regulation was left unchanged.

One set of comments asserted that current standards for electronic charts, charting systems, distribution of digital chart data and updates, electronic charting system size and cost, and the support infrastructure had fatal shortcomings. These statements reflect obsolete information, and the writer is referred, for example, to IHO Technical Resolution A3.11—"ENC/SENC Distribution Option," and to IEC draft standard 62376 "Electronic chart systems (ECS)—Operational and performance requirements, methods of testing, and required test results." No specific change to the NOAA Quality Assurance Program was proposed with these comments, and none were made.

One set of comments offered that § 996.5, "Alterations," appeared to permit NOAA to change program regulations without following the Administrative Procedure Act that allows for public comment. NOAA's intent was to follow such procedures in executing this section, but since it is redundant with NOAA's existing authority under the Administrative Procedure Act, the section was deleted from the regulations to eliminate confusion.

One set of comments thought the regulations should contain criteria for the acceptance of testing bodies, and pointed to the Coast Guard's procedures for accepting independent laboratories. § 996.20(4) of the rule was enhanced to include characteristics of such laboratories that were suggested by the commenter, but the procedures used by the Coast Guard were thought to be excessive for the NOAA program and were not added to the rule.

One set of comments objected to that portion of § 996.33, "Acceptance of program by non-Federal entities" which states that "information submitted to NOAA under this Program shall be deemed to be in the public domain, and no representation is made as to the protection of confidential, proprietary or otherwise restricted information." The comment stated that some products might be the result of proprietary processes that a producing company would not wish disclosed. After careful review of the information submission requirements in the regulation, it was determined that all were of an administrative nature necessary to run the program, and would be unlikely to contain any proprietary information. The one exception might be § 996.23(3), "Audit and decertification of hydrographic products." A new section, § 996.23(c), was inserted in the regulation, and the subsequent subsections appropriately renumbered, to permit producing companies to not provide information during an audit, but at the risk of decertification due to a resulting lack of information.

One set of comments queried whether foreign governments or foreign companies could participate in the Quality Assurance Program. At this time, NOAA believes the program would be open to foreign governments and foreign companies.

Comments were received that NOAA should reconsider its policy only to certify hydrographic products as meeting a standard rather than certifying them for a particular use. NOAA's policy would mean, for example, that NOAA will not certify products as suitable for a specific purpose such as a backdrop in Automated Identification Systems, or for meeting chart carriage regulations. Under the program, certification only means that there is an adopted NOAA standard, documented compliance tests, and that a product had passed the tests and was compliant with the standard. The comments asserted that such a policy did not meet the requirements of the Hydrographic Services Improvement Act; would not support the mandatory carriage of electronic charts that the Coast Guard has been directed to establish; and that it violates the Regulatory Flexibility Act.

The policy of certifying for "standards-compliance" rather than "use" recognizes that in most cases, NOAA does not have the authority to make the determination of suitability for use. The determination of suitability of a backdrop for an Automated Identification System, for example, lies with the Coast Guard. In other cases, suitability cannot be determined. For example, sport fishing maps (a potential hydrographic product) can be certified as to their data content and data quality, but in no way could NOAA certify that such maps would improve one's catch. Finally, in the specific case of electronic nautical charts, the federal government already provides official products for this purpose, and there are valid safety reasons for maintaining a single, official nautical chart or publication where federal regulations mandate carriage. NOAA's policy was supported in comments from the Hydrographic Services Review Panel, a federal advisory committee of individuals who are especially qualified to advise the Administrator of NOAA on

hydrographic program matters, and which was established by Congress. The panel commented that NOAA was correct in not certifying privately made electronic charts as meeting chart carriage regulations. They cited safety as the reason and urged NOAA to continue to maintain the single, official nautical charts where federal regulations mandate chart carriage.

The comments asserting that NOAA's proposed program was not in compliance with the Hydrographic Services Improvement Act did not specify in what way the program was out of compliance. NOAA continues to believe that this policy is in full compliance with the Act. The Act only requires certification against standards promulgated by the Administrator, and makes no statement about certification for a particular use. In fact, an earlier version of the 2002 Hydrographic Services Improvement Act amendments legislation included such a mandate, but the provision was specifically removed before final passage. The Hydrographic Services Review Panel agreed with NOAA, commenting that, in its opinion, the proposed Quality Assurance Program satisfied the statutory requirement established by Congress.

NOAA has provided, however, in a separate rulemaking, a process whereby private companies may download from the NOAA Web site and market exact copies of official NOAA Electronic Navigational Charts (ENC), may reformat and market copies of NOAA ENCs, and may package additional data with those ENCs and market the result. After completing a self-certification process to become distributors, such products would comply with federal chart carriage requirements. (See *Certification Requirements for Distributors of NOAA Electronic Navigational Chart/NOAA Hydrographic Products*, 69 FR 61165 (Oct. 15, 2004).) This provides additional commercial opportunities for private companies while preserving the safety of navigation.

As to whether NOAA's policy would deny adequate electronic chart coverage to support the mandatory carriage of electronic charts, which the Coast Guard has been directed to implement, NOAA sees no cause for concern, nor was that necessarily the purpose of the Act. NOAA already provides 100 percent coverage of its area of responsibility with official raster navigational charts (one type of electronic chart), 45 percent coverage with official electronic navigational charts (a second type of electronic chart) with completion of the full suite scheduled during 2007, and the U.S. Army Corps of Engineers anticipates completing full coverage of primary and secondary inland river routes with official electronic charts during 2007, thus serving vessels that carry 90 percent of the inland river shipping tonnage. Also, while the Coast Guard must promulgate electronic chart carriage regulations by January 1, 2007, the effective date of those regulations; exactly which vessels are to be covered; and what waivers may be issued is left to their discretion. NOAA, the Corps of Engineers, and the Coast Guard will continue to coordinate closely to insure that electronic chart carriage is not mandated before suitable, official charts are available.

One comment stated that the rule was contrary to the Regulatory Flexibility Act, in that, since the certified products would not be certified as meeting federal chart carriage regulations, a company supplying electronic charts would be unable to broaden their markets as fully as they would if chart carriage certification were part of the process. While NOAA appreciates that carriage-compliance certification could make the benefits of NOAA certification marginally greater, the proposed program still provides a net benefit to all companies wishing to participate. The program supports companies in making and selling electronic charts into the non-regulated market, which is 2 orders of magnitude larger than the regulated market. It supports the use of privately made electronic charts aboard regulated vessels if used as an aid to navigation, rather than as the means of meeting chart carriage regulations. It does not remove a market for privately made electronic charts since they never have been certified for regulatory carriage and do not have that market. Also, because NOAA and the Corps of Engineers give away, at no cost, official electronic charts for meeting carriage regulations, it appears that the portion of the market that the program does not make readily accessible to private companies would be small.

Changes From the Proposed Rule

Although NOAA intended from the outset to allow renewal of certification of products under subpart C, it became clear after the regulations were proposed that such a renewal process was not described in the regulations. NOAA considers inclusion of a renewal process to be an essential part and logical outgrowth of the certification process because it allows certified companies the option of renewing their certification for two additional years. The option to renew certifications will allow companies to continue to benefit from the increased sales of their product resulting from "certified" status. Therefore, a renewal process is now included in § 996.22(d) and (e).

Background

Definitions

Hydrographic products—any publicly or commercially available product produced by a non-Federal entity that includes or displays hydrographic data.

Hydrographic data—information acquired through hydrographic or bathymetric surveying, photogrammetry, geodetic, geospatial, or geomagnetic measurements, tide and current observations, or other methods, that is used in providing hydrographic services.

Hydrographic services—hydrographic services means:

—The management, maintenance, interpretation, certification, and dissemination of bathymetric, hydrographic, geodetic, geospatial, geomagnetic, and tide and current information, including the production of nautical charts, nautical information databases, and other products derived from hydrographic data;

—The development of nautical information systems; and

—Related activities.

The Act

The Hydrographic Services Improvement Act of 1998, as amended by the Hydrographic Services Improvement Act Amendments of 2002 (codified as 33 U.S.C. 892b), directs:

1. IN GENERAL—The Administrator—

A. By not later than 2 years after the date of enactment of the Hydrographic Services Improvement Act Amendments of 2002, shall, subject to the availability of appropriations, develop and implement a quality assurance program that is equally available to all applicants, under which the Administrator may certify hydrographic products that satisfy the standards promulgated by the Administrator under section 303(a)(3) of the Act;

B. May authorize the use of the emblem or any trademark of the Administration on a hydrographic product certified under subparagraph (A); and

C. May charge a fee for such certification and use.

Section 303(a)(3) referenced above states that the Administrator shall "promulgate standards for hydrographic services provided by the administration."

Statement of Policy

NOAA will act in accordance with the following policies in fulfilling its Quality Assurance Program responsibilities under the Hydrographic Services Improvement Act.

1. NOAA interprets the Act as primarily intending to stimulate the development of hydrographic products by the private sector. The intent of NOAA's participation in this private sector activity is to provide the public a measure of confidence in the content, quality, and adherence to published standards of the resulting hydrographic products. NOAA interprets the Act in a broad sense. Therefore, "standards" and "quality assurance program" are considered to be generic terms that apply to any means of satisfying the intent of the Act and the intent of NOAA's participation, and that are within NOAA's authorities.

2. Standards, and quality assurance tests and procedures, will preferably be written in collaboration with those affected, not just written and promulgated by NOAA. In some instances, NOAA may adopt an existing standard or quality assurance program, rather than originate one. NOAA may develop standards and quality assurance tests on its own initiative should, for example, it be deemed beneficial for those standards and tests to be established before the appearance of a particular hydrographic product. This approach may be used to stimulate the production of a product that NOAA anticipates would be beneficial.

3. The level to which standards are developed, and to which quality assurance is performed, may vary for different hydrographic products. For example, certification for manufacturers making exact copies of NOAA products may be implemented in a substantially differently manner from the certification of a complex cartographic product. NOAA considers all such "standards" and "certifications" as meeting the intent of the Act.

4. NOAA will work, to the extent practicable, through existing, recognized, standards and certification bodies. This will permit the use of proven methods of developing, documenting, and implementing standards and certification. It will leverage NOAA's resources with those of such bodies. It will provide a more widely accepted result than had NOAA promulgated a standard solely under its own name.

5. NOAA will establish the required Quality Assurance Program for hydrographic products. The Quality Assurance Program will be general procedures that apply to all hydrographic products, and specific tests and procedures that apply to specific hydrographic products. The specific quality assurance tests and procedures for a particular hydrographic product will be based on the standards identified by NOAA or written collaboratively with the affected parties.

6. Certification of a specific hydrographic product under the Quality Assurance Program will be at the option of NOAA. However, certification will be the goal in cases where NOAA decides to write or adopt standards. Any non-Federal entity will be permitted to submit for certification hydrographic products that it asserts are compliant with the NOAA-adopted standards.

7. Certification of products under the Program will mean that the hydrographic product has been found to be compliant with the NOAA-adopted standards for that particular hydrographic product. Certification conveys no express or implied warranty as to the merchantability or fitness for a particular purpose; conveys no express or implied liability on the part of the Government of the United States for the hydrographic products; and conveys no automatic, direct or indirect NOAA endorsement of any product or service. NOAA may audit hydrographic products it has certified, and may decertify hydrographic products based on its findings.

8. NOAA does not intend to write standards and perform quality assurance for every hydrographic product submitted by a non-Federal entity. NOAA will select those deemed appropriate for standards and certification by taking into account:

—The magnitude of the public benefit and enhancement of public safety that would be achieved compared to the commitment of resources that would be required;
—The breadth of support for standards and certification among all the affected communities;
—The practicality of writing and enforcing an effective standard and compliance tests;
—The availability of suitable, similar products that may already meet the needs of the public;
—NOAA's expertise related to that needed to write an appropriate standard;
—Availability of resources; and
—Other relevant criteria as they become apparent.

In general, NOAA does not intend to write standards and certify products that would be used to meet the nautical chart and publications carriage requirements mandated in the Code of Federal Regulations and elsewhere. The federal government already provides official products for this purpose, and there are valid safety reasons for maintaining a single complying product for regulated carriage.

9. Use of the NOAA emblem on certified hydrographic products will require separate written permission. Use of the NOAA emblem must satisfy an interest of the Agency, and must not result in embarrassment to the Agency. If the NOAA emblem is used on products that include other data or products, clear indication will be required as to what is NOAA certified. The inclusion of other data or products will not constitute any endorsement of, or favoritism toward, the other data or products by NOAA.

10. NOAA may charge for its standards and certification activities such sums as may be permitted or required under this Act, or under other statutory authorities.

11. NOAA will operate the Quality Assurance Program in an open and public manner. All standards, tests, and procedures will be publicly available. The public will be given ample notification of activities under the Quality Assurance Program, and will be given ample opportunity to comment and have their comments heard. This opportunity to participate in the Quality Assurance Program and the opportunity to submit hydrographic products for certification under that Program will be equally available to all.

12. In all matters, NOAA will proceed in a manner that maximizes public safety.

Discussion of Selected Sections of the Policy

Paragraph 1

NOAA interprets the Act as an attempt to increase the richness of the suite of hydrographic products available to the public, and to ensure the safety of those products. In addition, NOAA interprets the Act to include "services" as meeting the definition of "hydrographic products," and may choose to write or adopt standards, quality assurance tests and procedures, and to certify appropriate services. Nautical chart updating services, or an electronic navigational chart distribution service, are examples of services that NOAA may consider a "hydrographic product" under the Act.

Other tools within NOAA's authority may be used to meet the purposes of the Act. Depending on the complexity of the hydrographic product, and the amount of risk the public would be exposed to,

NOAA reserves the right to select any authorized means of establishing new products and providing a measure of confidence in the content, quality, and adherence to standards for those products. Thus, for purposes of accountability under the Act, NOAA is interpreting "standards," "quality assurance," and "certification" as generic terms describing an outcome rather than as a specific formalism or document. For example, some non-Federal entities may intend to reproduce exactly NOAA products such as the Tide Tables. In this case, a "standard" may be a simple agreement, in which the manufacturer agrees to certain standards of copy quality. Further, because the complexity is low, self-certification might be used as the means of compliance testing. Other such authorities available to NOAA that may be used include: business licenses, Agent Agreements, no-cost contracts, self-certification, adoption of industry standards, and the use of existing certification organizations.

Paragraph 2

Participation by the affected communities in writing standards and compliance tests provides an important guarantee that there is broad need for standards and certification, and that the resulting standard and certification meet the needs of the affected communities. Relevant communities might include: manufacturers, users, regulators, resellers, developers of products that use certified hydrographic products such as datasets, and manufacturers of competing or substitute products.

Participation in the drafting of standards and quality assurance tests and procedures must be substantive and continuing by the designated members of the affected communities. The responsibility will lie with the non-Federal entity submitting a hydrographic product for certification to propose a broadly based group of acknowledged representatives of affected groups, and to secure their participation in the writing of standards and compliance tests.

Paragraph 6

The Act leaves the certification of hydrographic products as optional for NOAA. The assumption will be, however, that if NOAA undertakes to write standards, it also intends to offer certification of the resulting hydrographic products. In general, NOAA will not undertake to write standards and compliance tests if it can foresee that certification will not be offered.

The decision to offer certification will be made on a case-by-case basis. Circumstances may arise that cause standards to be written, but certification to not be offered. Such circumstances might include:

—A resulting standard for which NOAA lacks confidence in the safety implications of products that might meet that standard;
—Lack of consensus among the affected organizations writing the standard and compliance tests;
—Failure of adoption of the draft standards by a participating standards-writing body;
—Standards that negatively impact the intent of the Act, such as those that might exclude existing, suitable products; or standards that benefit a single company;
—Adopted standards that are specious; or
—Other relevant reasons as they become apparent.

Paragraph 7

NOAA does not intend to certify products as suitable for any specific purpose such as for use as a backdrop in Automated Identification Systems. Certification only means that there is an adopted NOAA standard, documented compliance tests; and that the subject hydrographic product has been through the tests and was determined to be compliant with the standard.

Paragraph 8

NOAA does not interpret the Act as merely a way to provide manufacturers with a marketing claim for their product, or as a means for one manufacturer to differentiate his product from the competition, although that might be a resulting effect. Neither does NOAA interpret the Act as intending to result in "private standards" that may only apply to one manufacturer's product.

In addition, NOAA interprets the Act as intending to call forth new products, not substitutes for official ones being provided by the Administration. In general, NOAA does not intend to write standards and certify products that would be used to meet the nautical chart and publications carriage requirements mandated in the Code of Federal Regulations and elsewhere. The federal government already provides official products for this purpose, and there are valid safety reasons for maintaining a single, official nautical chart or publication where federal regulations mandate carriage, and for not certifying private products for that same purpose. These reasons include:

—Having all vessels making navigation decisions on exactly the same information, particularly in meeting situations or at night;
—Removing any confusion as to what products satisfy the federal regulations;
—Guaranteeing the timeliness and accuracy of updates to official charting products and their distribution;
—Removing ambiguity as to the status of non-certified data that may be included on or with certified private hydrographic products;
—Liability for other information when packaged with a certified "hydrographic product;" and
—The impracticality of NOAA policing all substitute official products—products on which data changes weekly.

Exceptions to this intention might include, for example, cases where NOAA specifically prepares a carriage-compliant product for manufacture and distribution by the non-Federal entities.

Paragraph 9

The presumption will be that use of the NOAA emblem will be permitted if NOAA proceeds with standards and certification. However, the use of the NOAA emblem will be carefully monitored. In particular, it will be monitored to insure that the use of the emblem is not done in a manner to imply the endorsement of any manufacturer; any other data, service, or product that may be packaged with a certified hydrographic product; or any particular use of a certified hydrographic product, and to monitor that its use not bring discredit upon the Agency or the Department.

Classification

A. Executive Order 12866

This proposed rule has been determined to be not significant for the purposes of Executive Order 12866.

B. Regulatory Flexibility Act

The Chief Counsel for Regulation of the Department of Commerce certifies to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule will not have a significant, economic impact on a substantial number of small entities. The purpose of this rule is to develop and implement a quality assurance program that is equally available to all applicants, under which the Administrator of NOAA may certify hydrographic products that satisfy standards promulgated by the Administrator. "Hydrographic

products" are any publicly or commercially available product produced by a non-Federal entity that includes or displays hydrographic data. The Administrator will fulfill this mandate by establishing procedures by which hydrographic products are proposed for certification; by which standards and compliance tests are developed, adopted, and applied for those products; and by which certification may be awarded or denied. NOAA is required to develop this Quality Assurance Program under the authority of 33 U.S.C. 892b.

The Small Business Administration guideline to separate small from large businesses is $4 million for Mapmaking firms and $5 million for Navigational Services to Shipping and Other Support Activities for Water Transportation. NOAA is unable to determine the total number of small entities that will be affected by this rule, as it does not specifically track this type of information, and because the law is extraordinarily broad in the range of hydrographic products that may be submitted for certification. However, based upon general knowledge of the industry, NOAA believes the majority of the entities affected may be small businesses.

Public comments were received on the proposed rule with respect to one proposed hydrographic product—electronic nautical charts intended for use by certain classes of regulated vessels. NOAA's regulations are intended only to certify hydrographic products as meeting a standard rather than certifying them for a particular use. In evaluating the comments, NOAA concluded that in most cases NOAA does not have the authority to make the determination of suitability for use. The determination of suitability of a backdrop for an Automated Identification System, for example, lies with the Coast Guard. In other cases, suitability cannot be determined. For example, sport fishing maps can be certified as to their data content and data quality, but NOAA could not certify that such maps would improve one's catch. Finally, in the specific case of electronic nautical charts, the federal government already provides official products for this purpose, and there are valid safety reasons for maintaining a single, official nautical chart or publication where federal regulations mandate carriage. NOAA's policy was supported in comments from the Hydrographic Services Review Panel, a federal advisory committee of individuals who are especially qualified to advise the Administrator of NOAA on hydrographic program matters, and which was established by Congress. The panel commented that NOAA was correct in not certifying privately made electronic charts as meeting chart carriage regulations. They cited safety as the reason and urged NOAA to continue to maintain the single, official nautical charts where federal regulations mandate chart carriage.

While NOAA appreciates that carriage-compliance certification could make the benefits of NOAA certification marginally greater, the proposed program still provides a net benefit to all companies wishing to participate. The program supports companies in making and selling electronic charts into the non-regulated market, which is 2 orders of magnitude larger than the regulated market. It supports the use of privately made electronic charts aboard regulated vessels if used as an aid to navigation rather than as the means of meeting chart carriage regulations. It does not remove a market for privately made electronic charts since they never have been certified for regulatory carriage and do not have that market. Also, because NOAA and the Corps of Engineers give away, at no cost, official electronic charts for meeting carriage regulations, it appears that the portion of the market that the program does not make readily accessible to private companies would be small. Finally, the number of companies that NOAA estimates might be affected by this certification for "standards compliance" as opposed to certification for "use" with respect to electronic nautical charts is between 3 and 9, not all of which may be small entities. Furthermore, the impact the program has on small entities will be positive. Thus the rule does not appear to rise to the level of causing a significant economic impact on a substantial number of small businesses.

The estimated economic impact to small entities for submitting hydrographic products under this program is not expected to be greater than $600 per product submitted for labor to prepare the application. In addition, it is expected that there will be an average charge of $5,000 per product submitted for compliance testing. This proposed rule is voluntary. Only those applicants who wish to submit hydrographic products and have them certified need apply. NOAA does not believe this cost will hurt small companies, and the estimated costs incurred should be offset through the benefits in increased sales of the product because of its "certified" status or else private companies would not choose to submit their products to this voluntary program.

C. Paperwork Reduction Act

This rule contains collection-of-information requirements subject to the Paperwork Reduction Act (PRA), which OMB has approved under control number 0648–0507.

The following requirements have been submitted to OMB for approval: 4 hours to prepare the application to have standards and compliance tests developed; 4 hours to prepare the application to have a specific hydrographic product certified; and 4 hours for an estimated, single request for NOAA to reconsider a decision made under the program. These estimates include the time for reviewing instructions, searching existing data sources, writing the application information and/or request for reconsideration, and for sending the applications to NOAA. Send comments regarding this burden estimate, or any other aspect of this data collection, including suggestions for reducing the burden, to NOS, (see **ADDRESSES**) and by e-mail to *David_Rostker@omb.eop.gov*, or fax to (202) 395–7285.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

There are no duplicative, overlapping, or conflicting Federal rules associated with this proposed rule.

List of Subjects in 15 CFR Part 996

Navigation (water), Hydrographic products, Certification requirements.

■ For the reasons stated in the preamble, NOS amends 15 CFR chapter IX by adding part 996 to read as follows:

Headings

Subchapter F—Quality Assurance and Certification Requirements for NOAA Hydrographic Products and Services

PART 996—QUALITY ASSURANCE AND CERTIFICATION REQUIREMENTS FOR NOAA HYDROGRAPHIC PRODUCTS AND SERVICES

Subpart A—General

Sec.

Subpart B—The Quality Assurance Program for Hydrographic Products

Authority: 33 U.S.C. 892b.

Subpart A—General

§ 996.1 Purpose and scope.

The National Oceanic and Atmospheric Administration (NOAA) was mandated to develop and implement a quality assurance program that is equally available to all applicants, under which the Administrator may certify hydrographic products that satisfy standards promulgated by the Administrator. "Hydrographic products" are any publicly or commercially available products produced by a non-Federal entity that include or display hydrographic data. The procedures established here by which hydrographic products are proposed for certification; by which standards and compliance tests are developed, adopted, and applied for those products; and by which certification may be awarded or denied are the mandated Quality Assurance Program. The execution of those procedures for specific hydrographic products is the implementation of the program.

§ 996.2 Definitions.

Agency means the National Oceanic and Atmospheric Administration.

Applicant means a non-Federal entity that is submitting a hydrographic product to the Quality Assurance Program for certification.

Certification means a determination made by NOAA that a hydrographic product submitted by a non-Federal entity has met the requirements established by NOAA for a particular hydrographic product or class.

Department means the Department of Commerce.

Hydrographic data means information acquired through hydrographic or bathymetric surveying, photogrammetry, geodetic, geospatial, or geomagnetic measurements, tide and current observations, or other methods, that is used in providing hydrographic services.

Hydrographic product means any publicly or commercially available product produced by a non-Federal entity that includes or displays hydrographic data.

Hydrographic product class means a group of hydrographic products with similar traits, attributes, purposes, or users.

Hydrographic services means

(1) The management, maintenance, interpretation, certification, and dissemination of bathymetric, hydrographic, geodetic, geospatial, geomagnetic, and tide and current information, including the production of nautical charts, nautical information databases, and other products derived from hydrographic data;

(2) The development of nautical information systems; and

(3) Related activities.

Quality Assurance Program means a set of procedures by which hydrographic products are proposed for certification; by which standards and compliance tests are developed, and, if suitable, are adopted by NOAA for those products; and by which certification of individual products may be awarded or denied.

Quality Assurance Program implementation means the execution of the Quality Assurance Program procedures for specific hydrographic products.

Sponsor means a non-Federal entity that is submitting a hydrographic product to the Quality Assurance Program for the development of standards and compliance tests.

§ 996.3 Fees.

NOAA may charge for its Quality Assurance Program activities such sums as may be permitted or required under this Act, or under other statutory authorities. Such sums are non-refundable. NOAA will attempt to identify any such charges upon first submission of a hydrographic product. However, the intent to charge and the amounts may change. NOAA will promptly notify the sponsor of any such changes, and will permit the sponsor to withdraw hydrographic products from consideration under the Quality Assurance Program should they so choose.

§ 996.4 Liability.

The Government of the United States shall not be liable for any negligence by producers of hydrographic products certified under this part.

Subpart B—The Quality Assurance Program for Hydrographic Products

§ 996.10 Submission and selection of hydrographic products for the development of standards and compliance tests.

(a) Any non-Federal entity may submit a hydrographic product to be considered for the development of standards and compliance tests under this Quality Assurance Program.

(b) Submission shall be made to the Quality Assurance Program address below, or to such other address as may be indicated in the future: Director (N/CS), ATTN: Hydrographic Product Quality Assurance Program, Office of Coast Survey, NOAA, 1315 East West Highway, Silver Spring, MD 20910.

(c) The submission shall include

(1) Name and description of the proposed hydrographic product.

(2) The non-Federal entity submitting the product for the development of standards and compliance tests, and contact information for that entity. This non-Federal entity shall be known as the sponsor.

(3) The names and contact information of proposed representatives of the affected communities who have committed to participate substantively in the writing of standards and compliance tests. Affected communities might include: manufacturers, users, regulators, resellers, developers of products that use certified hydrographic products such as datasets, and manufacturers of competing or substitute products.

(4) The names and contact information of the standards setting body, and the compliance testing body under whose authority it is proposed that the standards and compliance tests be written and adopted.

(5) Information deemed relevant by the sponsor for NOAA to consider in deciding whether to proceed with the development of standards, compliance tests, and certification. Such information should address at a minimum:

(i) The type and magnitude of the public benefits and enhancement of public safety that would be achieved;

(ii) The breadth of support for standards and certification among all the affected communities;

(iii) The practicality of writing and enforcing an effective and appropriate standard;

(iv) The availability of suitable, similar products that may already meet the needs of the public; and

(v) The required expertise needed to write an appropriate standard.

(d) NOAA may, at its option, define a hydrographic product class of which the proposed hydrographic product is a specific instance. Standards and compliance tests may then be prepared for the class rather than for an individual non-Federal entity's specific product.

(e) NOAA shall publicize, in the **Federal Register** or by other appropriate means, the hydrographic product or class in order to solicit comments on the proposal that standards and compliance tests be written and certification be offered for that hydrographic product or class. Comments might include, but are not limited to, general information; statements of interest in participating in the development of standards and compliance tests; or objections to acceptance of the hydrographic product or class into this Quality Assurance Program. Instructions for commenting and the duration of the comment period will be included in the announcement.

(f) NOAA shall decide, if its other obligations permit, within 60 calendar days of the close of the comment period whether to proceed with the development of standards, compliance tests, and certification for the proposed hydrographic product or class. NOAA may request further information, and shall have additional time as required to consider the information once received. NOAA's decision on whether to proceed shall be based on the following criteria:

(1) The magnitude of the public benefit and enhancement of public safety that would be achieved compared to the commitment of federal resources that would be required;

(2) The breadth of support for standards and certification among all the affected communities;

(3) The practicality of writing and enforcing an effective and appropriate standard;

(4) The availability of suitable, similar products that may already meet the needs of the public;

(5) NOAA's expertise related to the expertise needed to write an appropriate standard;

(6) Availability of resources; and

(7) Other relevant criteria as they become apparent.

(g) NOAA's decision as to whether the proposed hydrographic product or class is accepted into the Quality Assurance Program shall be publicly announced in the **Federal Register** or by other appropriate means, and a written notification shall be provided to the sponsor. The response shall include NOAA's reason for its decision based on the criteria enumerated above.

(h) Any party, including the sponsor, shall have an opportunity to request reconsideration of NOAA's decision. Said request shall be submitted in writing, to the Quality Assurance Program address, postmarked within 30 days of NOAA's announcement of its decision, and shall contain written material supporting the requestor's position. NOAA shall have, if its other obligations permit, 60 calendar days from the receipt of a request for reconsideration to either deny the request, or to reconsider and announce its decision.

(i) NOAA's decision, either the original decision if unappealed within 30 days, or the decision after the request for reconsideration, shall be considered final.

(j) NOAA itself may choose to identify a hydrographic product or class, which may or may not yet exist, but for which it intends to adopt standards, compliance tests, and to offer certification. In such cases, NOAA will be considered the sponsor. The procedures to be followed for NOAA-sponsored hydrographic products or classes shall be the same as for those sponsored by non-Federal entities, including the procedures for announcement, comment, and reconsideration.

§ 996.11 Development of standards for a hydrographic product or class.

(a) NOAA shall work, to the extent practicable, through existing, recognized, standards bodies in the writing and adopting of standards for a hydrographic product or class that NOAA has accepted into this program. It shall be the responsibility of the sponsor to propose an appropriate standards writing body. NOAA may accept this body at its discretion, or may select an alternate body. NOAA will then undertake, jointly with the sponsor and acknowledged representatives of the affected communities, to submit the proposal for writing standards to, and to secure the cooperation of, the selected standards writing body.

(b) Once accepted as a work item by the standards writing body, NOAA shall undertake, jointly with representatives of the affected community, members of the standards body, other governmental representatives, and the sponsor as appropriate, to write standards for the hydrographic product or class according to the practices of the standards body and the technical needs of the product. Participation in the writing of standards shall be determined according to the procedures of the standards writing body.

(c) NOAA shall then undertake, jointly with representatives of the affected community, members of the standards body and the body itself, other governmental representatives, and the sponsor as appropriate, to have the resulting standard officially adopted by the standards body according to the procedures of that body.

(d) NOAA may, at its option, proceed without the participation of an existing, recognized, standards body should it so choose. Such action might be taken, for example, if there were no appropriate standards body. In this eventuality, NOAA shall adhere to the following general procedure.

(1) Announce, in the **Federal Register** or by other appropriate means, NOAA's intention to organize and chair a working group to write and publish standards for the proposed hydrographic product or class;

(2) Solicit, via the **Federal Register** or by other appropriate means, participation and select, reject, and/or revoke permission to participate as NOAA deems appropriate so as to proceed in an orderly and representative manner in writing a standard;

(3) Initiate, schedule, host, and chair, or designate a chair for, the work of the working group;

(4) Circulate, via the **Federal Register** or by other appropriate means, the drafts of the working group;

(5) Announce, via the **Federal Register** or by other appropriate means, the NOAA proposed standard and provide an opportunity for public comment;

(6) Announce, via the **Federal Register** or by other appropriate means, and make available as a standard, the final version of the standard; and

(7) Provide the necessary administrative support.

(e) NOAA may, at its option, adopt an existing standard as the NOAA standard for this program. In this eventuality, NOAA shall adhere to the following general procedure.

(1) Announce, in the **Federal Register** or by other appropriate means, NOAA's intention to adopt an existing standard for the proposed hydrographic product or class; and

(2) Solicit, via the **Federal Register** or by other appropriate means including public meetings, comment on the standard that NOAA proposes to adopt, and shall consider the comments received.

(f) Alternatively, NOAA may at its option, proceed by writing a standard by itself. Such action might be used, for example, in cases where the standard is

obvious. Producing exact copies of existing NOAA products might be one such case. Once written, this NOAA-authored standard shall be made publicly available for comment, and comments shall be considered before NOAA publishes the final standard.

(g) At the conclusion of the standards writing, whether through an existing standards body, by a NOAA-convened working group, by adopting an existing standard, or by NOAA itself, NOAA shall consider the resulting standard and comments, and either adopt or reject the standard as the NOAA Quality Assurance Program Standard for the particular hydrographic product or class. NOAA's decision shall be publicly announced in the **Federal Register** or by other appropriate means.

(h) Any party may request NOAA to reconsider its decision to adopt or reject the standard by submitting its request in writing to the Quality Assurance Program address within 30 days of NOAA's announcement of its decision. NOAA shall have, if its other obligations permit, 60 calendar days from the receipt of a request for reconsideration to either deny the request, or to reconsider and announce its decision. NOAA's original decision if unappealed within 30 days, or its decision upon reconsideration shall be considered final.

§ 996.12 Development of standards compliance tests for a hydrographic product or class.

(a) NOAA shall work, to the extent practicable, through existing, recognized, compliance testing bodies in the writing and adopting of compliance tests for a hydrographic product or class. It shall be the responsibility of the sponsor to propose an appropriate compliance testing body. NOAA may accept this body at its discretion, or may select an alternate body. NOAA will then undertake, jointly with the sponsor and acknowledged representatives of the affected communities, to secure the cooperation of the selected compliance testing body.

(b) NOAA shall undertake, jointly with representatives of the affected community, members of the compliance testing body, other governmental representatives, and the sponsor as appropriate, to write compliance tests for the hydrographic product or class according to the practices of the compliance testing body and the Quality Assurance Program standard adopted by NOAA. Participation in the writing of compliance tests may be determined according to the procedures of the compliance testing body.

(c) NOAA shall then undertake, jointly with representatives of the affected community, members of the compliance testing body and the body itself, other governmental representatives, and the sponsor as appropriate, to have the resulting compliance tests adopted according to the procedures of that body.

(d) NOAA may, at its option, proceed without the participation of an existing, recognized, compliance testing body should it so choose. Such action might be taken, for example, if there were no appropriate compliance testing body. In this eventuality, NOAA will adhere to the following general procedure:

(1) Announce, in the **Federal Register** or by other appropriate means, NOAA's intention to organize and chair a working group to write and publish compliance tests for the hydrographic product or class;

(2) Solicit, via the **Federal Register** or by other appropriate means, participation and select, reject, and/or revoke permission to participate as NOAA deems appropriate so as to proceed in an orderly and representative manner in writing compliance tests;

(3) Initiate, schedule, host, and chair, or designate a chair for, the work of the working group;

(4) Circulate, via the **Federal Register**, or by other appropriate means, the drafts of the working group;

(5) Announce, via the **Federal Register** or by other appropriate means, a NOAA proposed final version of the compliance tests and provide an opportunity for public comment;

(6) Announce, via the **Federal Register** or by other appropriate means, and make available the final version of the compliance tests, and

(7) Provide the necessary administrative support.

(e) NOAA may, at its option, adopt existing compliance tests as the NOAA compliance tests for this program. In this eventuality, NOAA shall adhere to the following general procedure:

(1) Announce, in the **Federal Register** or by other appropriate means, NOAA's intention to adopt existing compliance tests for the proposed hydrographic product or class; and

(2) Solicit, via the **Federal Register** or by other appropriate means including public meetings, comment on the proposed compliance tests that NOAA proposes to adopt, and shall consider the comments received.

(f) Alternatively, NOAA may, at its option, proceed by writing compliance tests by itself. Such action might be used, for example, in cases where the tests are obvious. Producing exact copies of existing NOAA products might be one such case. Once written, these NOAA-authored tests shall be made publicly available for comment, and comments shall be considered before NOAA publishes the final compliance tests.

(g) At the conclusion of the compliance test writing, whether through an existing body, by a NOAA-convened working group, by adopting existing compliance tests, or by NOAA itself, NOAA shall consider the resulting compliance tests and comments, and either adopt or reject them as the NOAA Quality Assurance Program compliance tests for the particular hydrographic product standard. NOAA's decision shall be publicly announced in the **Federal Register** or by other appropriate means.

(h) Any party may request NOAA to reconsider its decision to adopt or reject the compliance tests by submitting its request in writing to the Quality Assurance Program address within 30 days of NOAA's announcement of its decision. NOAA shall have, if its other obligations permit, 60 calendar days after the receipt of a request for reconsideration to either deny the request, or to reconsider and announce its decision. NOAA's original decision if unappealed within 30 days, or its decision upon reconsideration shall be considered final.

§ 996.13 Determination of whether to offer certification for a hydrographic product or class.

(a) Certification of a hydrographic product or class shall be at the option of NOAA. NOAA may decide at any time whether or not to offer certification for a product or class. However, it is most likely that a determination will be made only after a non-Federal entity has submitted a specific product for certification. NOAA's decision shall be based on the following criteria:

(1) The suitability of the adopted standards and tests for their intended purpose;

(2) The availability of a qualified entity to perform the compliance tests;

(3) Availability of resources; and

(4) Other relevant criteria as they become apparent.

(b) NOAA's decision as to whether certification for a hydrographic product or class is offered shall be publicly announced in the **Federal Register** or by other appropriate means.

(c) Any entity may request NOAA to reconsider its decision to offer or not offer certification by submitting its request in writing to the Quality Assurance Program address within 30 days of NOAA's announcement of its decision. NOAA shall have, if its other

obligations permit, 60 calendar days after the receipt of a request for reconsideration to either deny the request, or to reconsider and announce its decision.

(d) NOAA's original decision if unappealed within 30 days, or its decision upon reconsideration, shall be considered final.

Subpart C—Certification of a Hydrographic Product and Decertification.

§ 996.20 Submission of a hydrographic product for certification.

(a) Upon adoption by NOAA of standards and compliance tests, any non-Federal entity may submit a hydrographic product for certification under a particular standard. This non-Federal entity shall be known as the applicant. Submission shall be made in writing to the Quality Assurance Program address. The submission shall include:

(1) Name and description of the hydrographic product and its product class if any;

(2) Identification and contact information for the non-Federal entity submitting the product for certification.

(3) The identification of the standard and compliance tests adopted by this Quality Assurance Program under which the hydrographic product is to be certified;

(4) A proposed, qualified, competent, independent compliance testing body to perform the compliance tests, which NOAA may accept at its discretion, or for which NOAA may select an alternative testing body;

(5) Other information deemed relevant by the sponsor or requested by NOAA.

(b) [Reserved]

§ 996.21 Performance of compliance testing.

(a) NOAA and the applicant shall submit the applicant's hydrographic product to the testing body for performance of the compliance tests. That body shall determine compliance or non-compliance of the hydrographic product with the NOAA-adopted standard, and shall provide to NOAA written documentation stating the results of the compliance tests according to its usual practices.

(b) Alternatively, NOAA may choose, at its option, to perform, have performed by a NOAA-designated entity, or waive the compliance tests for a hydrographic product. This alternative may be used, for example, when there is no qualified entity to perform the compliance tests, where the compliance tests are simple, or when self-certification of compliance would be appropriate.

(c) Items failing the compliance tests may be changed by the applicant and retested. Items passing the compliance test upon retest shall be deemed compliant as if they had passed said tests initially.

§ 996.22 Certification.

(a) A hydrographic product that has passed the compliance tests shall automatically be considered for certification by NOAA. NOAA shall make its certification determination, if its other obligations permit, within 60 calendar days following receipt of the compliance test results. NOAA shall make a certification determination based upon the following criteria:

(1) The results of the compliance tests;

(2) The potential for the hydrographic product to impair public safety;

(3) Successful completion of any administrative requirements, including the payment of required fees, as may be specified by NOAA;

(4) The potential for certification to cause embarrassment to the Agency or the Department;

(5) Other relevant criteria as they become apparent.

(b) Hydrographic products receiving a certification determination in the affirmative shall be designated as "certified" by NOAA. NOAA shall provide a written document to the sponsor indicating such, and shall announce its determination in the **Federal Register** or by other appropriate means. Certification shall mean that the hydrographic product has been found to be in compliance with the NOAA-adopted standard for that hydrographic product or class. Certification conveys no express or implied warranty as to the merchantability or fitness for a particular purpose; conveys no express or implied liability on the part of the Government of the United States for the hydrographic products; and conveys no automatic, direct or indirect NOAA endorsement of any product or service.

(c) Certification shall be for a term of 3 years unless otherwise specified by the Administrator.

(d) A certification may be renewed, at the request of sponsor and the option of NOAA, for a period of 2 years. Sponsors may request the renewal of a certification by writing to the Quality Assurance Program address at least 120 calendar days before the expiration of an existing certification. The request shall include:

(1) Identifying and contact information for the sponsor;

(2) Identifying information for the relevant hydrographic product(s) and the standard(s) under which they were certified;

(3) Evidence sufficient to assure NOAA that the hydrographic product still meets the standard under which it was certified; and

(4) Other information as may be requested by NOAA.

(e) NOAA shall decide within 60 calendar days, if its other obligations permit, whether to renew a certification. NOAA's decision shall be based on whether the hydrographic product continues to meet the applicable standard, and other relevant criteria as they become apparent.

(f) The sponsor shall have an opportunity to request reconsideration of NOAA's decision. Said request shall be submitted in writing, to the Quality Assurance Program address, postmarked within 30 days of NOAA's announcement of its decision, and shall contain written material supporting the requestor's position. NOAA shall have, if its other obligations permit, 30 calendar days from the receipt of a request for reconsideration to either deny the request, or to reconsider and announce its decision.

(g) NOAA's decision, either the original decision if unappealed within 30 days, or the decision after the request for reconsideration, shall be considered final.

§ 996.23 Audit and decertification of hydrographic products.

(a) NOAA may audit hydrographic products it has certified. NOAA may conduct audits without advance notification. However, visits to companies' facilities will be scheduled. Audits may include, but are not limited to:

(1) The producing companies as it may affect the certified product;

(2) Certified products;

(3) Processes used in making, distributing, and marketing certified products;

(4) Use of the NOAA emblem;

(5) Examination of manufacturers' public claims about certified hydrographic products;

(6) Other relevant criteria as they become apparent.

(b) NOAA may decertify a hydrographic product based on the findings of an audit. In general, a hydrographic product may be decertified if:

(1) The results of an audit indicate that the product no longer meets the standards under which it was certified;

(2) The product has been substantively changed from the product that was tested and certified;

(3) Implied or actual claims about the product, and/or other data or products linked to the product, are judged by NOAA to be untrue or misleading;

(4) The NOAA emblem was improperly or inappropriately displayed;

(5) Other relevant reasons as they become apparent.

(c) A producing company may decline to reveal information during an audit that it declares to be proprietary or for other reasons. In this eventuality, NOAA reserves the right to decertify based on lack of information should it deem that action appropriate.

(d) The entity producing the certified hydrographic product shall be notified in writing of NOAA's intent to decertify that product. Said entity shall have 30 days to request reconsideration of that intended action in writing to the Quality Assurance Program address. Said request shall contain the identification of the hydrographic product, the requestor, and sufficient information for NOAA to make a determination on the request for reconsideration. Alternatively, the entity may correct the deficiencies cited by NOAA within 30 days, notify NOAA in writing at the Quality Assurance Program address of the corrective action taken, and provide sufficient evidence for NOAA to judge the correctness and effectiveness of the corrective action taken.

(e) If a request for reconsideration is submitted, or if the producing entity asserts that the deficiencies have been corrected, NOAA shall have 60 calendar days, if its other obligations permit, to consider the request for reconsideration or the corrective action, at which time NOAA shall issue its decertification decision. The decision and NOAA's reason for its action shall be made public in the **Federal Register** or by other appropriate means, and the producing entity shall be notified in writing.

(f) NOAA's decertification, if unappealed or uncorrected within 30 days, shall be considered final. NOAA shall notify the producing entity of this action in writing, and announce the decertification in the **Federal Register** or by other appropriate means.

(g) Upon decertification, manufacturers shall discontinue all claims of certification, and shall discontinue use of the NOAA emblem.

Subpart D—Other Quality Assurance Program Matters

§ 996.30 Use of the NOAA emblem.

(a) Use of the NOAA emblem on certified hydrographic products requires separate written permission. Use of the NOAA emblem must satisfy an interest of the Agency, and must not result in embarrassment to the Agency or the Department. If the NOAA emblem is used on products that include other data or products, clear indication shall be made as to what is NOAA certified, and what is not NOAA certified. The inclusion of other data or products will not constitute any endorsement of, or favoritism toward, the other data or products by NOAA. Requests for use of the NOAA emblem shall be submitted in writing to the Quality Assurance Program address, and shall include:

(1) Name and description of the hydrographic product(s) on which the emblem will be displayed.

(2) Name and contact information for the entity requesting use of the NOAA emblem.

(3) Exact samples of all uses intended for the NOAA emblem including text claims with, within, or associated with the hydrographic product, its packaging, and advertising that a reasonable person might associate with the NOAA emblem.

(4) Proof of NOAA certification.

(5) Other relevant information as may later be specified.

(b) [Reserved]

§ 996.31 Termination of the Quality Assurance Program.

(a) NOAA reserves the right to terminate the Quality Assurance Program for a particular hydrographic product or class at any time before certification is awarded if it is deemed to be in the public interest to do so. NOAA shall give written notification to the sponsor and other interested parties should it decide to exercise this option, and shall state the reasons for its action. Reasons for termination may include, but are not limited to:

(1) The inability of the standards-drafting group to reach a consensus on the content of the standard;

(2) Valid objections to the existence of NOAA-certification of a particular hydrographic product or class;

(3) A negative impact on public safety should the hydrographic product receive certification;

(4) Other relevant reasons as they become apparent.

(b) The sponsor or other interested parties shall have 30 days to request a reconsideration of the termination action. Said request shall be in writing to the Quality Assurance Program address, and shall include written material supporting the appeal. NOAA shall have, if its other obligations permit, 60 calendar days from the receipt of a request for reconsideration to either deny the request, or to reconsider and announce its decision.

(c) NOAA's decision, either the original decision if unappealed within 30 days, or the decision after the request for reconsideration, shall be considered final.

§ 996.32 Appeals.

(a) Any entity may appeal a final decision made by the Agency under this Quality Assurance Program. Said appeal shall be submitted in writing to the Quality Assurance Program address, and shall contain at least:

(1) Identification and contact information of the appealing entity;

(2) A statement that this is an appeal to a final decision of the Quality Assurance Program;

(3) A description of what decision is being appealed;

(4) A thorough but concise argument as to why the requestor believes the Quality Assurance Program decision being appealed should be set aside.

(5) Other information as may later be determined to be relevant.

(b) Appeals shall be arbitrated by the Assistant Administrator for Ocean Services and Coastal Zone Management, NOAA, using procedures to be established at the time of the appeal, and which shall be appropriate to the nature and circumstances of the appeal. The determination from this arbitration shall be final for purposes of judicial review under the Administrative Procedure Act and other statutes.

§ 996.33 Acceptance of program by non-Federal entities.

By their voluntary entrance or participation in this Quality Assurance Program or its activities, all parties acknowledge and accept the procedures established by this program, including the finality of decisions. All parties acknowledge and accept that information submitted to NOAA under this Program shall be deemed to be in the public domain, and no representation is made as to the protection of confidential, proprietary or otherwise restricted information.

Dated: December 27, 2004.

Alan Neuschatz,

Associate Assistant Administrator for Management, Ocean Services and Coastal Zone Management, National Oceanic and Atmospheric Administration.

[FR Doc. 05–133 Filed 1–4–05; 8:45 am]

BILLING CODE 3510–JE–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[TD 9174]

RIN 1545–BD75

Substantial Understatement of Income Tax Liability

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document removes regulations relating to the addition to tax in the case of a substantial understatement of income tax liability and corrects an obsolete cross reference. The Internal Revenue Code (Code) provision imposing the addition to tax and cited in the cross reference was repealed in 1989. The changes made by this document will not affect taxpayers because the addition to tax does not apply to returns with a due date after December 31, 1989 (determined without regard to extensions).

DATES: The changes made by this document are effective January 5, 2005.

FOR FURTHER INFORMATION CONTACT: Audra M. Dineen, (202) 622–4940 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background and Explanation of Provisions

Section 6661 of the Code, as in effect before its repeal in 1989, imposed an addition to tax equal to 25 percent of the amount of the underpayment of tax attributable to any substantial understatement of income tax liability for a taxable year. Sections 1.6661–1 through 1.6661–6 of the Income Tax Regulations (26 CFR part 1) provided rules for determining whether an addition to tax should be imposed and for computing the amount of any such addition.

The Omnibus Budget Reconciliation Act of 1989, Public Law 101–239 (103 Stat. 2106), repealed section 6661 effective for tax returns due after December 31, 1989 (determined without regard to extensions) and substituted, in section 6662, an accuracy-related penalty applicable to those returns. The repeal of section 6661 has rendered §§ 1.6661–1 through 1.6661–6 obsolete. This Treasury decision removes those provisions and corrects an obsolete cross reference to section 6661 in the regulations under section 448 (relating to the limitation on the use of the cash method of accounting).

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations. In addition, because these regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Code, this document has been submitted to the Small Business Administration for comment on its impact on small business.

Drafting Information

The principal author of this document is Audra M. Dineen of the Office of Associate Chief Counsel, Procedure and Administration (Administrative Provisions and Judicial Practice Division).

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

■ Accordingly, 26 CFR parts 1 and 602 are amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read, in part, as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** In § 1.448–1T, paragraph (b)(1)(iii) is revised to read as follows:

§ 1.448–1T Limitation on the use of the cash receipts and disbursements method of accounting (temporary).

* * * * *

(b) * * *

(1) * * *

(iii) Tax shelter within the meaning of section 6662(d)(2)(C).

* * * * *

§§ 1.6661–1 through 1.6661–6 [Removed]

■ **Par. 3.** Sections 1.6661–1 through 1.6661–6 are removed.

PART 602—OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT

■ **Par. 4.** The authority citation for part 602 continues to read as follows:

Authority: 26 U.S.C. 7805.

■ **Par. 5.** In § 602.101, paragraph (b) is amended by removing the entries for "1.6661–3" and "1.6661–4" from the table.

Approved: December 9, 2004.

Mark Matthews,

Deputy Commissioner for Services and Enforcement.

Gregory Jenner,

Acting Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 05–200 Filed 1–4–05; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[TD 9173]

RIN 1545–BB22

Authority To Charge Fees for Furnishing Copies of Exempt Organizations' Material Open to Public Inspection

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: These final regulations adopt as final without change the temporary regulations published in the **Federal Register** on July 9, 2003, which amended the then-existing regulations regarding fees for copies of exempt organizations' material the IRS must make available to the public under section 6104 of the Internal Revenue Code (Code). These final regulations also adopt as final without change the conforming amendment included in the temporary regulations concerning the fees that an exempt organization may charge for furnishing copies of such material when required to do so.

DATES: These final regulations are effective January 5, 2005.

FOR FURTHER INFORMATION CONTACT: Sarah Tate, 202–622–4560 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The temporary regulations published at 68 FR 40768, July 9, 2003, amended the then-existing regulations to make clear that any fee assessed by the IRS for

furnishing copies of documents required to be made publicly available under section 6104 of the Code shall be no more than the fee under the IRS' Freedom of Information Act (FOIA) fee schedule. Those temporary regulations also amended the then-existing regulations to make clear that that an exempt organization may charge the applicable per-page copying fee under the IRS' FOIA fee schedule for any number of pages, without regard to the fee exclusion applicable to the IRS for the first 100 pages.

The IRS simultaneously published a notice of proposed rulemaking at 68 FR 40849, July 9, 2003, with a cross-reference to the text of the temporary regulations. The notice of proposed rulemaking invited public comment on the temporary regulations. The IRS has not received any public comments or any request for a public hearing. The IRS has not identified any reason that the text of the temporary regulations should be altered. The text of the temporary rule, now adopted as final, is identical to the text of that proposed rule.

Special Analyses

It has been determined that these final regulations are not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these final regulations, and because these final regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking preceding these final regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration (SBA) for comment on their impact on small businesses.

Drafting Information

The principal author of these final regulations is Sarah Tate, Office of the Associate Chief Counsel (Procedure and Administration), Disclosure and Privacy Law Division. However, other personnel from the IRS and Treasury Department participated in their development.

PART 301—PROCEDURE AND ADMINISTRATION

■ Accordingly, the IRS and the Department of the Treasury adopt as final without change the temporary regulations, amending 26 CFR part 301, which were published July 9, 2003.

Approved: December 28, 2004.

Mark E. Matthews,

Deputy Commissioner for Services and Enforcement.

Eric Solomon,

Acting Deputy Assistant Secretary of the Treasury.

[FR Doc. 05–199 Filed 1–4–05; 8:45 am]

BILLING CODE 4830–01–P

POSTAL SERVICE

39 CFR Part 501

Authorization to Manufacturer and Distribute Postage Meters

AGENCY: Postal Service.

ACTION: Final rule.

SUMMARY: This rule clarifies and enhances cautionary label markings required by Postal Service regulation to be placed on all postage meters to provide meter users with basic reminders on leasing, meter movement, and misuse. It also removes the obsolete requirement for the placement of a barcode label containing representation of meter serial numbers.

The meter manufacturer must promptly develop and implement a plan to change out the labels on existing meters leased or rented, including rebuilding, manufacturing, servicing, and inspection programs to expedite application of the new label. These plans must be approved by the Postage Technology Management office.

DATES: This rule is effective January 5, 2005.

FOR FURTHER INFORMATION CONTACT: Wayne Wilkerson, manager of Postage Technology Management, at 1735 N. Lynn Street, Rosslyn, VA 22209 or by telephone at 703–292–3691 or fax at 703–292–4073.

SUPPLEMENTARY INFORMATION: Title 39, *Code of Federal Regulations* (CFR) Part 501.23, Distribution Controls, section (r) requires postage meter manufacturers to affix a cautionary label to all postage meters to provide meter users with basic reminders on leasing, meter movement, and misuse. Further, section (r)(1) illustrates specific markings to be placed on cautionary labels. Experience with inadvertent use of the U.S. Postal Inspection Service telephone number to obtain general information has led to the need to clarify the label in order to emphasize manufacturer information and enhance direction to the customer. Section (2) currently requires a barcode label that is no longer relevant as a Postal Service requirement because of technology advances. The Postal Service has determined to remove the barcode label as an explicit requirement and leave it to the manufacturers' discretion depending on independent use of the barcode label.

List of Subjects in 39 CFR Part 501

Administrative practice and procedure, Postal Service.

The Amendment

■ For the reasons set out in this document, the Postal Service is amending 39 CFR part 501 as follows:

PART 501—AUTHORIZATION TO MANUFACTURE AND DISTRIBUTE POSTAGE METERS

■ 1. The authority citation for Part 501 continues to read as follows:

Authority: 5 U.S.C. 552(a); 39 U.S.C. 101, 401, 403, 404, 410, 2601, 2605; Inspector General Act of 1978, as amended (Pub. L. 95'452, as amended); 5 U.S.C. App. 3.

■ 2. Revise § 501.23(r) to read as follows:

§ 501.23 Distribution controls.

* * * * *

(r) Affix to all meters a cautionary label providing the meter user with basic reminders on leasing and meter movement.

(1) The cautionary label must be placed on all meters in a conspicuous and highly visible location. "PROPERTY OF [NAME OF MANUFACTURER]" as well as the manufacturer's toll-free number must be emphasized by capitalized bold type and preferably printed in red. The minimum width of the label should be 3.25 inches, and the minimum height should be 1.75 inches. The label should read as follows:

RENTED POSTAGE METER—NOT FOR SALE

PROPERTY OF [NAME OF MANUFACTURER]

(800) ###-####

Use of this meter is permissible only under U.S. Postal Service authorization. Call [Name of Manufacturer] at (800) ###- #### to relocate/return this meter.

WARNING! METER TAMPERING IS A FEDERAL OFFENSE.

IF YOU SUSPECT METER TAMPERING, CALL POSTAL INSPECTORS AT 1–800–372–8347

REWARD UP TO $50,000 for information leading to the conviction of any person who misuses postage meters resulting in the Postal Service not receiving correct postage payments.

(2) Exceptions to the formatting of required labeling are determined on a case-by-case basis. Any deviation from standardized meter labeling

requirements must be approved in writing by the Postal Service.

* * * * *

Neva Watson,

Attorney, Legislative.

[FR Doc. 05–134 Filed 1–4–05; 8:45 am]

BILLING CODE 7710–12–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0409; FRL–7691–1]

Chlorothalonil; Re-establishment of Tolerance for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation re-establishes a time-limited tolerance for combined residues of the fungicide chlorothalonil and its metabolite, 4-hydroxy- 2,5,6-trichloroisophthalonitrile in or on ginseng at 0.10 parts per million (ppm). This tolerance will expire and is revoked on December 31, 2007. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on ginseng. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA) requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18.

DATES: This regulation is effective January 5, 2005. Objections and requests for hearings must be received on or before March 7, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit III. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2004–0409. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 South Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Barbara Madden, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6463; e-mail address: *Madden.Barbara@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET *(http://www.epa.gov/edocket/),* you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at *http://www.epa.gov/fedrgstr/.* A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/.*

II. Background and Statutory Findings

EPA issued a final rule, published in the **Federal Register** of November 7, 2001 (66 FR 56233) (FRL–6807–1), which announced that on its own initiative under section 408 of the FFDCA; 21 U.S.C. 346a, as amended by the FQPA (Public Law 104–170), it established a time-limited tolerance for the combined residues chlorothalonil and its metabolite, 4-hydroxy- 2,5,6-trichloroisophthalonitrile in or on ginseng at 0.10 ppm, with an expiration date of December 31, 2003. EPA established the tolerance because section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18. Such tolerances can be established without providing notice or period for public comment.

EPA received a request to extend the use of chlorothalonil on ginseng for this year's growing season since the State of Wisconsin issued a crisis exemption pursuant to section 18 of FIFRA to control *Botrytis cincera.* Botrytis, also called gray mold, causes stem and leaf blight throughout the growing season. Ginseng is a perennial crop that is typically harvested in the third or fourth year. Registered alternatives are available for control of Botrytis during the first two years of the ginseng crop but none are registered for use during years when the crop will be harvested. After having reviewed the submission, EPA concurs that emergency conditions exist. EPA has authorized under FIFRA section 18 the use of chlorothalonil on ginseng for control of Botrytis in Wisconsin.

EPA assessed the potential risks presented by residues of chlorothalonil in or on ginseng. In doing so, EPA considered the safety standard in section 408(b)(2) of the FFDCA, and decided that the necessary tolerance under section 408(l)(6) of the FFDCA would be consistent with the safety standard and with FIFRA section 18. The data and other relevant material have been evaluated and discussed in the final rule published in the **Federal Register** of November 7, 2001 (66 FR 56233) (FRL–6807–1). Based on that data and information considered, the Agency reaffirms that re-establishment of the time-limited tolerance will

continue to meet the requirements of section 408(l)(6) of the FFDCA. Therefore, the time-limited tolerance is re-established. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations (CFR). Although this tolerance will expire and is revoked on December 31, 2007, under section 408(l)(5) of the FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on ginseng after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA and the application occurred prior to the revocation of the tolerance. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

III. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need To Do To File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2004–0409 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before March 7, 2005.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, # 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit III.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2004–0409, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

IV. Statutory and Executive Order Reviews

This final rule re-establishes a time-limited tolerance under section 408 of the FFDCA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 petition under section 408 of the FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and

responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any "tribal implications" as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive Order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes." This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

V. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 20, 2004,

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

§ 180.275 [Amended]

■ 2. In § 180.275, amend paragraph (b) by revising the date "12/31/03" to read "12/31/07."

[FR Doc. 05–51 Filed 1–4–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0394; FRL–7689–7]

Thiamethoxam; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of thiamethoxam and its metabolite, (CGA–322704) in or on legume vegetables, root vegetables (except sugar beet), strawberries, bushberries, juneberries, lingonberries, salal, cranberries, spearmint, peppermint, rapeseed, mustard, flax, safflower, crambe, borage, and potatoes. In addition, the tolerance expression for tuberous and corm vegetable crop subgroup (1C) is revised to a tolerance expression for tuberous and corm crop subgroup (except potato) (1D). Syngenta Crop Protection, Inc. and Interregional Research Project 4 requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective January 5, 2005. Objections and requests for hearings must be received on or before March 7, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2004–0394. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 South Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Dani Daniel, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5409; e-mail address: *daniel.dani@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of This Document and Other Related Information?

In addition to using EDOCKET (*http://www.epa.gov/edocket/*), you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm/*.

II. Background and Statutory Findings

In the **Federal Register** of June 2, 2004 (69 FR 31110) (FRL–7361–1), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 2E6363, 3E6781, 3E6800, 3E6805, 3E6806, 3E6807, 4E6819, and 0F6142) by Syngenta Crop Protection, Inc., P.O. Box 18300 Greensboro, NC 27419–8300, and Interregional Research Project 4 (IR–4), 681 US Highway 1 South, North Brunswick, NJ 08902–3390. The petitions requested that 40 CFR 180.565 be amended by establishing tolerances for combined residues of the insecticide thiamethoxam, 3-[(2-chloro-5-thiazolyl)methyl]tetrahydro-5-methyl-N-nitro-4H-1,3,5-oxadiazin-4-imine and its metabolite CGA-322704 (N-(2-chloro-thiazol-5-ylmethyl)-N'-methyl-N"-nitro-guanidine), in or on legume vegetables group 6 at 0.02 parts per million (ppm) (3E6805), peppermint and spearmint at 4.0 ppm (2E6363); root vegetables (except sugar beet) crop subgroup 1B at 0.1 ppm and for radish tops at 0.80 ppm (4E6819); strawberry at 0.30 ppm (3E6800); cranberry at 0.01 ppm (3E6781); bushberry crop subgroup 13B and juneberry, lingonberry and salal at 0.25 ppm (3E6807); rapeseed seed, mustard seed, flax seed, safflower seed, crambe seed, and borage seed at 0.02 ppm (3E6806); and potato at 0.25 ppm (0F6142). In addition, due to the establishment of the individual tolerance for potato, it was requested that the tolerance expression for tuberous and corm crop subgroup 1C be revised to a tolerance expression for tuberous and corm (except potato) crop subgroup 1D. That notice included a summary of these petitions prepared by Syngenta Crop Protection, Inc. and IR-4, the registrant. As a result of the residue data submitted to support these requests, the proposed tolerance level for peppermint and spearmint was subsequently revised to 1.5 ppm; the proposed tolerance level for root vegetables (except sugar beet) crop subgroup 1B was subsequently revised to 0.02 ppm; the proposed tolerance level for bushberry crop subgroup 13B and juneberry, lingonberry and salal was subsequently revised to 0.20 ppm; and the proposed tolerance for cranberry was revised to 0.02 ppm. There were no comments received in response to the notice of filing.

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for a tolerance for combined residues of thiamethoxam and its metabolite CGA–322704 on legume vegetables group 6 at 0.02 ppm, peppermint and spearmint at 1.5 ppm; root vegetables (except sugar beet) crop subgroup 1B at 0.02 ppm and for radish tops at 0.80 ppm; strawberry at 0.30 ppm; cranberry at 0.02 ppm; bushberry crop subgroup 13B and juneberry, lingonberry and salal at 0.20 ppm; rapeseed seed, mustard seed, flax seed, safflower seed, crambe seed, and borage seed at 0.02 ppm; and potato at 0.25 ppm. In addition, due to the establishment of the individual tolerance for potato, it was requested that the tolerance expression for tuberous and corm crop subgroup 1C be revised to a tolerance expression for tuberous and corm (except potato) crop subgroup 1D. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

In assessing the human health risks associated with the existing and proposed uses of thiamethoxam, EPA has included exposure to thiamethoxam as well as its metabolite CGA–322704 when evaluating exposure from the dietary (food only) pathway. This approach was developed when the Agency received the first food-use request for registration of thiamethoxam and determined that the CGA–322704 metabolite/degradate, as well as the parent compound, are residues of concern in food; no exposure to CGA–322704 in drinking water was considered likely following application of thiamethoxam. At the time, toxicological information regarding CGA–322704 was not available, and it was assumed that thiamethoxam and this metabolite are toxicologically equivalent for estimation of dietary risk. Subsequently, the Agency received a petition requesting registration of the insecticide clothianidin. Upon review of that petition, the Agency discovered that CGA–322704 and clothianidin are identical. With the registration of clothianidin uses, the Agency has largely complete toxicological databases for both thiamethoxam and CGA–322704 (referred to in the remainder of this rule as clothianidin). While some of the toxic effects observed following dosing with the two active ingredients are similar, it is not clear that they are toxicologically equivalent.

To date, the Agency has not formally examined the toxicity data to determine if it is appropriate to separate exposure to the parent compound thiamethoxam

from exposure to thiamethoxam's metabolite clothianidin when assessing the aggregate risk associated with thiamethoxam tolerances. Therefore, EPA has taken the very conservative approach of analzying the non-cancer risk of thiamethoxam by both (1) aggregating exposure to thiamethoxam and its metabolite clothianidin resulting from use of thiamethoxam and clothianidin residues resulting from use of clothianidin as an active ingredient and comparing this aggregate exposure to relevant endpoints for thiamethoxam; and (2) aggregating exposure to clothianidin resulting from thiamethoxam use and from use of clothianidin as an active ingredient and comparing this aggregate exposure to relevant endpoints for clothianidin. EPA has taken the further conservative step of assuming that, in instances where both thiamethoxam and clothianidin are registered for use on a crop, both pesticides will, in fact, be used on that crop. Despite this very conservative approach, thiamethoxam non-cancer risks (taking into account clothianidin exposure) are well below the Agency's level of concern (LOC).

Pending formal reconsideration of toxicological equivalency for thiamethoxam and the clothianidin metabolite, aggregate risks from both thiamethoxam and clothianidin are presented below.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by thiamethoxam as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed are discussed in the **Federal Register** of September 17, 2003 (68 FR 54386) (FRL–7327–5). The nature of the toxic effects caused by the metabolite clothianidin are discussed in the **Federal Register** of May 30, 2003 (68 FR 32390) (FRL–7306–8).

B. Toxicological Endpoints

The dose at which the NOAEL from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological LOC. However, the LOAEL is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

Three other types of safety or uncertainty factors may be used: "Traditional uncertainty factors;" the "special FQPA safety factor;" and the "default FQPA safety factor." By the term "traditional uncertainty factor," EPA is referring to those additional uncertainty factors used prior to FQPA passage to account for database deficiencies. These traditional uncertainty factors have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term "special FQPA safety factor" refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The "default FQPA safety factor" is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional uncertainty factor or a special FQPA safety factor).

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by an UF of 100 to account for interspecies and intraspecies differences and any traditional uncertainty factors deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of safety factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}), one in a million (1×10^{-6}), or one in ten million (1×10^{-7}). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a "point of departure" is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated.

A summary of the toxicological endpoints for thiamethoxam used for human risk assessment is shown in Table 1 of this unit:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR THIAMETHOXAM FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF and LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (general population including infants and children)	NOAEL = 100 mg/kg/day UF = 100 Acute RfD = 1 mg/kg/day	FQPA SF = 10 aPAD = acute RfD ÷ FQPA SF = 0.1 mg/kg/day	Acute mammalian neurotoxicity study in the rat LOAEL = 500 mg/kg/day based on treatment-related neurobehavioral effects observed in the FOB and LMA testing (drooped palpebral closure, decreased rectal temperature and locomotor activity, increased forelimb grip strength)

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR THIAMETHOXAM FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF and LOC for Risk Assessment	Study and Toxicological Effects
Chronic dietary (all populations)	NOAEL = 0.6 mg/kg/day UF = 100 Chronic RfD = 0.006 mg/kg/day	FQPA SF = 10 cPAD = chronic RfD ÷ FQPA SF = 0.0006 mg/kg/day	2–Generation reproduction study LOAEL = 1.8 mg/kg/day based on increased incidence and severity of tubular atrophy in testes of F^1 generation males.
Oral nondietary (all durations)	NOAEL = 0.6 mg/kg/day	Residential LOC for MOE = 1,000	2–Generation reproduction study LOAEL = 1.8 mg/kg/day based on increased incidence and severity of tubular atrophy in testes of F^1 generation males.
Dermal (all durations)	Oral study NOAEL = 0.6 mg/kg/day (dermal absorption rate = 27%)	Resdiential LOC for MOE = 1,000	2-Generation reproduction study LOAEL = 1,8 mg/kg/day based on increased incidence and severity of tubular atrophy in testes of F^1 generation males.
Inhalation (all durations)	Oral study NOAEL = 0.6 mg/kg/day(inhalation absorption rate = 100%)	Residential LOC for MOE = 1,000	2–Generation reproduction study LOAEL = 1.8 mg/kg/day based on increased incidence and severity of tubular atrophy in testes of F^1 generation males.
Cancer (oral, dermal, inhalation)	Likely carcinogen for humans based on increased incidence of hepatocellular adenomas and carcinomas in male and female mice. Quantification of risk based on most potent unit risk: Male mouse liver adenoma and/or carcinoma combined tumor rate. The upper bound estimate of unit risk, $Q1^*$ (mg/kg/day) ^{2} is 3.77 x 10 ^{2} in human equivalents.		

A summary of the toxicological endpoints for the metabolite clothianidin used for human risk assessment is shown in Table 2 of this unit:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR CLOTHIANIDIN FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (Females 13–50 years of age)	Developmental NOAEL = 25 mg/kg/day UF = 1,000 Acute RfD = 0.025 mg/kg	FQPA SF = 1 aPAD = acute RfD ÷ FQPA SF = 0.025 mg/kg	Developmental rabbit study Developmental LOAEL = 75 mg/kg/day based on an increased litter incidence of a missing lobe of the lung.
Acute dietary (General population)	NOAEL = 25 mg/kg/day UF = 1,000 Acute RfD = 0.025 mg/kg	FQPA SF = 1 aPAD = acute RfD ÷ FQPA SF = 0.025 mg/kg	Special Neurotoxicity/Pharmacology Study in Mice and Rats LOAEL = 50 mg/kg based on transient signs of decreased spontaneous motor activity, tremors and deep respirations.
Chronic dietary (All populations)	Offspring NOAEL = 9.8 mg/kg/day UF = 1,000 Chronic RfD = 0.0098 mg/kg/day	FQPA SF = 1 cPAD = chronic RfD ÷ FQPA SF = 0.0098 mg/kg/day	2–Generation Reproduction Study Offspring LOAEL = 31.2 mg/kg/day based on decreased mean body weight gain and delayed sexual maturation, decreased absolute thymus weights in F^1 pups and an increase in stillbirths in both generations.
Incidental Oral (All durations)	NOAEL = 9.8 mg/kg/day	Residential LOC for MOE = 1,000	2–Generation reproduction study Offspring LOAEL = 31.2 mg/kg/day based on decreased mean body weight gain and delayed sexual maturation, decreased absolute thymus weights in F^1 pups and an increase in stillbirths in both generations.

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR CLOTHIANIDIN FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and LOC for Risk Assessment	Study and Toxicological Effects
Dermal (All durations)	Oral study NOAEL = 9.8 mg/kg/day (dermal absorption rate = 1%)	Residential LOC for MOE = 1,000	2–Generation reproduction study Offspring LOAEL = 31.2 mg/kg/day based on decreased mean body weight gain and delayed sexual maturation, decreased absolute thymus weights in F^1 pups and an increase in stillbirths in both generations.
Inhalation (All durations)	Oral study NOAEL = 9.8 mg/kg/day (inhalation absorption rate = 100%)	Residential LOC for MOE = 1,000	2–Generation reproduction study Offspring LOAEL = 31.2 mg/kg/day based on decreased mean body weight gain and delayed sexual maturation, decreased absolute thymus weights in F^1 pups and an increase in stillbirths in both generations.
Cancer (oral, dermal, inhalation)	Classification: Not likely to be carcinogenic to humans.		

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.565) for the combined residues of thiamethoxam and its metabolite clothianidin in or on a variety of raw agricultural commodities. Tolerances for thiamethoxam are established on barley, canola, cotton, sorghum, wheat, imported coffee, pecan, stone fruit, succulent bean, sunflower, tuberous and corm vegetables crop subgroup, fruiting vegetables, crop group, tomato paste, cucurbit vegetables crop group, pome fruits crop group, field corn forage, field corn stover, sweet corn stover, field corn grain, popcorn grain, sweet corn (kernal and cob with husk removed), milk, and the meat and meat by products of cattle, goats, horses, and sheep. Since clothianidin is a major metabolite of thiamethoxam, residues of clothianidin that would theoretically result from registered and pending uses of clothianidin and residues that would theoretically result from the metabolism of thiamethoxam are included in the analysis. Risk assessments were conducted by EPA to assess dietary exposures from thiamethoxam in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. In conducting the acute dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: EPA conducted the acute dietary exposure analysis based on highly conservative assumptions. The residues of concern for the acute analysis are thiamethoxam and its metabolite clothianidin. The assessment for thiamethoxam assumed that 100% of the registered and proposed crops were treated and that all treated crops and livestock had residues of concern at the tolerance level. The general U.S. population and all population subgroups have exposure and risk estimates which are below EPA's LOC (i.e., the aPADs are all below 100%). The most highly exposed subgroup is children 1 to 2 years of age. The exposure estimate for children 1 to 2 years of age is 0.01099 mg/kg/day, which is equivalent to 11% of the aPAD.

For the metabolite clothianidin, the acute analysis is a conservative assessment that was based on tolerance level residues and the assumption of 100 percent crop treated (PCT) for established and proposed clothianidin uses. For the commodities that have both thiamethoxam tolerances and established or proposed clothianidin tolerances (i.e., sweet corn, field corn, pop corn, canola, milk, and pome fruit), the proposed clothianidin tolerances are added to the residues that could result from use of thiamethoxam. The general U.S. population and all population subgroups have exposure and risk estimates which are below EPA's LOC (i.e., the aPADs are all below 100%). The most highly exposed population subgroup is infants less than 1 year old, which utilizes 80% of the aPAD.

ii. *Chronic exposure.* In conducting the chronic dietary risk assessment EPA used the DEEM-FCID™, which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide CSFII, and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The residues of concern for the chronic analysis are thiamethoxam and its metabolite clothianidin. The chronic analysis for thiamethoxam was based on anticipated residues in the form of average field trial residue values, and the analysis included percent crop estimates. The general U.S. population and all population subgroups have exposure and risk estimates which are below EPA's LOC (i.e., the cPADs are all below 100%). The most highly exposed subgroup is children 1 to 2 years of age. The exposure estimate for children 1 to 2 years of age is 0.000103 mg/kg/day, which is equivalent to 17% of the cPAD.

For clothianidin, the chronic analysis is a relatively conservative assessment that was based on tolerance level residues and the assumption of 100% crop treated for established and proposed clothianidin uses, with the exception of anticipated residues (AR) for apples and pears. For the commodities that have both thiamethoxam tolerances and established or proposed clothianidin tolerances (i.e., sweet corn, field corn, pop corn, canola, and milk), the

proposed clothianidin tolerances are added to the residues that could result from use of thiamethoxam. For apples and pears, the highest average field trial (HAFT) levels from the residue field trials were added to the residues that could result from use of thiamethoxam. The general U.S. population and all population subgroups have exposure and risk estimates which are below EPA's LOC (i.e., the cPADs are all below 100%). The most highly exposed population subgroup is children 1 to 2 years of age, which utilizes 15% of the cPAD.

iii. *Cancer.* The residue of concern for the cancer analysis is thiamethoxam, *per se.* The residues of its metabolite clothianidin were removed from the cancer analysis because the metabolite was found to be "not likely to be carcinogenic to humans" when it was evaluated as an active ingredient. The cancer analysis was based on average field trial residue values as well as PCT estimates. The estimated dietary exposure to the U.S. population is 0.000263 mg/kg/day.

iv. *Anticipated residue and PCT information.* Section 408(b)(2)(E) of the FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must pursuant to section 408(f)(1) require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. For the present action, EPA will issue such data call-ins for information relating to anticipated residues as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Such data call-ins will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F) of FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:For existing uses, the Agency used estimates of PCT for the chronic exposure assessment which was determined using USDA's National Agricultural Statistics Service (NASS) Usage Data (1999–2003) and EPA Proprietary Usage Data (2001–2003). The chronic PCT estimates that were used for existing uses are shown in Table 3:

TABLE 3.—THIAMETHOXAM ESTIMATES OF CROP TREATED FOR EXISTING USES

Commodity	Percent Crop Treated
Apples	5
Barley	1
Canola	55
Cantaloupes	13
Casabas	44
Cottonseed	20
Crabapples	20
Cucumbers	5
Field corn, grain	6
Fruiting vegetables (except cucurbits - Crop group 8)	15
Honeydew melons	13
Loquats	53
Pears	9
Popcorn	6
Potatoes	41
Pumpkins	44
Quinces	53
Sorghum (including milo)	9
Squash	44
Sunflowers	25
Sweet corn	6

TABLE 3.—THIAMETHOXAM ESTIMATES OF CROP TREATED FOR EXISTING USES—Continued

Commodity	Percent Crop Treated
Tuberous and Corm Vegetables - Crop subgroup 1C (except potatoes)	33
Watermelons	13
Wheat	2

For the new uses, the Agency used PCT estimates for the chronic exposure assessment based on usage data and market share projections as follows. Market share projections for the new uses for thiamethoxam were obtained from the registrant and compared to 1999–2003 USDA NASS Usage Data and EPA 2001–2003 Proprietary Usage Data for the historically, most widely used insecticide for control of insect pests for each crop. As a result of this comparison, the highest, most conservative PCT estimate for each crop was used for the chronic exposure assessment. These highly conservative estimates should not underestimate actual usage of thiamethoxam on the new crops/sites. To further support the reliability of these PCT estimates, as a condition of registration, the registrant will be required to agree to report annually on the market share attained for the new uses for which thiamethoxam is registered. As a condition of registration, they will also be required to agree to mitigate dietary risk as deemed appropriate by the Agency should the market share data raise a concern for increased dietary risk. The Agency will then compare that market share information with the PCT estimates used to evaluate potential dietary risk. In those instances where percent market share is approaching or exceeding the predicted PCT estimate used in the Agency's risk assessment, EPA will conduct a new dietary risk assessment to evaluate the new dietary risk. If the market share data raise a concern for increased pesticide risk, the Agency will act to mitigate that dietary risk and could employ several approaches, including but not limited to production caps, geographical limitations, removal of uses, or other means deemed appropriate by the Agency. The chronic PCT estimates that were used for existing uses are shown in Table 4:

TABLE 4.—THIAMETHOXAM ESTIMATES OF CROP TREATED FOR NEW USES

Commodity	Percent Crop Treated
Beans, lima	38
Beans, snap	37
Bushberries	55
Carrots	20
Cranberries	29
Mint	9
Peas, green processed	36
Peas (including dried peas)	44
Soybeans	11
Strawberries	46

The Agency believes that the three conditions listed in this Unit III. have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which thiamethoxam may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for thiamethoxam in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of thiamethoxam.

The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The screening concentration in ground water (SCIGROW) model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will use FIRST (a Tier 1 model) before using PRZM/EXAMS (a Tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. Both FIRST and PRZM/EXAMS incorporate an index reservoir environment, and both models include a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a screen for sorting out pesticides for which it is unlikely that drinking water concentrations would exceed human health LOC.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs), which are the model estimates of a pesticide's concentration in water. EECs derived from these models are used to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to thiamethoxam they are further discussed in the aggregate risk sections in Unit E.

Based on the PRZM/EXAMS and SCIGROW models, the EECs of thiamethoxam for acute exposures are estimated to be 11.4 parts per billion (ppb) for surface water and 5 ppb for ground water. The EECs for chronic non-cancer exposures are estimated to be 0.77 ppb for surface water and 1.94 ppb for ground water. The EECs for cancer exposures are estimated to be 0.31 ppb for surface water and 1.94 ppb for ground water.

Clothianidin is not a significant degradate of thiamethoxam in water. Therefore, residues of clothianidin in water were estimated based on applications of clothianidin as an active ingredient. Based on the FIRST and SCIGROW models, the EECs of clothianidin for acute exposures are estimated to be 7.29 parts per billion (ppb) for surface water and 5.84 ppb for ground water. The EECs for chronic exposures are estimated to be 1.35 ppb for surface water and 5.84 ppb for ground water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Thiamethoxam is not registered for use on any sites that would result in residential exposure.

Clothianidin is currently registered for use on turfgrasses. Exposures and risk resulting from clothianidin residues on turfgrasses are included in the aggregate risk assessment for clothianidin.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to thiamethoxam and any other substances and thiamethoxam does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that thiamethoxam has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine

which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's OPP concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's Web site at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

1. *In general.* Section 408 of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.* The developmental toxicity studies indicated no quantitative or qualitative evidence of increased susceptibility of rat or rabbit fetus to *in utero* exposure based on the fact that the developmental NOAELs are either higher than or equal to the maternal NOAELs. However, the reproductive studies indicate effects in males rats in the form of increased incidence and severity of testicular tubular atrophy. These data are considered to be evidence of increased quantitative susceptibility for male pups when compared to the parents.

3. *Conclusion.* There is a complete toxicity data base for thiamethoxam and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X special safety factor to protect infants and children should be retained, based on the following factors: Effects on endocrine organs observed across species; the significant decrease in alanine amino transferase levels in the companion animal studies and in the dog studies; the mode of action of this chemical in insects (interferes with the nicotinic acetyl choline receptors of the insect's nervous system); the transient clinical signs of neurotoxicity in several studies across species; and the suggestive evidence of increased quantitative susceptibility in the rat reproduction study.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against EECs. DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water (e.g., allowable chronic water exposure (mg/kg/day) = cPAD − (average food + residential exposure)). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the EPA's Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to thiamethoxam will occupy 4% of the aPAD for the U.S. population, 2% of the aPAD for females 13 years and older, 10% of the aPAD for infants less than one year old, and 11% of the aPAD for children 1 to 2 years old. In addition, there is potential for acute dietary exposure to thiamethoxam in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in Table 5 of this unit:

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO THIAMETHOXAM

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
General U.S. Population	0.1	4	11.4	5	3,400
All infants (less than one year old)	0.1	10	11.4	5	900
Children 1–2 years old	0.1	11	11.4	5	890
Females 13–49 years old	0.1	2	11.4	5	2,900

Sources of clothianidin residues in food include uses of both thiamethoxam and clothianidin. Toxicological doses and endpoints for clothianidin were used to calculate risk. The acute dietary exposure from food to the metabolite clothianidin will occupy 18% of the aPAD for the U.S. population, 12% of the aPAD for females 13 years and older, 80% of the aPAD for infants less than one year old, and 60% of the aPAD for children 1 to 2 years old. In addition, there is potential for acute dietary exposure to clothianidin in drinking water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in Table 6 of this unit:

TABLE 6.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO CLOTHIANIDIN

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
General U.S. Population	0.025	18	7.29	5.84	710
All infants (less than one year old)	0.025	80	7.29	5.84	48
Children 1–2 years old	0.025	60	7.29	5.84	92
Females 13–49 years old	0.025	12	7.29	5.84	640

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to thiamethoxam from food will utilize 6% of the cPAD for the U.S. population, 11% of the cPAD for infants less than one year old, and 17% of the cPAD for children 1 to 2 years old. There are no residential uses for thiamethoxam that result in chronic residential exposure to thiamethoxam. In addition, there is potential for chronic dietary exposure to thiamethoxam in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 7 of this unit:

TABLE 7.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO THIAMETHOXAM

Population Subgroup	cPAD (mg/kg)	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.0006	6	0.77	1.94	20
All infants (less than one year old)	0.0006	11	0.77	1.94	5.4
Children 1–2 years old	0.0006	17	0.77	1.94	5
Females 13–49 years old	0.0006	5	0.77	1.94	17

Sources of clothianidin residues in food include uses of both thiamethoxam and clothianidin. Toxicological doses and endpoints for clothianidin were used to calculate risk. Exposure to the metabolite clothianidin from food will utilize 6% of the cPAD for the U.S. population, 13% of the cPAD for infants less than one year old, and 15% of the cPAD for children 1 - 2 years old. Combined residential exposure estimates range from an MOE of 1,300 for combined oral and dermal exposure to toddlers (treated turf + treated soil + dermal) to 8,900 for dermal exposure to adults (application + post-application) adults. In addition, there is potential for chronic dietary exposure to the metabolite clothianidin in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 8 of this unit:

TABLE 8.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO CLOTHIANIDIN

Population Subgroup	cPAD (mg/kg)	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.0098	6	1.35	5.84	320
All infants (less than one year old)	0.0098	13	1.35	5.84	85
Children 1–2 years old	0.0098	15	1.35	5.84	83
Females 13–49 years old	0.0098	5	1.35	5.84	280
Adults 50+ years old	0.0098	5	1.35	5.84	330

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Thiamethoxam is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's LOC.

Short-term aggregate exposures from the metabolite clothianidin result in aggregate MOEs of 5,900 for the general U.S. population, 1,100 for children 1 to 2 years old, and 6,200 for females 13 to 49 years old. These aggregate MOEs do not exceed the Agency's LOC for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of clothianidin in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's LOC, as shown in Table 9 of this unit:

TABLE 9.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO CLOTHIANIDIN

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate LOC	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
General U.S. population	5,900	1,000	1.35	5.84	280
Children 1–2 years old	1,100	1,000	1.35	5.84	8.7
Females 13–49 years old	6,200	1,000	1.35	5.84	250

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Thiamethoxam is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's LOC.

Intermediate-term aggregate exposures from the metabolite clothianidin result in aggregate MOEs of 5,900 for the general U.S. population, 1,100 for children 1 to 2 years old, and 6,200 for females 13 to 49 years old. These aggregate MOEs do not exceed the Agency's LOC for aggregate exposure to food and residential uses. In addition, intermediate-term DWLOCs were calculated and compared to the EECs for chronic exposure of clothianidin in ground water and surface water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect intermediate-term aggregate exposure to exceed the Agency's LOC, as shown in Table 10 of this unit:

TABLE 10.—AGGREGATE RISK ASSESSMENT FOR INTERMEDIATE-TERM EXPOSURE TO CLOTHIANIDIN

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate LOC	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Intermediate-Term DWLOC (ppb)
General U.S. population	5,900	1,000	1.35	5.84	280
Children 1–2 years old	1,100	1,000	1.35	5.84	8.7
Females 13–49 years old	6,200	1,000	1.35	5.84	250

5. *Aggregate cancer risk for U.S. population.* In conducting the aggregate cancer risk assessment, only dietary and drinking water pathways of exposure were considered. At this time, there are no uses for thiamethoxam that would result in any non-occupational, non-dietary exposure (i.e., there are no dermal or inhalation routes of exposure that should be included in an aggregate assessment). A DWLOC was derived for the general U.S. population based on EPA's LOC for cancer or a risk in the range of 1 in 1 million. The DWLOC is compared to the estimated environmental concentrations of thiamethoxam in surface and ground water and is used to determine whether or not aggregate cancer exposures are likely to result in risk estimates that exceed EPA's LOC. Table 11 of this unit summarizes the drinking water estimated concentrations of thiamethoxam in surface water and ground water and the associated DWLOC for cancer:

TABLE 11.—AGGREGATE RISK ASSESSMENT FOR CANCER EXPOSURE TO THIAMETHOXAM

Population Subgroup	Maximum Exposure mg/kg/day	Food Exposure mg/kg/day	Maximum Water Exposure mg/kg/day	Cancer DWLOC ppb	Ground Water EEC ppb	Surface Water EEC ppb
General U.S. population	7.96×10^{-5}	7.96×10^{-5}	7.96×10^{-5}	1.87	1.94	0.31

For cancer, the DWLOC is slightly less than the ground water EEC. However, the cancer DWLOC is based on a conservative estimate of dietary exposure. Available information from actual prospective ground water monitoring data demonstrates that actual thiamethoxam residues in groundwater occur at or below 0.05 ppb. This interim analysis suggests that actual long-term residues of thiamethoxam in ground water will be significantly less than the levels predicted by the SCIGROW model. A significant decrease in the level of thiamethoxam in drinking water results in an aggregate risk estimate that is unlikely to exceed EPA's LOC for cancer. Further, the DWLOC numerical computation was done using a cancer risk figure of 1 in 1 million although EPA has repeatedly found that risk figures marginally higher than 1 in 1 million fall within the range of a 1 in 1 million risk.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to thiamethoxam residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (aqueous acetonitrile solvent extraction, liquid-liquid partitioning and solid-phase extraction cleanup, and high pressure liquid chromatography/ultraviolet (HPLC/UV) analysis) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov.*

B. International Residue Limits

There are no international residue limits for thiamethoxam.

V. Conclusion

Therefore, the tolerance is established for combined residues of thiamethoxam, 3-[(2-chloro-5-thiazolyl)methyl]tetrahydro-5-methyl-N-nitro-4H-1,3,5-oxadiazin-4-imine and its metabolite (N-(2-chloro-thiazol-5-ylmethyl)-N'-methyl-N''-nitro-guanidine), in or on legume vegetables group 6 at 0.02 ppm, peppermint and spearmint at 1.5 ppm; root vegetables (except sugar beet) crop subgroup 1B at 0.02 ppm and for radish tops at 0.80 ppm; strawberry at 0.30 ppm; cranberry at 0.02 ppm; bushberry crop subgroup 13B and juneberry, lingonberry and salal at 0.20 ppm; rapeseed seed, mustard seed, flax seed, safflower seed, crambe seed, and borage seed at 0.02 ppm; and potato at 0.25 ppm. In addition, the tolerance expression for tuberous and corm crop subgroup 1C is revised to a tolerance expression for tuberous and corm (except potato) crop subgroup 1D.

VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need To Do To File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2004–0394 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before March 7, 2005.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES.** Mail your copies, identified by docket ID number OPP–2004–0394, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES.** You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov.* Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any "tribal implications" as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive Order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes." This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 22, 2004.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.565 is amended by alphabetically adding commodities to the table in paragraph (a) to read as follows:

§ 180.565 Thiamethoxam; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Borage, seed	0.02
* * *	* *
Bushberry, subgroup 13B	0.20
* * *	* *
Crambe, seed	0.02
Cranberry	0.02
Flax, seed	0.02
* * *	* *
Juneberry	0.20
Lingonberry	0.20
* * *	* *
Mustard, seed	0.02
Peppermint	1.5
Potato	0.25
Radish, tops	0.80
Rapeseed, seed	0.02
Safflower, seed	0.02
Salal	0.20
* * *	* *
Spearmint	1.5
Strawberry	0.3
* * *	* *
Vegetable, legume, group 6	0.02
Vegetable, root, except sugar beet, subgroup 1B	0.02

* * * * *

■ 3. Section 180.565 is amended by revising the tolerance expression for Tuberous and Corm Vegetables Crop Subgroup in the table in paragraph (a) to

read Vegetable, tuberous and corm, except potato, subgroup 1D.

* * * * *

[FR Doc. 05–89 Filed 1–4–05; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[CC Docket No. 96–128; FCC 04–251]

The Pay Telephone Reclassification and Compensation Provisions of the Telecommunications Act of 1996

AGENCY: Federal Communications Commission.

ACTION: Final rule; petitions for reconsideration.

SUMMARY: By this document, we consider four petitions for reconsideration of our *Report and Order* which established detailed rules (the "rules" or "Payphone Compensation Rules") ensuring that payphone service providers (PSPs) are "fairly compensated" for each and every completed payphone-originated call. This *Order on Reconsideration* does not change the compensation framework adopted last year, but rather refines and builds upon its approach. The Commission provides guidance on the types of contracts that it would deem to be reasonable methods of compensating PSPs, extends the time period that carriers must retain certain payphone records, and clarifies the rules' reporting, certification, and audit requirements.

DATES: Effective January 5, 2005, except for § 64.1310(g) which contains information collection requirements that are not effective until approved by the Office of Management and Budget. The Commission will publish a document in the **Federal Register** announcing the effective date of that section.

ADDRESSES: A copy of any comments on the Paperwork Reduction Act information collection requirements contained herein should be submitted to Judith B. Herman, Federal Communications Commission, Room 1–C804, 445 12th Street, SW., Washington, DC 20554, or via the Internet to *Judith-B.Herman@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: Darryl Cooper Attorney-Advisor, Competition Policy Division, Wireline Competition Bureau, at (202) 418–7131, or via the Internet at *darryl.cooper@fcc.gov* or Denise A. Coca, Attorney-Advisor, Competition Policy Division, Wireline Competition Bureau, at (202) 418–0574, or via the Internet at *denise.coca@fcc.gov.* For additional information concerning the Paperwork Reduction Act information collection requirements contained in this document, contact Judith B. Herman at 202–418–0214, or via the Internet to *Judith-B.Herman@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Order on Reconsideration*, CC Docket No. 96–128, FCC 04–251, adopted October 20, 2004, and released October 22, 2004. Filings and comments are also available for public inspection and copying during regular business hours at the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC, 20554. They may also be purchased from the Commission's copy contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 1 (800) 378–3160 or (202) 4880–5300, facsimile (202) 488–5563, or via e-mail at *http://www.bcpiweb.com.*

Synopsis of the Order on Reconsideration and the Report and Order

I. Introduction

1. In this *Order on Reconsideration*, we consider four petitions for reconsideration of our *Report and Order* adopted on September 30, 2003, which established detailed rules ensuring that PSPs are "fairly compensated" for each and every completed payphone-originated call (Implementation of the Pay Telephone Reclassification and Compensation Provisions of the Telecommunications Act of 1996, CC Docket No. 96–128, *Report and Order*, 68 FR 62751–01, (November 6, 2003)). This *Order on Reconsideration*, released on October 22, 2004, does not change this compensation framework, but rather refines and builds upon its approach. In the *Order on Reconsideration*, the Commission provides guidance on the types of contracts that it would deem to be reasonable methods of compensating PSPs, extends the time period that carriers must retain certain payphone records, and clarifies the rules' reporting, certification, and audit requirements.

II. Background

2. The *Report and Order* held that the last facilities-based long distance carrier in a call path—either an interexchange carrier (IXC) or a switched-based reseller (SBR)—is responsible for compensating PSPs. For local calls, where a local exchange carrier (LEC) completes a call, that LEC is responsible for compensation. The Payphone Compensation Rules define these responsible carriers as "Completing Carriers" and require them to develop their own system of tracking calls to completion, the accuracy of which must be confirmed and attested to by a third party auditor. Completing Carriers are required to compensate the PSPs on a quarterly basis for calls that are completed on the Competing Carriers' platforms; to provide quarterly reports to the PSPs; and their chief financial officers (CFOs) must attest to the accuracy of the quarterly payment amount. The Payphone Compensation Rules also imposed reporting requirements on an "Intermediate Carrier," defined in the rules as "a facilities-based long distance carrier that switches payphone calls to other facilities-based long distance carriers." Additionally, the Payphone Compensation Rules also give parties flexibility to agree to alternative compensation arrangements (ACA) so that small Completing Carriers may avoid the expense of instituting a tracking system and undergoing an audit.

III. Discussion

3. In the *Order on Reconsideration*, the Commission considers four petitions for reconsideration filed in response to the *Report and Order* in this docket. The *Order on Reconsideration* clarifies and modifies the *Report and Order* by adopting the following changes: (1) Clarifying that a Completing Carrier must give a PSP adequate notice of an ACA prior to its effective date, with sufficient time for the PSP to object to an ACA, and prior to the termination of an ACA; (2) clarifying that, in a complaint proceeding under the Payphone Compensation Rules, a Completing Carrier may assert as an affirmative defense that the PSP's objection to an ACA was unreasonable; (3) clarifying that Completing Carriers are required to report only completed calls in their quarterly reports; (4) extending the time period that carriers must retain certain payphone records, for dispute resolution purposes, from 18 to 27 months; (5) clarifying that quarterly reports should use industry standard formats; (6) clarifying the responsibilities of LECs under the Payphone Compensation Rules; (7) clarifying that a Completing Carrier may post its System Audit Report and § 64.1320(e) statement on its website or on a clearinghouse's website, instead of transmitting these documents to every PSP; (8) clarifying that a Completing Carrier's CFO may issue a single blanket

certification addressed to all PSPs to which the carrier owes compensation, and such certification may be transmitted electronically or posted on the web; and (9) clarifying that where a clearinghouse is performing some of a Completing Carrier's compensation obligations, the Completing Carrier's auditor may rely upon, under certain circumstances, a third party's audit of the clearinghouse.

IV. Procedural Matters

4. *Final Paperwork Reduction Act Analysis.* This document contains modified information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. It will be submitted to the Office of Management and Budget (OMB) for review under section 3507(d) of the PRA. OMB, the general public, and other Federal agencies are invited to comment on the new or modified information collection requirements contained in this proceeding. In addition, we note that pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4), we previously sought specific comment on how the Commission might "further reduce the information collection burden for small business concerns with fewer than 25 employees."

5. In this present document, we have assessed the effects of extending the time period that carriers must maintain verification data. The amendment to § 64.1310(g), which extends the time carriers must maintain verification data from 18 to 27 months, will not adversely affect businesses with fewer than 25 employees. This amendment only requires carriers to maintain the data an additional 9 months and the cost and paperwork burden on carriers should be minimal. Furthermore, the amendment to § 64.1310(g) is in the public interest because it will help to ensure that the data is available throughout the statute of limitations period. We seek comment on this amendment.

6. The Commission will send a copy of the *Order on Reconsideration,* including a copy of this Final Regulatory Flexibility Certification, in a report to Congress pursuant to the Congressional Review Act. In addition, the *Order on Reconsideration* and this final certification will be sent to the Chief Counsel for Advocacy of the SBA, and will be published in the **Federal Register**.

7. *Final Regulatory Flexibility Certification.* The Regulatory Flexibility Act of 1980, as amended (RFA), requires that a regulatory flexibility analysis be prepared for notice-and-comment rulemaking proceedings, unless the agency certifies that "the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities." The RFA generally defines the term "small entity" as having the same meaning as the terms "small business," "small organization," and "small governmental jurisdiction." In addition, the term "small business" has the same meaning as the term "small business concern" under the Small Business Act. A "small business concern" is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the Small Business Administration (SBA).

8. As required by the RFA, an Initial Regulatory Flexibility Analysis (IRFA) was incorporated in the **Federal Register** summary of the *Further Notice of Proposed Rulemaking* (Implementation of the Pay Telephone Reclassification and Compensation Provisions of the Telecommunications Act of 1996, CC Docket No. 96–128, *Further Notice of Proposed Rulemaking,* 68 FR 32720, (June 2, 2003)). The Commission sought written public comments on the proposals in the *FNPRM,* including comments on the IRFA. On September 30, 2003, the Commission adopted a *Report and Order* that included a Final Regulatory Flexibility Analysis (FRFA) that conformed to the RFA. In response to four petitions for reconsideration of the *Report and Order,* the Commission adopted this *Order on Reconsideration.*

9. In this *Order on Reconsideration,* the Commission clarifies its payphone compensation rules in ways that will not have a significant economic impact on a substantial number of small entities. As described below, the *Order on Reconsideration* essentially refines and builds upon the payphone compensation rules by clarifying certain ambiguities in the rules and by decreasing certain administrative burdens on carriers.

10. Specifically, we clarify the conditions that a payphone service provider (PSP) may impose on an alternative compensation arrangement (ACA) between an interexchange carrier (IXC) and a switch-based reseller (SBR). In the preceding *Report and Order,* the rules give parties flexibility to agree to ACAs to avoid compliance with any or all of the payphone compensation rules. However, in this *Order on Reconsideration,* we clarify that an ACA may be posted on the web to give PSPs adequate notice and time to object to the ACA. We also clarify that notice of termination may be placed on the web. This way, Completing Carriers will not be required to send a copy of the ACA and seek affirmative consent from as many as 5500 PSPs. We believe that these clarifications are merely administrative, and therefore the result of the use of the web will be to confer benefits rather than impose burdens on small SBRs. Therefore, these clarifications will not have a significant economic impact on small entities.

11. Additionally, the record in this proceeding demonstrates that PSPs might use their veto power over ACAs in a manner that would unreasonably interfere with an SBR's ability to enter into ACAs. For instance, demands by PSPs that an ACA contain a provision that forces IXCs to assume ultimate responsibility for the payphone compensation obligations of SBRs would undermine the Commission's determination in the *Report and Order* that IXCs are not liable for such payphone compensation. Such behavior would have the effect of deterring IXCs and SBRs from entering into ACAs. Accordingly, to ensure a level playing field for IXCs, SBRs, and PSPs, we clarify our rules to make clear that PSPs do not hold unlimited veto power over an ACA. This *Order on Reconsideration* therefore clarifies that, in a complaint proceeding under the rules, a Completing Carrier may assert as an affirmative defense that the PSP's objection to an ACA was unreasonable. We believe this clarification confers a benefit on small SBRs by allowing them to freely enter into ACAs, thereby avoiding the costs of maintaining a tracking system as well as the costs of a large audit liability. Small PSPs will not be burdened by this ACA procedure because they will likely receive compensation for 100% of all payphone-originated calls, regardless of whether they are completed. For these reasons, we believe this clarification will not impose a significant economic impact on small entities.

12. We also clarify that Completing Carriers are only required to report completed payphone calls and not uncompleted calls or the duration that a circuit is kept open for such calls. In the preceding *Report and Order,* the Commission had already placed extensive requirements on carriers to ensure that payment is based on accurate data: they were obliged to create tracking systems, file System Audit Reports, create a dispute resolution process, provide Completing and Intermediate Carrier Reports, and have their chief financial officer (CFO) certify their quarterly payments. With respect to uncompleted and call duration, we find that the burden and

cost to carriers to report this information outweigh any marginal, additional benefit to PSPs. By not adding additional costly reporting requirements on carriers, this clarification instead confers a benefit on small SBRs. Since no additional costs are being incurred or additional duties imposed on carriers, this clarification adopted in this *Order on Reconsideration* will not have a significant economic impact on small entities.

13. The rules also extend the data retention requirement for completed call data from 18 months to 27 months, because the statute of limitations for bringing lawsuits for payphone compensation is 24 months after the close of a calendar quarter, and because the PSPs need access to this data. Although a number of small SBRs will have to retain records for an additional 9 months, we believe the effect of this revision will not be economically significant. Carriers were already required to retain this data for 18 months under the rules we adopted last year and therefore the effect of this change will be minimal. As we explain in the *Order on Reconsideration,* no commenter provided any data to support its position that it would unacceptably increase the cost for small entities. Should there be a minor increase in costs, that burden is outweighed by having the benefit of a more efficient record-keeping system.

14. To encourage consistency between the various reports required by the payphone compensation rules, we also clarify that carriers should follow one of the standard industry formats established by national clearinghouses. In this *Order on Reconsideration,* we do not require carriers to follow a particular format because we believe that it is neither appropriate nor necessary for the Commission to make up a format. Furthermore, parties did not quantify the cost to update the reports. In the event a small SBR decides to update the reports to meet industry standards, we believe the cost to do so will be minimal and therefore this clarification will not have a significant economic impact on small entities.

15. Similarly, the Commission's clarification concerning the responsibilities of local exchange carriers (LECs) as Completing Carriers does not significantly impact small entities. This clarification addresses a concern that some LECs who pay PSPs through bill credits are not compensating PSPs when a PSP is not served by the LEC or when the LEC acts as an IXC. In this *Order on Reconsideration,* we simply clarify that a LEC is responsible for compensation for calls made to access code numbers or subscriber toll-free numbers that a LEC maintains. We do not impose any additional responsibilities on LECs and therefore the clarification will not have a significant economic impact on small entities.

16. This *Order on Reconsideration* further clarifies and removes potentially burdensome paperwork requirements allowing the use of electronic methods to comply with our audit and CFO reporting requirements. First, we clarify that system audit reports may be posted on a website instead of requiring them to be sent to as many as 5500 PSPs. Second, these rules also clarify that a Completing Carrier CFO may certify the carrier's quarterly payments to all PSPs in a single document and may post this certification on the web, instead of sending individualized certifications to PSPs. The Commission believes that complying with the rules electronically is no more burdensome than submitting copies. It will also be less expensive for carriers to post the reports and certifications on the web rather than to send paper copies to PSPs. Therefore, these clarifications will not have a significant economic impact on small entities.

17. We also clarify that SBRs and other Completing Carriers may rely on a system audit of a payphone clearinghouse (instead of re-auditing the clearinghouse themselves). We expect that this clarification will benefit small SBRs economically because they will not have to pay for a separate audit of the clearinghouse.

18. Therefore, we certify that the requirements of the *Order on Reconsideration* will not have a significant economic impact on a substantial number of small entities.

Ordering Clauses

19. Accordingly, pursuant to authority contained in sections 1, 4, and 276 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154, and 276, *it is ordered* that the policies, rules, and requirements set forth herein *are adopted.*

20. *It is further ordered* that part 64 of the Commission's rules, 47 CFR part 64, *is amended* by revising § 64.1310(a) and (g), and § 64.1320(a), (b), and (e) as set forth in Appendix B to this *Order on Reconsideration.*

21. *It is further ordered* that the Petition for Clarification or Partial Reconsideration filed by APCC *is granted in part and denied in part,* to the extent discussed herein.

22. *It is further ordered* that the petition for Clarification or, in the Alternative, Reconsideration filed by AT&T *is granted,* to the extent discussed herein.

23. *It is further ordered* that the Petition for Reconsideration and Clarification filed by the RBOC Coalition *is denied.*

24. *It is further ordered* that the Petition for Reconsideration filed by Sprint *is denied.*

25. *It is further ordered* that the Request for Stay filed by APCC *is denied as moot.*

26. *It is further ordered* that for good cause found, the rules set forth in Appendix B *are effective* January 5, 2005, except for § 64.1310(g) which contains information collection requirements that are not effective until approved by the Office of Management and Budget. The Commission will publish a document in the **Federal Register** announcing the effective date of that section.

27. *It is further ordered* that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *shall send* a copy of this *Order on Reconsideration,* including the Final Regulatory Flexibility Certification, to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects in 47 CFR Part 64

Telephone, Telecommunications.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

Final Rules

■ For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 64 as follows:

PART 64—MISCELLANEOUS RULES RELATING TO COMMON CARRIERS

■ 1. The authority citation for part 64 continues to read as follows:

Authority: 47 U.S.C. 154, 254(k); secs. 403(b)(2)(B), (c), Public Law 104–104, 110 Stat. 56. Interpret or apply 47 U.S.C. 201, 218, 225, 226, 228, and 254(k) unless otherwise noted.

■ 2. Section 64.1310 is amended by revising paragraphs (a) introductory text, (a)(3), (a)(4)(i) and paragraph (g) to read as follows:

§ 64.1310 Payphone compensation procedures.

(a) Unless the payphone service provider consents to an alternative compensation arrangement, each Completing Carrier identified in § 64.1300(a) shall compensate the payphone service provider in

accordance with paragraphs (a)(1) through (a)(4) of this section. A payphone service provider may not unreasonably withhold its consent to an alternative compensation arrangement.

* * * * *

(3) When payphone compensation is tendered for a quarter, the chief financial officer of the Completing Carrier shall submit to each payphone service provider to which compensation is tendered a sworn statement that the payment amount for that quarter is accurate and is based on 100% of all completed calls that originated from that payphone service provider's payphones. Instead of transmitting individualized statements to each payphone service provider, a Completing Carrier may provide a single, blanket sworn statement addressed to all payphone service providers to which compensation is tendered for that quarter and may notify the payphone service providers of the sworn statement through any electronic method, including transmitting the sworn statement with the § 64.1310(a)(4) quarterly report, or posting the sworn statement on the Completing Carrier or clearinghouse website. If a Completing Carrier chooses to post the sworn statement on its website, the Completing Carrier shall state in its § 64.1310(a)(4) quarterly report the web address of the sworn statement.

(4) * * *

(i) A list of the toll-free and access numbers dialed and completed by the Completing Carrier from each of that payphone service provider's payphones and the ANI for each payphone;

* * * * *

(g) Each Completing Carrier and each Intermediate Carrier must maintain verification data to support the quarterly reports submitted pursuant to paragraphs (a)(4) and (c) of this section for 27 months after the close of that quarter. This data must include the time and date that each call identified in paragraphs (a)(4) and (c) of this section was made. This data must be provided to the payphone service provider upon request.

■ 3. Section 64.1320 is amended by revising paragraphs (a), (b), and (e) to read as follows:

§ 64.1320 Payphone call tracking system audits.

(a) Unless it has entered into an alternative compensation arrangement pursuant to § 64.1310(a) that relieves it of its § 64.1310(a)(1) tracking system obligation, each Completing Carrier must undergo an audit of its § 64.1310(a)(1) tracking system by an independent third party auditor whose responsibility shall be, using audit methods approved by the American Institute for Certified Public Accountants, to determine whether the call tracking system accurately tracks payphone calls to completion.

(b) By the effective date of these rules, each Completing Carrier in paragraph (a) of this section must file an audit report from the auditor (the "System Audit Report") regarding the Completing Carrier's compliance with § 64.1310(a)(1) as of the date of the audit:

(1) With the Commission's Secretary in CC Docket No. 96–128;

(2) With each payphone service provider for which it completes calls and a Completing Carrier may comply with this paragraph's requirement to file copies of the System Audit Report with each payphone service provider by posting the System Audit Report on its website or a clearinghouse website; and

(3) With each facilities-based long distance carrier from which it receives payphone calls.

* * * * *

(e) At the time of filing of a System Audit Report with the Commission, the Completing Carrier shall file with the Commission's Secretary, the payphone service providers and the facilities-based long distance carriers identified in paragraph (b) of this section, a statement that includes the name of the Completing Carrier, and the name, address and phone number for the person or persons responsible for handling the Completing Carrier's payphone compensation and for resolving disputes with payphone service providers over compensation, and this statement shall be updated within 60 days of any changes of such persons. If a Completing Carrier chooses to notify payphone service providers of this statement and its System Audit Report by posting these two documents on its website or a clearinghouse website, then this statement shall include the web address for these two documents.

* * * * *

[FR Doc. 05–173 Filed 1–4–05; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 04–3849; MM Docket No. 00–226; RM–10001]

Radio Broadcasting Services; Fair Bluff, NC, Johnsonville, Litchfield Beach, and Olanta, SC

AGENCY: Federal Communications Commission.

ACTION: Final rule; dismissal of petition for reconsideration.

SUMMARY: At the request of Joint Petitioner Waccamaw Neck Broadcasting Company, licensee of Station WPDT(FM), Channel 286A, Johnsonville, South Carolina this document dismisses the Joint Petition for Reconsideration of the *Report and Order*, 66 FR 18088 (October 24, 2001), in this proceeding, filed by Atlantic Broadcasting Co., Inc., permittee of Station WSIM(FM), Channel 287C3, Fair Bluff, North Carolina, and Waccamaw Neck Broadcasting Company.

FOR FURTHER INFORMATION CONTACT: Victoria M. McCauley, Media Bureau (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Memorandum Opinion and Order, MM Docket No. 00–226, adopted December 15, 2004, and released December 17, 2004. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Information Center at Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC 20554. The document may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 1–800–378–3160 or *http://www.BCPIWEB.com*. Document is not subject to the Congressional Review Act. The Commission, is, therefore, not required to submit a copy of this Report and Order to GAO, pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A) because the proposed rule was dismissed, herein.

Federal Communications Commission.

John A. Karousos,

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. 05–116 Filed 1–4–05; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 04–3848; MB Docket No. 04–340, RM–11062; MB Docket No. 04–327, RM–11063]

Radio Broadcasting Services; Crosbyton, TX and Union Gap, WA

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Audio Division, at the request of Charles Crawford, allots Channel 264C3 at Crosbyton, Texas, as the community's first local aural transmission service. *See* 69 FR 54762, published September 10, 2004. Channel 264C3 can be allotted to Crosbyton in compliance with the Commission's minimum distance separation requirements, provided there is a site restriction of 12.5 kilometers (7.7 miles) east of the community. The reference coordinates for Channel 264C3 at Crosbyton are 33–41–30 North Latitude and 101–06–31 West Longitude. The Audio Division, at the request of Linda A. Davidson, allots Channel 285A at Union Gap, Washington, as the community's first local aural transmission service. *See* 69 FR 54761, published September 10, 2004. Channel 285A can be allotted to Union Gap in compliance with the Commission's minimum distance separation requirements, provided there is a site restriction of 3.4 kilometers (2.1 miles) southeast of the community. The reference coordinates for Channel 285A at Union Gap are 46–31–48 North Latitude and 120–27–18 West Longitude. Because the reference coordinates at Union Gap are located within 320 kilometers (199 miles) of the Canadian border, concurrence of the Canadian Government has been obtained. Filing windows for Channel 264C3 at Crosbyton, Texas and Channel 285A at Union Gap, Washington will not be opened at this time. Instead, the issue of opening a filing window for these channels will be addressed by the Commission in a subsequent order.

DATES: Effective January 31, 2005.

ADDRESSES: Federal Communications Commission, 445 Twelfth Street, SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Helen McLean, Media Bureau, (202) 418–2738.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order,* MB Docket Nos. 04–340 and 04–327, adopted December 15, 2004, and released December 17, 2004. The full text of this Commission decision is available for inspection and copying during regular business hours at the FCC's Reference Information Center, Portals II, 445 Twelfth Street, SW., Room CY–A257, Washington, DC 20554. The complete text of this decision may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 1–800–378–3160 or *http://www.BCPIWEB.com.* The Commission will send a copy of this *Report and Order* in a report to be sent to Congress and the General Accounting Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73

Radio, Radio broadcasting.

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334 and 336.

§ 73.202 [Amended]

■ 2. Section 73.202(b), the Table of FM Allotments under Texas, is amended by adding Crosbyton, Channel 264C3.

■ 3. Section 73.202(b), the Table of FM Allotments under Washington, is amended by adding Union Gap, Channel 285A.

Federal Communications Commission.

John A. Karousos,

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. 05–115 Filed 1–4–05; 8:45 am]

BILLING CODE 6712–01–P

Proposed Rules

Federal Register
Vol. 70, No. 3
Wednesday, January 5, 2005

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–19989; Directorate Identifier 2004–NM–151–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 767–300 and –400ER Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Boeing Model 767–300 and –400ER series airplanes. This proposed AD would require replacing the in-flight entertainment cooling card, located in the P50 card file in the main equipment center, with a new, improved cooling card. This proposed AD is prompted by a report of an improperly designed component on the in-flight entertainment (IFE) cooling card, which may cause the IFE cooling system to incorrectly interpret signals from airplane system interfaces. We are proposing this AD to prevent failure of the IFE cooling card to configure itself correctly in response to input signals from airplane system interfaces during a forward cargo fire, which could result in the IFE cooling fan causing smoke to penetrate occupied areas of the airplane.

DATES: We must receive comments on this proposed AD by February 22, 2005.

ADDRESSES: Use one of the following addresses to submit comments on this proposed AD.

- DOT Docket Web site: Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- Government-wide rulemaking Web site: Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- Mail: Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., Nassif Building, room PL–401, Washington, DC 20590.
- By fax: (202) 493–2251..
- Hand Delivery: Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207.

You can examine the contents of this AD docket on the Internet at *http://dms.dot.gov*, or in person at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., room PL–401, on the plaza level of the Nassif Building, Washington, DC. This docket number is FAA–2004–19989; the directorate identifier for this docket is 2004–NM–151–AD.

FOR FURTHER INFORMATION CONTACT:

Technical information: Clint Jones, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM–150S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 917–6471; fax (425) 917–6590.

Plain language information: Marcia Walters, *marcia.walters@faa.gov*.

SUPPLEMENTARY INFORMATION:

Docket Management System (DMS)

The FAA has implemented new procedures for maintaining AD dockets electronically. As of May 17, 2004, new AD actions are posted on DMS and assigned a docket number. We track each action and assign a corresponding directorate identifier. The DMS AD docket number is in the form "Docket No. FAA–2004–99999." The Transport Airplane Directorate identifier is in the form "Directorate Identifier 2004–NM–999–AD." Each DMS AD docket also lists the directorate identifier ("Old Docket Number") as a cross-reference for searching purposes.

Comments Invited

We invite you to submit any relevant written data, views, or arguments regarding this proposed AD. Send your comments to an address listed under **ADDRESSES**. Include "Docket No. FAA–2004–19989; Directorate Identifier 2004–NM–151–AD" in the subject line of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments submitted by the closing date and may amend the proposed AD in light of those comments.

We will post all comments we receive, without change, to *http://dms.dot.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed AD. Using the search function of that Web site, anyone can find and read the comments in any of our dockets, including the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You can review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you can visit *http://dms.dot.gov*.

We are reviewing the writing style we currently use in regulatory documents. We are interested in your comments on whether the style of this document is clear, and your suggestions to improve the clarity of our communications that affect you. You can get more information about plain language at *http://www.faa.gov/language* and *http://www.plainlanguage.gov*.

Examining the Docket

You can examine the AD docket on the Internet at *http://dms.dot.gov*, or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the DOT street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after the DMS receives them.

Discussion

We have received a report that on a Boeing Model 767–400ER series airplane, the field programmable gate array component on the in-flight entertainment (IFE) cooling card was improperly designed. During flight, this improperly designed component may cause failure of the cooling card to correctly configure itself in response to input signals from airplane system

interfaces. The report also indicates that, during functional testing or other ground operations, the improperly designed component may cause nuisance failure indications for components in the IFE cooling system that are monitored by the IFE cooling card. If the IFE cooling card is configured correctly, the IFE cooling fan will shut down during an in-flight event such as a cargo fire, smoke in the flight deck, electronic equipment override selection, or IFE equipment smoke. Failure of the IFE cooling card to configure itself correctly in response to input signals from airplane system interfaces during a forward cargo fire, if not corrected, could result in the IFE cooling fan causing smoke to penetrate occupied areas of the airplane.

Boeing Model 767–300 series airplanes use the same IFE cooling card as that on the Boeing Model 767–400ER series airplanes. Therefore, the Boeing Model 767–300 series airplanes are subject to the same unsafe condition.

Relevant Service Information

We have reviewed Boeing Special Attention Service Bulletins 767–21–0188 (for Model 767–300 series airplanes) and 767–21–0189 (for Model 767–400ER series airplanes), both dated May 27, 2004. The service bulletins describe procedures for replacing the IFE cooling card with a new, improved cooling card. The service bulletins state that the replacement and associated functional test may be accomplished by following the procedures in the applicable Boeing 767 Airplane Maintenance Manual, or an "operator's equivalent procedure." Accomplishing the actions specified in the service information is intended to adequately address the unsafe condition.

FAA's Determination and Requirements of the Proposed AD

We have evaluated all pertinent information and identified an unsafe condition that is likely to exist or develop on other airplanes of this same type design. Therefore, we are proposing this AD, which would require accomplishing the actions specified in the service information described previously, except as discussed under "Difference Between the Proposed AD and Service Information."

Difference Between the Proposed AD and Service Information

Boeing Special Attention Service Bulletins 767–21–0188 and 767–21–0189 both specify that an operator's equivalent procedure may be used for replacing the IFE cooling card, and for accomplishing the associated functional test. However, this proposed AD specifies that replacement of the IFE cooling card must be done according to the procedures in the chapter/subject of the applicable Boeing 767 Airplane Maintenance Manual specified in the service bulletins. This proposed AD would allow operator's equivalent procedures to be used for the functional test.

Costs of Compliance

There are about 32 airplanes of the affected design in the worldwide fleet. The following table provides the estimated costs for U.S. operators to comply with this proposed AD.

ESTIMATED COSTS

Action	Work hours	Average labor rate per hour	Parts	Cost per airplane	Number of U.S.-registered airplanes	Fleet cost
Replacement	1	$65	$9,500	$9,565	16	$153,040

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this AD.

Regulatory Findings

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the proposed regulation:

1. Is not a "significant regulatory action" under Executive Order 12866;

2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Boeing: Docket No. FAA–2004–19989; Directorate Identifier 2004–NM–151–AD.

Comments Due Date

(a) The Federal Aviation Administration (FAA) must receive comments on this AD action by February 22, 2005.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Boeing Model 767–300 series airplanes as listed in Boeing Special Attention Service Bulletin 767–21–0188, dated May 27, 2004; and Boeing Model 767–400ER series airplanes, as listed in Boeing Special Attention Service Bulletin 767–21–0189, dated May 27, 2004; certificated in any category.

Unsafe Condition

(d) This AD was prompted by a report of an improperly designed component on the in-flight entertainment (IFE) cooling card, which may cause the IFE cooling system to incorrectly interpret signals from airplane system interfaces. We are issuing this AD to prevent failure of the IFE cooling card to configure correctly in response to input signals from airplane system interfaces during a forward cargo fire, which could result in the IFE cooling fan causing smoke to penetrate occupied areas of the airplane.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Replacement of IFE Cooling Card

(f) Within 18 months after the effective date of this AD: Replace the IFE cooling card, part number (P/N) 285T1198–101, located in the P50 card file in the main equipment center, with a new, improved cooling card, P/N 285T1198–102. Do the replacement by accomplishing all of the actions specified in the Accomplishment Instructions of Boeing Special Attention Service Bulletin 767–21–0188 (for Boeing Model 767–300 series airplanes); or 767–21–0189 (for Boeing Model 767–400ER series airplanes); both dated May 27, 2004; as applicable. Where the service bulletins state that the replacement may be done using an "operator's equivalent procedure," the replacement must be done according to the procedures in the chapter/subject of the applicable Boeing 767 Airplane Maintenance Manual specified in the service bulletins.

Parts Installation

(g) As of the effective date of this AD, no person may install an IFE cooling card, P/N 285T1198–101, on any airplane.

Alternative Methods of Compliance (AMOCs)

(h) The Manager, Seattle Aircraft Certification Office, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

Issued in Renton, Washington, on December 27, 2004.

Kevin M. Mullin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–165 Filed 1–4–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–19990; Directorate Identifier 2004–NM–199–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 767–200, –300, and –300F Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Boeing Model 767–200, –300, and –300F series airplanes. This proposed AD would require installing a new, improved foam seal around certain ducts in the forward cargo compartment. This proposed AD is prompted by the detection of incorrectly installed smoke barrier seals around the electrical/electronic equipment air supply and exhaust ducts. We are proposing this AD to prevent fire extinguishing agent from leaking out of the seals around the ducts in the forward cargo compartment in the event of an in-flight fire, which could result in failure to extinguish the fire and consequent smoke or fire extinguishing agent entering a compartment occupied by passengers or crew.

DATES: We must receive comments on this proposed AD by February 22, 2005.

ADDRESSES: Use one of the following addresses to submit comments on this proposed AD.

- DOT Docket Web site: Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- Government-wide rulemaking Web site: Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- Mail: Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, room PL–401, Washington, DC 20590.
- By fax: (202) 493–2251.
- Hand Delivery: Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207.

You can examine the contents of this AD docket on the Internet at *http://dms.dot.gov*, or in person at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., room PL–401, on the plaza level of the Nassif Building, Washington, DC. This docket number is FAA–2004–19990; the directorate identifier for this docket is 2004–NM–199–AD.

FOR FURTHER INFORMATION CONTACT:

Technical information: Barbara Mudrovich, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM–150S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 917–6477; fax (425) 917–6590.

Plain language information: Marcia Walters, *marcia.walters@faa.gov.*

SUPPLEMENTARY INFORMATION:

Docket Management System (DMS)

The FAA has implemented new procedures for maintaining AD dockets electronically. As of May 17, 2004, new AD actions are posted on DMS and assigned a docket number. We track each action and assign a corresponding directorate identifier. The DMS AD docket number is in the form "Docket No. FAA–2004–99999." The Transport Airplane Directorate identifier is in the form "Directorate Identifier 2004–NM–999–AD." Each DMS AD docket also lists the directorate identifier ("Old Docket Number") as a cross-reference for searching purposes.

Comments Invited

We invite you to submit any relevant written data, views, or arguments regarding this proposed AD. Send your comments to an address listed under **ADDRESSES.** Include "Docket No. FAA–2004–19990; Directorate Identifier 2004–NM–199–AD" in the subject line of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments submitted by the closing date and may amend the proposed AD in light of those comments.

We will post all comments we receive, without change, to *http://dms.dot.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed AD. Using the search function of that Web site, anyone can find and read the comments in any of our dockets, including the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You can

review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you can visit *http://dms.dot.gov*.

We are reviewing the writing style we currently use in regulatory documents. We are interested in your comments on whether the style of this document is clear, and your suggestions to improve the clarity of our communications that affect you. You can get more information about plain language at *http://www.faa.gov/language* and *http://www.plainlanguage.gov*.

Examining the Docket

You can examine the AD docket on the Internet at *http://dms.dot.gov*, or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the DOT street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after the DMS receives them.

Discussion

During production of certain Boeing Model 767–200, –300, and –300F series airplanes, incorrectly installed smoke barrier seals were found in the forward cargo compartment. The seals were located around the air supply and exhaust ducts of the electronic equipment bay. If these seals are not installed correctly, smoke and fire extinguishing agent could leak out of the ducts in the event of a fire, entering a compartment occupied by passengers or crew.

Relevant Service Information

We have reviewed Boeing Alert Service Bulletin 767–26A0119, Revision 1, dated July 15, 2004. The service bulletin describes procedures for installing a new, improved foam seal around certain ducts in the forward cargo compartment, as follows:

- For Group 1 and 2 airplanes: Installing a new, improved foam seal around the four cooling air supply and exhaust ducts in the electrical/electronic equipment bay.
- For Group 2 airplanes: Installing a new, improved foam seal around the avionics cooling and refrigeration unit (ACRU) duct.

Accomplishing the actions specified in the service information is intended to adequately address the unsafe condition.

FAA's Determination and Requirements of the Proposed AD

We have evaluated all pertinent information and identified an unsafe condition that is likely to exist or develop on other airplanes of this same type design. Therefore, we are proposing this AD, which would require accomplishing the actions specified in the service information described previously.

Costs of Compliance

There are about 468 airplanes of the affected design in the worldwide fleet. This proposed AD would affect about 342 airplanes of U.S. registry.

For Group 1 and 2 airplanes: The proposed foam seal installation around the cooling air supply and exhaust ducts would take about 2 work hours per airplane, at an average labor rate of $65 per work hour. The cost of parts would be minimal. Based on these figures, the estimated cost of the proposed installation is $130 per airplane.

For Group 2 airplanes: The proposed foam seal installation around the ACRU duct would take about 2 work hours per airplane, at an average labor rate of $65 per work hour. The cost of parts would be minimal. Based on these figures, the estimated cost of the proposed installation is $130 per airplane.

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this AD.

Regulatory Findings

We have determined that this proposed AD will not have federalism implications under Executive Order 13132. This proposed AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the proposed regulation:

1. Is not a "significant regulatory action" under Executive Order 12866;

2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Boeing: Docket No. FAA–2004–19990; Directorate Identifier 2004–NM–199–AD.

Comments Due Date

(a) The Federal Aviation Administration (FAA) must receive comments on this AD action by February 22, 2005.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Boeing Model 767–200, –300, and –300F series airplanes, certificated in any category; as listed in Boeing Alert Service Bulletin 767–26A0119, Revision 1, dated July 15, 2004.

Unsafe Condition

(d) This AD was prompted by the detection of incorrectly installed smoke barrier seals around the electrical/electronic equipment air supply and exhaust ducts. We are issuing this AD to prevent fire extinguishing agent from leaking out of the seals around the ducts in the forward cargo compartment in the event of an in-flight fire, which could result in failure to extinguish the fire and consequent smoke or fire extinguishing agent entering a compartment occupied by passengers or crew.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Seal Installation

(f) Within 24 months or 8,000 flight hours after the effective date of this AD, whichever is first: Do the applicable actions required by paragraphs (f)(1) and (f)(2) of this AD by doing all the actions specified in the Accomplishment Instructions of Boeing Alert Service Bulletin 767–26A0119, Revision 1, dated July 15, 2004.

(1) For Group 1 and 2 airplanes: Install a foam seal around the four cooling air supply and exhaust ducts in the electrical/electronic equipment bay in the forward cargo compartment.

(2) For Group 2 airplanes: Install a foam seal around the avionics cooling and refrigeration unit duct in the forward cargo compartment.

Credit for Actions Accomplished Previously

(g) Accomplishing the applicable actions before the effective date of this AD in accordance with Boeing Alert Service Bulletin 767–26A0119, dated April 19, 2001; is considered acceptable for compliance with the corresponding actions in paragraph (f)(1) of this AD.

Alternative Methods of Compliance (AMOCs)

(h) The Manager, Seattle Aircraft Certification Office, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

Issued in Renton, Washington, on December 27, 2004.

Kevin M. Mullin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–166 Filed 1–4–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–19988; Directorate Identifier 2004–NM–30–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 727–200 Series Airplanes Equipped With a No. 3 Cargo Door

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Boeing Model 727–200 series airplanes equipped with a No. 3 cargo door. This proposed AD would require repetitive detailed and high frequency eddy current inspections for cracking of the forward, lower corner frame and forward end of the lower beam of the No. 3 cargo door, and corrective actions if necessary. The proposed AD provides an optional terminating action for the repetitive inspections. This proposed AD is prompted by reports of cracking at the forward, lower corner frame and lower beam of the No. 3 cargo door. We are proposing this AD to detect and correct cracking of the forward, lower corner frame and forward end of the lower beam of the No. 3 cargo door, which could result in failure of the affected door stops, loss of the cargo door, and consequent rapid decompression of the airplane.

DATES: We must receive comments on this proposed AD by February 22, 2005.

ADDRESSES: Use one of the following addresses to submit comments on this proposed AD.

- DOT Docket Web site: Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- Government-wide rulemaking Web site: Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- Mail: Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, room PL–401, Washington, DC 20590.
- By fax: (202) 493–2251.
- Hand Delivery: Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

You can get the service information identified in this proposed AD from Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207.

You may examine the contents of this AD docket on the Internet at *http://dms.dot.gov*, or in person at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., room PL–401, on the plaza level of the Nassif Building, Washington, DC.

FOR FURTHER INFORMATION CONTACT:

Technical information: Daniel F. Kutz, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 917–6456; fax (425) 917–6590.

Plain language information: Marcia Walters, *marcia.walters@faa.gov*.

SUPPLEMENTARY INFORMATION:

Docket Management System (DMS)

The FAA has implemented new procedures for maintaining AD dockets electronically. As of May 17, 2004, new AD actions are posted on DMS and assigned a docket number. We track each action and assign a corresponding directorate identifier. The DMS AD docket number is in the form "Docket No. FAA–2004–99999." The Transport Airplane Directorate identifier is in the form "Directorate Identifier 2004–NM–999–AD." Each DMS AD docket also lists the directorate identifier ("Old Docket Number") as a cross-reference for searching purposes.

Comments Invited

We invite you to submit any written relevant data, views, or arguments regarding this proposed AD. Send your comments to an address listed under **ADDRESSES**. Include "Docket No. FAA–2004–19988; Directorate Identifier 2004–NM–30–AD" in the subject line of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments submitted by the closing date and may amend the proposed AD in light of those comments.

We will post all comments we receive, without change, to *http://dms.dot.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed AD. Using the search function of that Web site, anyone can find and read the comments in any of our dockets, including the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you may visit *http://dms.dot.gov*.

We are reviewing the writing style we currently use in regulatory documents. We are interested in your comments on whether the style of this document is clear, and your suggestions to improve the clarity of our communications that affect you. You can get more information about plain language at *http://www.faa.gov/language* and *http://www.plainlanguage.gov*.

Examining the Docket

You may examine the AD docket in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the DOT

street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after the DMS receives them.

Discussion

We have received reports of cracking on the forward, lower corner frame and lower beam of the No. 3 cargo door, on certain Boeing Model 727–200 series airplanes. The affected airplanes had approximately 32,773 to 70,187 flight hours and 33,383 to 54,541 pressurization cycles. Investigation revealed that the cracking was caused by fatigue as a result of the cabin pressurization cycles. This condition, if not corrected, could result in failure of the affected door stops, loss of the cargo door, and consequent rapid decompression of the airplane.

Relevant Service Information

We have reviewed Boeing Special Attention Service Bulletin 727–52–0149, dated October 16, 2003. The service bulletin describes procedures for repetitive detailed and high frequency eddy current (HFEC) inspections for cracking of the forward, lower corner frame and forward end of the lower beam of the No. 3 cargo door. Generally, the initial inspection is done before accumulating 30,000 total flight cycles or within 2,000 flight cycles after the release date of the service bulletin, whichever is later. The service bulletin also states the inspections should be repeated at intervals not to exceed 4,500 flight cycles. The service bulletin also includes procedures for corrective actions. For airplanes on which cracking is found, the corrective actions include repairing areas with cracking. The repair procedures include fabricating/installing repair parts and a preventative modification, which eliminates the need for the repetitive inspections. The preventative modification includes installing beam modification parts and a frame reinforcement angle on the No. 3 cargo door. The preventative modification can also be done on airplanes on which no cracking is found. We have determined that accomplishing the actions specified in the service bulletin will adequately address the unsafe condition.

FAA's Determination and Requirements of the Proposed AD

We have evaluated all pertinent information and identified an unsafe condition that is likely to exist or develop on other airplanes of this same type design. Therefore, we are proposing this AD, which would require repetitive detailed and HFEC inspections for cracking of the forward, lower corner frame and lower beam of the No. 3 cargo door, and corrective actions if necessary. The proposed AD would require you to use the service information described previously to perform these actions. The proposed AD provides an optional terminating action for the repetitive inspections.

Costs of Compliance

This proposed AD would affect about 390 Model 727–200 series airplanes worldwide. The following table provides the estimated costs for U.S. operators to comply with this proposed AD.

ESTIMATED COSTS

Action	Work hours	Average labor rate per hour	Parts	Cost per airplane	Number of U.S.-registered airplanes	Fleet cost
Detailed and HFEC Inspections, per inspection cycle	2	$65	None	$130	274	$35,620

Authority for this Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this AD.

Regulatory Findings

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the proposed regulation:

1. Is not a "significant regulatory action" under Executive Order 12866;

2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Boeing: Docket No. FAA–2004–19988; Directorate Identifier 2004–NM–30–AD.

Comments Due Date

(a) The Federal Aviation Administration (FAA) must receive comments on this AD action by February 22, 2005.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Boeing Model 727–200 series airplanes, equipped with a No. 3

cargo door, as listed in Boeing Special Attention Service Bulletin 727–52–0149, dated October 16, 2003; certificated in any category.

Unsafe Condition

(d) This AD was prompted by reports of cracking at the forward, lower corner frame and lower beam of the No. 3 cargo door. We are proposing this AD to detect and correct cracking of the forward, lower corner frame and forward end of the lower beam of the No. 3 cargo door, which could result in failure of the affected door stops, loss of the cargo door, and consequent rapid decompression of the airplane.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Repetitive Detailed and High Frequency Eddy Current (HFEC) Inspections

(f) Do detailed and HFEC inspections for cracking of the forward, lower corner frame and forward end of the lower beam of the No. 3 cargo door by accomplishing all of the applicable actions specified in the Accomplishment Instructions of Boeing Special Attention Service Bulletin 727–52–0149, dated October 16, 2003. Do the inspections at the times specified in the applicable table in paragraph 1.E., "Compliance," of the service bulletin, except as required by paragraph (g) of this AD. Repeat the inspections thereafter at intervals not to exceed 4,500 flight cycles. Doing the applicable actions in paragraph (h) or (j) of this AD terminates the repetitive inspections.

(g) Where the service bulletin specified in paragraph (f) of this AD provides a threshold relative to the release date of the service bulletin, this AD requires compliance within the applicable threshold following the effective date of this AD, if the "total airplane flight cycles" or "total replaced door flight cycles" threshold has been exceeded.

Corrective Actions

(h) For airplanes on which cracking is found during any inspection required by paragraph (f) of this AD: Before further flight, do all of the applicable corrective actions specified in the Accomplishment Instructions of Boeing Special Attention Service Bulletin 727–52–0149, dated October 16, 2003. Repairing any affected area terminates the repetitive inspections required by paragraph (f) of this AD.

Parts Installation

(i) Any replacement No. 3 cargo door installed on any airplane after the effective date of this AD must be inspected or modified in accordance with either paragraph (i)(1) or (i)(2) of this AD, as applicable.

(1) If the number of total flight cycles on the door can be positively determined: Do the actions required by paragraphs (f) and (h) of this AD, as applicable, or paragraph (j) of this AD. Do the actions at the times specified in Table 2 of paragraph 1.E., "Compliance," of Boeing Special Attention Service Bulletin 727–52–0149, dated October 16, 2003.

(2) If the number of total flight cycles on the door cannot be positively determined: Do the actions required by paragraphs (f) and (h) of this AD, as applicable, or paragraph (j) of this AD, before installing the door.

Optional Terminating Action

(j) Concurrently with doing the inspection required by paragraph (f) of this AD, if no cracking is found, doing the preventative modification specified in paragraph 3.B.2. of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 727–52–0149, dated October 16, 2003, terminates the repetitive inspections required by paragraph (f) of this AD.

Alternative Methods of Compliance (AMOCs)

(k)(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19.

(2) An AMOC that provides an acceptable level of safety may be used for any repair for cracking required by this AD, if it is approved by a Boeing Company Designated Engineering Representative who has been authorized by the Manager, Seattle ACO, to make such findings. For a repair method to be approved, the approval must specifically reference this AD.

Issued in Renton, Washington, on December 27, 2004.

Kevin M. Mullin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–167 Filed 1–4–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–19987; Directorate Identifier 2004–NM–203–AD]

RIN 2120–AA64

Airworthiness Directives; McDonnell Douglas Model 717–200 Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain McDonnell Douglas Model 717–200 airplanes. This proposed AD would require replacing eight brake fuses of the hydraulic quantity limiter with new or modified and reidentified fuses. This proposed AD is prompted by reports indicating that brake fuses of the hydraulic quantity limiter of the main landing gear have failed. We are proposing this AD to prevent loss of both hydraulic and brake systems if one fuse on each hydraulic system were to fail simultaneously, and consequent reduced controllability of the airplane.

DATES: We must receive comments on this proposed AD by February 22, 2005.

ADDRESSES: Use one of the following addresses to submit comments on this proposed AD.

- DOT Docket Web site: Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- Government-wide rulemaking Web site: Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- Mail: Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, room PL–401, Washington, DC 20590.
- By fax: (202) 493–2251.
- Hand Delivery: Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Boeing Commercial Airplanes, Long Beach Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Data and Service Management, Dept. C1–L5A (D800–0024).

You can examine the contents of this AD docket on the Internet at *http://dms.dot.gov*, or in person at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., room PL–401, on the plaza level of the Nassif Building, Washington, DC. This docket number is FAA–2004–19987; the directorate identifier for this docket is 2004–NM–203–AD.

FOR FURTHER INFORMATION CONTACT:

Technical information: Albert Lam, Aerospace Engineer, Systems and Equipment Branch, ANM–130L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California 90712–4137; telephone (562) 627–5346; fax (562) 627–5210.

Plain language information: Marcia Walters, *marcia.walters@faa.gov.*

SUPPLEMENTARY INFORMATION:

Docket Management System (DMS)

The FAA has implemented new procedures for maintaining AD dockets electronically. As of May 17, 2004, new AD actions are posted on DMS and assigned a docket number. We track each action and assign a corresponding directorate identifier. The DMS AD docket number is in the form "Docket No. FAA–2004–99999." The Transport Airplane Directorate identifier is in the

form "Directorate Identifier 2004–NM–999–AD." Each DMS AD docket also lists the directorate identifier ("Old Docket Number") as a cross-reference for searching purposes.

Comments Invited

We invite you to submit any relevant written data, views, or arguments regarding this proposed AD. Send your comments to an address listed under **ADDRESSES.** Include "Docket No. FAA–2004–19987; Directorate Identifier 2004–NM–203–AD" in the subject line of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments submitted by the closing date and may amend the proposed AD in light of those comments.

We will post all comments we receive, without change, to *http://dms.dot.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed AD. Using the search function of that Web site, anyone can find and read the comments in any of our dockets, including the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You can review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you can visit *http://dms.dot.gov*.

We are reviewing the writing style we currently use in regulatory documents. We are interested in your comments on whether the style of this document is clear, and your suggestions to improve the clarity of our communications that affect you. You can get more information about plain language at *http://www.faa.gov/language* and *http://www.plainlanguage.gov*.

Examining the Docket

You can examine the AD docket on the Internet at *http://dms.dot.gov*, or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the DOT street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after the DMS receives them.

Discussion

We have received reports indicating that brake fuses of the hydraulic quantity limiter of the main landing gear (MLG) have failed on several McDonnell Douglas Model 717–200 airplanes. The failures occurred at the brake fuse cap due to fatigue, resulting in hydraulic fluid and pressure loss from the affected system. Typically, the failure would manifest itself when full braking pressure is applied (*e.g.*, at the beginning of a rejected takeoff or when the parking brake is set). This condition, if not corrected, could result in loss of both hydraulic and brake systems if one fuse on each hydraulic system were to fail simultaneously, and consequent reduced controllability of the airplane.

Relevant Service Information

We have reviewed Boeing Alert Service Bulletin 717–32A0031, dated September 10, 2004. The service bulletin describes procedures for replacing eight brake fuses of the hydraulic quantity limiter with new or modified and reidentified fuses. Accomplishing the actions specified in the service information is intended to adequately address the unsafe condition.

The service bulletin refers to Parker Hanninfin Corporation Stratoflex Products Division Service Bulletin 836SD–8–6–20, Revision 1, dated June 23, 2004, as an additional source of service information for modifying and reidentifying the brake fuses.

FAA's Determination and Requirements of the Proposed AD

We have evaluated all pertinent information and identified an unsafe condition that is likely to exist or develop on other airplanes of this same type design. Therefore, we are proposing this AD, which would require accomplishing the actions specified in the Boeing service information described previously.

Costs of Compliance

There are about 133 airplanes of the affected design in the worldwide fleet and 103 airplanes on the U.S. registry. The following table provides the estimated costs for U.S. operators to comply with this proposed AD.

ESTIMATED COSTS

Action	Work hours	Average labor rate per hour	Parts	Cost per airplane
Option 1. Replacement with new brake fuses	9	$65	No Charge	$585
Option 2. Replacement with modified and reidentified brake fuses	13	65	No Charge	845

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, "General requirements." Under that section, the FAA is charged with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this AD.

Regulatory Findings

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the proposed regulation:

1. Is not a "significant regulatory action" under Executive Order 12866;

2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

McDonnell Douglas: Docket No. FAA–2004–19987; Directorate Identifier 2004–NM–203–AD.

Comments Due Date

(a) The Federal Aviation Administration (FAA) must receive comments on this AD action by February 22, 2005.

Affected ADs

(b) None.

Applicability

(c) This AD applies to McDonnell Douglas Model 717–200 airplanes, fuselage numbers 5002 through 5134 inclusive; certificated in any category.

Unsafe Condition

(d) This AD was prompted by reports indicating that brake fuses of the hydraulic quantity limiter of the main landing gear (MLG) have failed. We are issuing this AD to prevent loss of both hydraulic and brake systems if one fuse on each hydraulic system were to fail simultaneously, and consequent reduced controllability of the airplane.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Compliance Times

(f) At the applicable time in Table 1 of this AD, do the action required by paragraph (g) of this AD.

TABLE 1.—COMPLIANCE TIMES

For airplanes having—	Compliance time
(1) Less than 5,000 total flight cycles as of the effective date of this AD	Within 3,600 flight cycles after the effective date of this AD.
(2) 5,000 or more total flight cycles as of the effective date of this AD ..	Within 1,500 flight cycles after the effective date of this AD.

Replacement

(g) Replace the eight brake fuses of the hydraulic quantity limiter by doing either Option 1 or Option 2 in Table 2 of this AD in accordance with Boeing Alert Service Bulletin 717–32A0031, dated September 10, 2004.

TABLE 2.—REPLACEMENT

Option—	Replace eight fuses having part number (P/N) 7918282–5503 with—
1	New fuses having P/N 7918282–5505.
2	Modified and reidentified fuses having P/N 7918282–5505.

Note 1: Boeing Alert Service Bulletin 717–32A0031 refers to Parker Hanninfin Corporation Stratoflex Products Division Service Bulletin 836SD–8–6–20 Revision 1, dated June 23, 2004, as an additional source of service information for modifying and reidentifying the brakes fuses.

Parts Installation

(h) As of the effective date of this AD, no person may install a brake fuse, P/N 7918282–5503, on any airplane.

Alternative Methods of Compliance (AMOCs)

(i) The Manager, Los Angeles Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

Issued in Renton, Washington, on December 27, 2004.

Kevin M. Mullin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–168 Filed 1–4–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–19986; Directorate Identifier 2004–NM–247–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 737–600, –700, –800, and –900 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Boeing Model 737–600, –700, –800, and –900 series airplanes. This proposed AD would require installing and testing an updated version of the operational program software of the flight control computers. This proposed AD is prompted by a report of an airplane pitching up with rapidly decreasing indicated airspeed after the flightcrew set a new altitude into the autopilot. We are proposing this AD to prevent anomalous autopilot operation that produces a hazardous combination of airplane attitude and airspeed, which could result in loss of control of the airplane.

DATES: We must receive comments on this proposed AD by February 22, 2005.

ADDRESSES: Use one of the following addresses to submit comments on this proposed AD.

- DOT Docket Web site: Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- Government-wide rulemaking Web site: Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- Mail: Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, room PL–401, Washington, DC 20590.
- By fax: (202) 493–2251.

• Hand Delivery: Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207.

You can examine the contents of this AD docket on the Internet at *http://dms.dot.gov*, or in person at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., room PL–401, on the plaza level of the Nassif Building, Washington, DC. This docket number is FAA–2004–19986; the directorate identifier for this docket is 2004–NM–247–AD.

FOR FURTHER INFORMATION CONTACT:

Technical information: Gregg Nesemeier, Aerospace Engineer, Systems and Equipment Branch, ANM–130S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 917–6479; fax (425) 917–6590.

Plain language information: Marcia Walters, *marcia.walters@faa.gov*.

SUPPLEMENTARY INFORMATION:

Docket Management System (DMS)

The FAA has implemented new procedures for maintaining AD dockets electronically. As of May 17, 2004, new AD actions are posted on DMS and assigned a docket number. We track each action and assign a corresponding directorate identifier. The DMS AD docket number is in the form "Docket No. FAA–2004–99999." The Transport Airplane Directorate identifier is in the form "Directorate Identifier 2004–NM–999–AD." Each DMS AD docket also lists the directorate identifier ("Old Docket Number") as a cross-reference for searching purposes.

Comments Invited

We invite you to submit any relevant written data, views, or arguments regarding this proposed AD. Send your comments to an address listed under **ADDRESSES.** Include "Docket No. FAA–2004–19986; Directorate Identifier 2004–NM–247–AD" in the subject line of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments submitted by the closing date and may amend the proposed AD in light of those comments.

We will post all comments we receive, without change, to *http://dms.dot.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed AD. Using the search function of that Web site, anyone can find and read the comments in any of our dockets, including the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You can review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you can visit *http://dms.dot.gov*.

We are reviewing the writing style we currently use in regulatory documents. We are interested in your comments on whether the style of this document is clear, and your suggestions to improve the clarity of our communications that affect you. You can get more information about plain language at *http://www.faa.gov/language* and *http://www.plainlanguage.gov*.

Examining the Docket

You can examine the AD docket on the Internet at *http://dms.dot.gov*, or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the DOT street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after the DMS receives them.

Discussion

We received a report that a Boeing Model 737–700 series airplane pitched up with rapidly decreasing indicated airspeed (IAS) after the flightcrew set a new altitude into the autopilot. During the incident, the airplane was leveling from a climb at 4,000 feet when the flightcrew set the altitude select knob of the autopilot mode control panel (MCP) to continue to climb to 8,000 feet. The flight data recorder indicated that the airplane had attained a pitch attitude of 27° nose-high and an airspeed of 135 knots IAS (near or into stickshaker) before the flightcrew recovered from the pitch up. Post-flight assessment of this event revealed an anomaly in the software of the enhanced digital flight control system (EDFCS) flight control computers (FCCs); if the altitude select knob of the MCP is rotated during a 200 millisecond window between the altitude capture and altitude hold modes, a new reference altitude between the previously selected altitude and the newly selected altitude is stored as the reference. The altitude hold control law then attempts to fly to this new reference altitude. This condition can result in a pitch-up to an excessive, nose-high altitude with anomalous autopilot operation that produces a hazardous combination of airplane attitude and airspeed, and if not corrected, could result in loss of control of the airplane.

The EDFCS FCCs and their software on certain Model 737–600, –800, and –900 series airplanes are identical to those on the affected Model 737–700 series airplane. Therefore, all of these models may be subject to the same unsafe condition.

Relevant Service Information

We have reviewed Boeing Alert Service Bulletin 737–22A1164, dated May 20, 2004. The service bulletin describes procedures for installing and testing an updated version of the operational program software of the EDFCS FCCs. Accomplishing the actions specified in the service information is intended to adequately address the unsafe condition.

FAA's Determination and Requirements of the Proposed AD

We have evaluated all pertinent information and identified an unsafe condition that is likely to exist or develop on other airplanes of this same type design. Therefore, we are proposing this AD, which would require accomplishing the actions specified in the service information described previously.

Costs of Compliance

There are about 155 airplanes of the affected design in the worldwide fleet. This proposed AD would affect about 34 airplanes of U.S. registry. The proposed actions would take about 2 work hours per airplane, at an average labor rate of $65 per work hour. Required parts would cost about $0 per airplane. Based on these figures, the estimated cost of the proposed AD for U.S. operators is $4,420, or $130 per airplane.

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil

aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this proposed AD.

Regulatory Findings

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the proposed regulation:

1. Is not a "significant regulatory action" under Executive Order 12866;

2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Boeing: Docket No. FAA–2004–19986; Directorate Identifier 2004–NM–247–AD.

Comments Due Date

(a) The Federal Aviation Administration (FAA) must receive comments on this AD action by February 22, 2005.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Boeing Model 737–600, –700, –800, and –900 series airplanes, certificated in any category, as listed in Boeing Alert Service Bulletin 737–22A1164, dated May 20, 2004.

Unsafe Condition

(d) This AD was prompted by a report of an airplane pitching up with rapidly decreasing indicated airspeed after the flightcrew set a new altitude into the autopilot. We are issuing this AD to prevent anomalous autopilot operation that produces a hazardous combination of airplane attitude and airspeed, which could result in loss of control of the airplane.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Install and Test Updated Software

(f) Within 12 months after the effective date of this AD, install and test an updated version of the operational program software of the enhanced digital flight control system (EDFCS) flight control computers (FCCs), in accordance with Boeing Alert Service Bulletin 737–22A1164, dated May 20, 2004.

Alternative Methods of Compliance (AMOCs)

(g) The Manager, Seattle Aircraft Certification Office, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

Issued in Renton, Washington, on December 27, 2004.

Kevin M. Mullin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–169 Filed 1–4–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–19998; Directorate Identifier 2004–NM–224–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 777–200 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Boeing Model 777–200 series airplanes. This proposed AD would require replacing the pressure switches on the override/jettison fuel pumps with new pressure switches, and replacing the ship side electrical connectors for the pressure switches on override/jettison fuel pumps with new connectors. This proposed AD is prompted by reports that the "FUEL LOW CENTER" message does not activate when the fuel level in the center tank is low. We are proposing this AD to prevent the fuel pumps in the center fuel tank from running dry and becoming a potential ignition source, which could result in a fuel tank explosion.

DATES: We must receive comments on this proposed AD by February 22, 2005.

ADDRESSES: Use one of the following addresses to submit comments on this proposed AD.

- DOT Docket Web site: Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- Government-wide rulemaking Web site: Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- Mail: Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, room PL–401, Washington, DC 20590.
- By fax: (202) 493–2251.
- Hand Delivery: Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207.

You can examine the contents of this AD docket on the Internet at *http://dms.dot.gov*, or in person at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., room PL–401, on the plaza level of the Nassif Building, Washington, DC. This docket number is FAA–2004–19998; the directorate identifier for this docket is 2004–NM–224–AD.

FOR FURTHER INFORMATION CONTACT:

Technical information: Margaret Langsted, Aerospace Engineer, Propulsion Branch, ANM–140S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 917–6500; fax (425) 917–6590.

Plain language information: Marcia Walters, *marcia.walters@faa.gov.*

SUPPLEMENTARY INFORMATION:

Docket Management System (DMS)

The FAA has implemented new procedures for maintaining AD dockets electronically. As of May 17, 2004, new AD actions are posted on DMS and

assigned a docket number. We track each action and assign a corresponding directorate identifier. The DMS AD docket number is in the form "Docket No. FAA–2004–99999." The Transport Airplane Directorate identifier is in the form "Directorate Identifier 2004–NM–999–AD." Each DMS AD docket also lists the directorate identifier ("Old Docket Number") as a cross-reference for searching purposes.

Comments Invited

We invite you to submit any relevant written data, views, or arguments regarding this proposed AD. Send your comments to an address listed under **ADDRESSES.** Include "Docket No. FAA–2004–19998; Directorate Identifier 2004–NM–224–AD" in the subject line of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments submitted by the closing date and may amend the proposed AD in light of those comments.

We will post all comments we receive, without change, to *http://dms.dot.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed AD. Using the search function of that Web site, anyone can find and read the comments in any of our dockets, including the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You can review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you can visit *http://dms.dot.gov*.

We are reviewing the writing style we currently use in regulatory documents. We are interested in your comments on whether the style of this document is clear, and your suggestions to improve the clarity of our communications that affect you. You can get more information about plain language at *http://www.faa.gov/language* and *http://www.plainlanguage.gov*.

Examining the Docket

You can examine the AD docket on the Internet at *http://dms.dot.gov*, or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the DOT street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after the DMS receives them.

Discussion

We have received reports indicating that the "FUEL LOW CENTER" message on the engine indication and crew alerting system (EICAS) did not come on during flight when the fuel quantity in the center tank was low (400 lbs or less), on several Boeing Model 777–200 series airplanes. A Boeing Model 777–200 series airplane was flight-tested to evaluate the problem. An analysis of the data collected indicated a problem with the design of the system tubing at the inlet of the center fuel tank pump. That design allows some residual fuel to collect near the pump impeller after the center tank fuel supply has been exhausted. As a result, the center tank pump produces sustained pressure above its low pressure switch range of 4–7 pounds per square inch gage (psig) when the main tank boost pumps supply back pressure against the center pump discharge check valve. Failure of the "FUEL LOW CENTER" message and the pump low pressure lights to come on when the center tank becomes empty, if not corrected, could result in the pumps running dry and becoming a potential ignition source in the fuel tank, which could consequently cause a fuel tank explosion.

Relevant Service Information

We have reviewed Boeing Special Attention Service Bulletin 777–28–0036, dated September 2, 2004. The service bulletin describes procedures for replacing the pressure switches on the override/jettison fuel pump with new pressure switches, and replacing the ship side electrical connectors for the pressure switches on the override/jettison fuel pumps with new connectors. Accomplishing the actions specified in the service information is intended to adequately address the unsafe condition.

FAA's Determination and Requirements of the Proposed AD

We have evaluated all pertinent information and identified an unsafe condition that is likely to exist or develop on other airplanes of this same type design. Therefore, we are proposing this AD, which would require accomplishing the actions specified in the service information described previously.

Costs of Compliance

There are about 61 airplanes of the affected design in the worldwide fleet. The following table provides the estimated costs for U.S. operators to comply with this proposed AD.

ESTIMATED COSTS

Action	Work hours	Average labor rate per hour	Parts	Cost per airplane	Number of U.S.-registered airplanes	Fleet cost
Replacement	3	$65	$13,430	$13,625	21	$286,125

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or

on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the proposed regulation:

1. Is not a "significant regulatory action" under Executive Order 12866;

2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Boeing: Docket No. FAA–2004–19998; Directorate Identifier 2004–NM–224–AD.

Comments Due Date

(a) The Federal Aviation Administration (FAA) must receive comments on this AD action by February 22, 2005.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Boeing Model 777–200 series airplanes, certificated in any category; as listed in Boeing Special Attention Service Bulletin 777–28–0036, dated September 2, 2004.

Unsafe Condition

(d) This AD was prompted by reports that the "FUEL LOW CENTER" message does not activate when the fuel level in the center tank is low. We are issuing this AD to prevent the fuel pumps in the center fuel tank from running dry and becoming a potential ignition source, which could result in a fuel tank explosion.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Replacement

(f) Within 24 months after the effective date of this AD, replace the pressure switches on the override/jettison fuel pumps with new pressure switches, and replace the ship side electrical connectors for the pressure switches on the override/jettison fuel pumps with new connectors, in accordance with the Accomplishment Instructions of Boeing Special Attention Service Bulletin 777–28–0036, dated September 2, 2004.

Alternative Methods of Compliance (AMOCs)

(g) The Manager, Seattle Aircraft Certification Office, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

Issued in Renton, Washington, on December 27, 2004.

Kevin M. Mullin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–170 Filed 1–4–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2001–NM–89–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 777–200 and –300 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Supplemental notice of proposed rulemaking; reopening of comment period.

SUMMARY: This document revises an earlier proposed airworthiness directive (AD), applicable to certain Boeing Model 777–200 and –300 series airplanes. That proposed AD would have required a one-time inspection of the clevis end of the vertical tie rods that support the center stowage bins to measure the exposed thread, installation of placards that advise of weight limits for certain electrical racks, a one-time inspection and records check to determine the amount of weight currently installed in those electrical racks, corrective actions, and replacement of the vertical tie rods for the center stowage bins or electrical racks with new improved tie rods, as applicable. This new action revises the proposed rule by revising the applicability to include additional airplanes. The actions specified by this new proposed AD are intended to prevent failure of the vertical tie rods supporting certain electrical racks and the center stowage bins, which could cause the center stowage bins or electrical racks to fall onto passenger seats below during an emergency landing, impeding an emergency evacuation or injuring passengers. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by January 31, 2005.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2001–NM–89–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: *9-anm-nprmcomment@faa.gov.* Comments sent via fax or the Internet must contain "Docket No. 2001–NM–89–AD" in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 or 2000 or ASCII text.

The service information referenced in the proposed rule may be obtained from Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Robert Kaufman, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM–150S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 917–6433; fax (425) 917–6590.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained

in this action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the proposed AD is being requested.
- Include justification (*e.g.*, reasons or data) for each request.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this action must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 2001–NM–89–AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2001–NM–89–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to add an airworthiness directive (AD), applicable to certain Boeing Model 777–200 and –300 series airplanes, was published as a first supplemental notice of proposed rulemaking (NPRM) in the **Federal Register** on June 23, 2004 (69 FR 34966). That action proposed to require a one-time inspection of the clevis end of the vertical tie rods that support the center stowage bins to measure the exposed thread, installation of placards that advise of weight limits for certain electrical racks, a one-time inspection and records check to determine the amount of weight currently installed in those electrical racks, corrective actions, and replacement of the vertical tie rods for the center stowage bins or electrical racks with new improved tie rods, as applicable. The original NPRM and first supplemental NPRM were prompted by a report indicating that, under certain conditions on Boeing Model 777–200 and –300 series airplanes, the vertical tie rods that attach the center stowage bins and electrical racks to the airplane structure can break. That condition, if not corrected, could result in the racks or stowage bins falling onto passenger seats below during an emergency landing, impeding an emergency evacuation or injuring passengers.

Comments

We have duly considered the comments received in response to the first supplemental NPRM.

Request To Add Additional Airplanes

One commenter notes that an airplane in its fleet that should be subject to the proposed AD is missing from the applicability of the first supplemental NPRM. The commenter states that it intends to accomplish the requirements on all of its airplanes.

We agree that several line numbers were inadvertently omitted from the applicability of the first supplemental NPRM. Therefore, we are issuing this second supplemental NPRM and have revised the applicability statement to state that this supplemental NPRM applies to airplanes having line numbers 002 through 283 inclusive. We find that the estimated number of affected airplanes in the Cost Impact section of the first supplemental NPRM is correct; thus, we have not changed this section of this second supplemental NPRM.

Request To Revise Compliance Time for Determining Installed Weight

One commenter requests that we revise paragraph (a)(2) of the first supplemental NPRM to delete the words "before further flight." The commenter states that any airplane on which placards have been installed according to paragraph (a)(1) of the proposed AD before the effective date of the AD will be grounded upon the effective date of the AD until the inspection and records check to determine the weight installed in placarded electrical racks is done.

We agree and have revised paragraph (a)(2) of this second supplemental NPRM to specify a separate compliance time of 12 months after the effective date of the AD for airplanes on which the actions in paragraph (a)(1) were done before the effective date of the AD. For airplanes on which the actions in paragraph (a)(1) are done after the effective date of this AD, the actions in paragraph (a)(2) would continue to be required before further flight after the installation of the placards required by paragraph (a)(1).

Request To Give Credit for Actions Accomplished Previously

One commenter requests that we revise paragraph (a)(1) of the first supplemental NPRM to include the words "except as provided by paragraph (e) of this AD." The commenter states that adding this phrase will allow credit to operators who have already accomplished some of the AD requirements by doing Revision 1 of the service bulletin.

We do not agree that any change is necessary in this regard. Paragraph (e) of the first supplemental NPRM, as well as this second supplemental NPRM, states that actions done before the effective date of the AD according to Boeing Special Attention Service Bulletin 777–25–0144, dated January 25, 2001; or Revision 1, dated January 10, 2002; are acceptable for compliance with the corresponding actions required by this AD, which includes the actions in paragraph (a)(1).

Comment on Cost Impact Estimate

One commenter estimates that approximately 205 work hours, including the time needed for rework, will be necessary to accomplish the requirements of the first supplemental NPRM on its fleet of 19 airplanes. The commenter estimates that it will incur a total cost of $59,500, including parts and labor.

Because the commenter states that it has no objection to the proposed requirements, we infer that the commenter is providing these data for our information. We find that the costs estimated by the commenter are consistent with the cost stated in the Cost Impact section of this second supplemental NPRM. No change is necessary in this regard.

Conclusion

Since a certain change explained above expands the scope of the first supplemental NPRM, we have determined that it is necessary to reopen the comment period to provide additional opportunity for public comment.

Cost Impact

There are approximately 282 airplanes of the affected design in the worldwide fleet. The FAA estimates that 84 airplanes of U.S. registry would be affected by this proposed AD.

For all airplanes: The records check and inspection to determine the weight currently installed in electrical rack E7 would take approximately 1 work hour per airplane to accomplish, at an average labor rate of $65 per work hour. Based on these figures, the cost impact

of this proposed records check and inspection on U.S. operators is estimated to be $5,460, or $65 per airplane.

For all airplanes: It would take approximately 1 work hour to accomplish the proposed installation of a placard specifying weight limits for electrical rack E7, at an average labor rate of $65 per work hour. Required parts would cost approximately $29. Based on these figures, the cost impact of this proposed placard installation on U.S. operators is estimated to be $7,896, or $94 per electrical rack.

For airplanes subject to the records check and inspection to determine the weight currently installed in electrical rack E9, E11, E13, or E15: It would take approximately 1 work hour per electrical rack (up to 4 racks per airplane) to accomplish, at an average labor rate of $65 per work hour. Based on these figures, the cost impact of this proposed records check and inspection is estimated to be as much as $260 per airplane.

For airplanes subject to the installation of a placard specifying weight limits for electrical rack E9, E11, E13, or E15: It would take approximately 1 work hour per electrical rack to accomplish, at an average labor rate of $65 per work hour. Required parts would cost approximately $29 per electrical rack. Based on these figures, the cost impact of this proposed installation is estimated to be as much as $376 per airplane.

For airplanes subject to the inspection of the clevis end of the vertical support tie rod for the center stowage bin to measure the exposed thread: It would take as much as 3 work hours per airplane (0.25 work hour per tie rod, with up to 12 subject tie rods per airplane) at an average labor rate of $65 per work hour. Based on these figures, the cost impact of this proposed inspection is estimated to be as much as $195 per airplane.

For airplanes subject to the replacement of the vertical tie rods that support the center stowage bins: It would take as much as 6 work hours per airplane (0.5 work hour per tie rod, with up to 12 subject tie rods per airplane) at an average labor rate of $65 per work hour. Required parts would cost as much as $3,020 per airplane. Based on these figures, this proposed replacement is estimated to be as much as $3,410 per airplane.

For airplanes subject to the replacement of the vertical tie rods that support the electrical racks: It would take as much as 2 work hours per airplane (0.5 work hour per tie rod with up to 4 subject tie rods per airplane) at an average labor rate of $65 per work hour. Required parts would cost as much as $3,012 per airplane. Based on these figures, this proposed replacement is estimated to be as much as $3,142 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Impact

The regulations proposed herein would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this proposal would not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Boeing: Docket 2001–NM–89–AD.

Applicability: Model 777–200 and –300 series airplanes; certificated in any category; line numbers 002 through 283 inclusive.

Compliance: Required as indicated, unless accomplished previously.

To prevent failure of the vertical tie rods supporting certain electrical racks and the center stowage bins, which could cause the center stowage bins or electrical racks to fall onto passenger seats below during an emergency landing, impeding an emergency evacuation or injuring passengers, accomplish the following:

Inspection To Determine Weight and Placard Installation

(a) For airplanes in the groups listed in the table under paragraph 3.B.1.b.(3) of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 777–25–0144, Revision 2, dated January 15, 2004: Within 5 years after the effective date of this AD, do the applicable actions in paragraphs (a)(1) and (a)(2) of this AD.

(1) Install placards that show weight limits for electrical racks E7, E11, and E15; as applicable; per the Accomplishment Instructions of the service bulletin.

(2) For each electrical rack on which a placard was installed per paragraph (a)(1) of this AD: At the applicable compliance time specified in paragraph (a)(2)(i) or (a)(2)(ii) of this AD, perform a one-time inspection and records check to determine the weight of equipment installed in that electrical rack. This records review and inspection must include determining what extra equipment, if any, has been installed in the subject rack of the airplane, performing a detailed

inspection to determine whether this equipment is installed on the airplane, calculating the total weight of the installed equipment, and comparing that total to the weight limit specified on the placard installed per paragraph (a)(1) of this AD. If the weight is outside the limits specified in the placard to be installed per the service bulletin, before further flight, remove equipment from the rack to meet the weight limit specified in the placard.

(i) For airplanes on which the actions required by paragraph (a)(1) of this AD were done before the effective date of this AD: Within 12 months after the effective date of this AD.

(ii) For airplanes on which the actions required by paragraph (a)(1) of this AD are done after the effective date of this AD: Before further flight after installing the placards.

Note 1: For the purposes of this AD, a detailed inspection is defined as: "An intensive visual examination of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required."

Inspection To Measure Exposed Thread and Corrective Actions

(b) For airplanes in the groups listed in the table under paragraph 3.B.1.b.(1) of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 777–25–0144, Revision 2, dated January 15, 2004: Within 5 years after the effective date of this AD, perform a detailed inspection of the clevis end of the vertical support tie rod for the center stowage bin to measure the exposed thread, per the Accomplishment Instructions of the service bulletin. If the measurement of the exposed thread is outside the limits specified in Figure 2 of the service bulletin, before further flight, perform all corrective actions specified in steps 2 through 14 inclusive of Figure 2 of the service bulletin (including installing a threaded sleeve, torquing the jam nuts, inserting a pin in the witness hole to ensure that the witness hole is blocked by the clevis shank, and making any applicable adjustment of the clevis). Perform the corrective actions per the Accomplishment Instructions of the service bulletin, except as provided by paragraph (e) of this AD.

Replacement of Tie Rods for Center Stowage Bin

(c) For airplanes in Group 21, as listed in the Airplane Group column of the table under 3.B.1.b.(2) of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 777–25–0144, Revision 2, dated January 15, 2004: Within 5 years after the effective date of this AD, replace the vertical support tie rods for the center stowage bin with new improved tie rods (including replacing the existing tie rod with a new improved tie rod, torquing the jam nuts, inserting a pin in the witness hole to ensure that the witness hole is blocked by the clevis shank, and making any applicable adjustment of the clevis) by doing all actions specified in steps 1 through 8 of Figure 3 of the service bulletin. Do these actions per the Accomplishment Instructions of the service bulletin. Any required adjustment of the clevis must be done before further flight.

Inspection To Determine Weight, Tie Rod Replacement, and Placard Installation

(d) For airplanes in the groups listed in the table under paragraph 3.B.1.b.(4) of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 777–25–0144, Revision 2, dated January 15, 2004: Do the actions in paragraphs (d)(1), (d)(2), and (d)(3) of this AD.

(1) Within 5 years after the effective date of this AD, replace the vertical support tie rods for electrical racks E9, E11, and E13 (including replacing the existing tie rods with new improved tie rods, replacing an existing tie rod clamp with a new improved tie rod clamp, performing a free-play inspection of certain electrical racks, adjusting jam nuts as applicable, performing a general visual inspection through the witness hole to make sure tie rod threads are visible, and making any applicable adjustment to ensure tie rod threads are visible) by doing all actions specified in Figures 5, 6, 7, and 9 of the service bulletin; as applicable. Do these actions per the Accomplishment Instructions of the service bulletin. Any required adjustment must be done before further flight.

(2) Before further flight after accomplishing paragraph (d)(1) of this AD, install placards that show weight limits for electrical racks E9, E11, and E13; as applicable; per the Accomplishment Instructions of the service bulletin.

(3) For each electrical rack on which a placard was installed per paragraph (d)(2) of this AD: Before further flight after accomplishing paragraphs (d)(1) and (d)(2) of this AD, perform a one-time inspection and records check to determine the weight of equipment installed in that electrical rack. This records review and inspection must include determining what, if any, extra equipment has been installed in the subject racks of the airplane, performing a detailed inspection to determine that this equipment is installed on the airplane, calculating the total weight of the installed equipment, and comparing that total to the weight limit specified on the placard installed per paragraph (d)(2) of this AD. If the weight is outside the limits specified in the placard, before further flight, remove equipment from the rack to meet the weight limit specified in the placard.

Actions Accomplished Previously

(e) Actions accomplished before the effective date of this AD per the Accomplishment Instructions of Boeing Special Attention Service Bulletin 777–25–0144, dated January 25, 2001; or Revision 1, dated January 10, 2002; are acceptable for compliance with the corresponding actions required by this AD, provided that the additional actions specified in Part 2 or.3 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 777–25–0144, Revision 2, dated January 15, 2004, are accomplished within the compliance time specified in this AD.

Alternative Methods of Compliance

(f) In accordance with 14 CFR 39.19, the Manager, Seattle Aircraft Certification Office, FAA, is authorized to approve alternative methods of compliance (AMOCs) for this AD.

Issued in Renton, Washington, on December 27, 2004.

Kevin M. Mullin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–171 Filed 1–4–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

15 CFR Part 904

[Docket No. 040902252–4252–01; I.D. 092804C]

RIN 0648–AS54

Civil Procedures

AGENCY: Office of General Counsel for Enforcement and Litigation, National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; amendments and technical refinements to Civil Procedures; reopening of the comment period.

SUMMARY: In a proposed rule published in the **Federal Register** on October 12, 2004, NOAA requested comments on proposed revisions to its Civil Procedures which govern the Agency's administrative proceedings for the assessment of civil penalties; suspension, revocation, modification, or denial of permits; issuance and use of written warnings; and release or forfeiture of seized property. The comment period for the proposed rule closed on December 13, 2004. Comments addressed various issues and included requests to extend the comment period. The intent of this document is to announce the reopening of the public comment period.

DATES: Written comments must be received on or before January 31, 2005.

ADDRESSES: Send comments to Meggan Engelke-Ros, Enforcement Attorney, Office of General Counsel for Enforcement and Litigation, NOAA. Comments may be submitted by:

- Mail to 8484 Georgia Avenue, Suite 400, Silver Spring, MD 20910;
- E-mail to *Part904.comments@noaa.gov*; or

• Webform at the Federal eRulemaking Portal: *www.regulations.gov*. Follow the instructions at that site for submitting comments.

FOR FURTHER INFORMATION CONTACT: Meggan Engelke-Ros or Susan S. Beresford, 301–427–2202.

SUPPLEMENTARY INFORMATION: As announced in the **Federal Register** on October 12, 2004 (69 FR 60569), NOAA is proposing revisions to its Civil Procedures which govern the Agency's administrative proceedings for the assessment of civil penalties; suspension, revocation, modification, or denial of permits; issuance and use of written warnings; and release or forfeiture of seized property. The comment period for the proposed rule closed on December 13, 2004. While NOAA received comments expressing opinions about whether, and in what way, its Civil Procedures should be revised, NOAA was also asked to extend the comment period beyond the original 60 days. NOAA has reopened the comment period to provide the public an additional opportunity to comment on the proposed revisions. The agency believes these additional comments will aid in the evaluation of the proposed revisions. Comments received between December 13, 2004, and the publication date of this document will be given full consideration by NOAA.

Background

In October 2004, NOAA proposed revisions (69 FR 60569) to the civil procedure rules that apply to its administrative proceedings under 15 CFR part 904. Part 904 has been largely unchanged since 1987 and the proposed changes were intended to: (1) conform the civil procedure rules to changes in applicable Federal laws and regulations; (2) improve efficiency and fairness of administrative proceedings; (3) clarify any ambiguities or inconsistencies in the existing civil procedure rules; (4) eliminate redundant language and correct language errors; and (5) conform the civil procedure rules to current Agency practice.

NOAA invites comments on all aspects of the revisions proposed to part 904 from all interested parties. Information on the time period for submission of comments and directions for their submission may be found in the DATES and ADDRESSES section of this document.

It has been determined that this rule is not a "significant regulatory action" under the terms of Executive Order 12866 and is therefore not subject to OMB review.

Authority: 16 U.S.C. 1801–1882; 16 U.S.C. 1531–1543; 16 U.S.C. 1361–1407; 16 U.S.C. 3371–3378; 16 U.S.C. 1431–1439; 16 U.S.C. 773–773k; 16 U.S.C. 951–961; 16 U.S.C. 1021–1032; 16 U.S.C. 3631–3644; 42 U.S.C. 9101 *et seq.*; 30 U.S.C. 1401 *et seq.*; 16 U.S.C. 971–971k; 16 U.S.C. 781 *et seq.*; 16 U.S.C. 2401–2413; 16 U.S.C. 2431–2444; 16 U.S.C. 972–972h; 16 U.S.C. 916–916l; 16 U.S.C. 1151–1175; 16 U.S.C. 3601–3608; 16 U.S.C. 1851 note; 15 U.S.C. 4201 *et seq.*; Pub. L. 102–587; 106 Stat. 5039.

Dated: December 29, 2004.

Jane H. Chalmers,

Acting General Counsel, National Oceanic and Atmospheric Administration.

[FR Doc. 04–28751 Filed 12–30–04; 3:39 pm]

BILLING CODE 3510–12–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 357

[Docket No. 1982N–0166]

RIN 0910–AF51

Orally Administered Drug Products for Relief of Symptoms Associated With Overindulgence in Food and Drink for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the tentative final monograph (TFM) for over-the-counter (OTC) orally administered drug products for relief of symptoms associated with overindulgence in food and drink to include an additional use for products that contain bismuth subsalicylate as an active ingredient labeled for the relief of symptoms of upset stomach due to overindulgence resulting from food and drink. This proposal is part of FDA's ongoing review of OTC drug products.

DATES: Submit written or electronic comments by April 5, 2005. Please see section X of this document for the proposed effective date of any final rule that may publish based on this proposal.

ADDRESSES: You may submit comments, identified by Docket No. 1982N–0166 or RIN 0910–AF51, by any of the following methods:

• Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

• Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

• E-mail: *fdadockets@oc.fda.gov*. Include Docket No. 1982N–0166 or RIN 0910–AF51 in the subject line of your e-mail message.

• FAX: 301–827–6870.

• Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No. or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to *http://www.fda.gov/dockets/ecomments*, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Request for Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/dockets/ecomments*and/or the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2307.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 1, 1982 (47 FR 43540), FDA published an advance notice of proposed rulemaking to establish a monograph for OTC orally administered drug products for relief of symptoms associated with overindulgence in alcohol and food, together with the recommendations of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products (the Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in these drug products (§ 330.10(a)(6) (21 CFR 330.10(a)(6))).

In the **Federal Register** of December 24, 1991 (56 FR 66742). FDA published the proposed rule (in the form of a TFM) for OTC orally administered drug products for relief of symptoms associated with overindulgence in food and drink. In the **Federal Register** of May 5, 1993 (58 FR 26886), FDA proposed to amend the overindulgence TFM to include a Reye's syndrome warning for OTC drug products containing bismuth subsalicylate. In the

Federal Register of April 17, 2003 (68 FR 18861), FDA published a final rule to revise the Reye's syndrome warning (§ 201.314(h) (21 CFR 201.314(h))) to include OTC drug products containing nonaspirin salicylates (e.g., bismuth subsalicylate) as active ingredients. FDA stated that there was no need to address this warning in a separate rule for overindulgence drug products containing bismuth subsalicylate (68 FR 18861 at 18862). Thus, the April 17, 2003, final rule completed the May 5, 1993, proposed rule. Products containing bismuth subsalicylate as an active ingredient must contain the required Reye's syndrome warning statement as of April 19, 2004, except that products with annual sales less than $25,000 have until April 18, 2005, to be in compliance.

In the **Federal Register** of March 17, 1999 (64 FR 13254), FDA established a standardized format and content for the labeling of all OTC drug products (see § 201.66). The labeling in the TFM and the labeling in this amendment are not in that format. However, the labeling in the final monograph (FM) will incorporate the standardized labeling format and content. In response to the TFM, FDA received a number of comments and is addressing part of one comment in this document. The remaining comments will be addressed in the final rule. All "OTC Volumes" cited throughout this document refer to information on public display in the Division of Dockets Management (see **ADDRESSES**).

II. The Comment's Recommendation, Arguments, and Data

One comment recommended that FDA include combination upset stomach/antiflatulent (antigas) drug products containing bismuth subsalicylate and simethicone in the overindulgence monograph for the relief of upset stomach and gas due to overindulgence in food and drink. The comment provided the following arguments and data to support its recommendation.

- FDA's "General Guidelines for OTC Drug Combination Products, September 1978" (Ref. 1) provide that Category I active ingredients from different therapeutic categories may be combined to treat different symptoms concurrently if each ingredient is present within its established safe and effective dosage range, and the combination meets the OTC drug combination policy in all other respects. FDA's OTC drug combination regulations (§ 330.10(a)(4)(iv)) provide that an OTC drug may combine two or more safe and effective active ingredients and may be generally recognized as safe and effective when each active ingredient makes a contribution to the claimed effect(s); when combining of the active ingredients does not decrease the safety or effectiveness of any of the individual active ingredients; and when the combination, when used under adequate directions for use and warnings against unsafe use, provides rational concurrent therapy for a significant proportion of the target population. A combination drug product containing bismuth subsalicylate and simethicone would combine two Category I active ingredients as specified in these Guidelines and meet the requirements of this regulation.
- FDA proposed bismuth subsalicylate as safe and effective for the relief of symptoms of upset stomach associated with overindulgence in food and drink in the TFM, and simethicone is included in the antiflatulent monograph (21 CFR part 332). Bismuth subsalicylate acts in the stomach to relieve upset stomach/indigestion symptoms such as nausea, heartburn, and fullness, while simethicone acts in the stomach to break up gas bubbles resulting from overindulgence in food and drink. Together, these active ingredients will provide relief from upset stomach symptoms occurring in the presence of gas.
- Combining the active ingredients does not decrease the safety and effectiveness of either ingredient. The comment cited data to support that (1) Bismuth subsalicylate does not decrease the foam-reducing capacity of simethicone (Ref. 2), (2) serum salicylate bioavailability of a combination of bismuth subsalicylate-simethicone was equivalent to bismuth subsalicylate alone in dogs (Ref. 3), and (3) the combination and bismuth subsalicylate alone in rats provided equivalent stomach protection against alcohol (Ref. 4).
- The combination provides rational concurrent therapy for a significant proportion of the target population. The comment noted a consumer study of 285 subjects suffering from upset stomach due to overindulgence in which 56 percent of the subjects reported gas as one of their symptoms (Ref. 5). The comment mentioned another consumer study of 159 adults who reported having gas concurrently with symptoms for which bismuth subsalicylate has been shown to be effective (Ref. 6). The percent of adults reporting gas with each symptom included: Fullness/bloating (57), upset stomach (55), indigestion (44), and heartburn (24).
- Antacid-simethicone combination products were included in the antacid monograph (21 CFR part 331) and the antiflatulent monograph without any supporting clinical data. FDA's determination to allow this combination was based on a reasonable expectation that simethicone will be effective if used in combination with an antacid drug product (38 FR 31260 at 31266, November 12, 1973). Further, FDA has proposed that any antacid covered by the antacid monograph may be labeled "for the relief of * * * upset stomach associated with * * * overindulgence in food and drink" (56 FR 66754 at 66756, December 24, 1991). FDA did not review any clinical data to support the indication of upset stomach and gas due to overindulgence in food and drink.

III. FDA's Evaluation of the Comment's Recommendation

FDA has evaluated the comment's recommendation and reconsidered the Panel's review of bismuth subsalicylate for the relief of symptoms of upset stomach associated with overindulgence in food and drink. The Panel stated that upset stomach that occurs as a result of overindulgence in food and drink consists of a group of symptoms that includes heartburn, fullness, and nausea (47 FR 43540 at 43543 and 43545). One of the indications statements that the Panel recommended for products containing bismuth subsalicylate included these symptoms: "For the relief of upset stomach associated with" (select one or more of the following: "nausea," "heartburn," and "fullness") "due to overindulgence in the combination of food and drink." (See 47 FR 43540 at 43550 and 43558.) FDA proposed this indication statement without the words "the combination of" in § 357.950(b)(2) of the TFM (see 56 FR 66742 at 66751).

The Panel discussed the consumer study of 285 subjects (Ref. 5) (47 FR 43540 at 43545), cited by the comment, and noted that 96 percent of the subjects had at least one of the symptoms of "gas (fullness), heartburn (or acid indigestion), or nausea" and that 56 percent [the highest percentage] reported gas as one of their symptoms. The Panel cited studies by Newsom (Ref. 7) and by Berkowitz (Ref. 8) (47 FR 43540 at 43548 to 43549) to support the effectiveness of bismuth subsalicylate for treating upset stomach due to overindulgence. The Newsom study was subsequently published in the *Archives of Internal Medicine* (Ref. 9).

Newsom conducted a randomized, placebo-controlled, double-blind, multiple-crossover study (Refs. 7 and 9) to evaluate the effectiveness of bismuth

subsalicylate to relieve symptoms in subjects with a history of episodic, acute (having a short and relatively severe course) indigestion. The study involved 48 adult subjects 18 to 49 years old (20 men, 28 women). Two additional subjects began the study but were later excluded by the investigator because of abnormal laboratory values. The study medication consisted of either 16.7 milligrams per milliliter (mg/mL) of bismuth subsalicylate suspended in the vehicle or a placebo of vehicle only. The two preparations were similar in appearance, flavor, and viscosity. Each subject received three bottles of each formulation with a computer-generated random sequence of use for treating six episodes over a 7-month period. The subjects were instructed to take the study medication only when they experienced two or more of the symptoms and to take 30 mL every 30 minutes as needed for a total of eight doses (up to 240 minutes). Subjects recorded specific symptoms and the time they first occurred, rating symptom severity on a 10-point scale 15 and 30 minutes after each dose. Subjects reported the time when relief occurred. After six episodes, each subject evaluated each preparation three times.

Newsom defined indigestion or acute gastrointestinal discomfort as a symptom complex consisting of two or more of the following symptoms occurring during or after ingestion of food: Nausea, heartburn, upper-abdominal pain, flatulence (gas) and eructation (belching), sense of fullness, or a feeling of abdominal distention. *Stedman's Medical Dictionary* (Ref. 10) defines indigestion as a nonspecific term for a variety of symptoms resulting from a failure of proper digestion and absorption of food in the alimentary tract [relating to the organs of digestion]. FDA notes that the investigator's definition of indigestion or acute gastrointestinal discomfort is consistent with the Stedman's definition in that the dictionary's term is nonspecific and the investigator's symptoms relate to the digestive system.

The 48 test subjects had no significant differences in reported symptoms or identified causes in the six individual episodes of symptoms. Eating specific foods was the most commonly identified cause of symptoms, followed by overeating. The overall relief of symptoms showed more episodes treated with bismuth subsalicylate were relieved (132/144) than were episodes treated with placebo (121/144). However, the difference between the two groups was not statistically significant ($0.05<p<0.10$). However, when time to relief was evaluated in 30-minute intervals, the episodes treated with bismuth subsalicylate were relieved in 90 minutes (median) compared to 120 minutes (median) for episodes treated with placebo. The difference was statistically significant ($p<0.01$). In addition, the differences in time to relief were significant at the time intervals of 31 to 60, 61 to 90, and 91 to 120 minutes ($p<0.01$). Beginning at 30 to 45 minutes post-medication, a statistically significant more rapid decrease in severity of nausea, heartburn, flatulence and eructation, and sense of fullness occurred in the subjects receiving bismuth subsalicylate compared to subjects receiving placebo. The feeling of abdominal distension was less severe at 90 minutes with bismuth subsalicylate, but the severity of upper abdominal pain was no different with either treatment. Comparing the time to relief shows that bismuth subsalicylate provided significantly faster relief than placebo for nausea, heartburn, flatulence and eructation, and sense of fullness. FDA concludes that this study supports that bismuth subsalicylate relieves the symptoms of flatulence and eructation, which are symptoms from gas. The study also supports that bismuth subsalicylate relieves the sense of fullness, which might be related to gas.

Berkowitz conducted a randomized, placebo-controlled, double-blind study (Ref. 8) to evaluate the effectiveness of bismuth subsalicylate to relieve gastrointestinal symptoms, commonly termed as "upset stomach," from consumption of food and drink. One hundred thirty two healthy adult subjects fasted for 6 hours and then were provided unlimited quantities of provocative food and drink. The subjects were provided a diary to record eight symptoms, degree of discomfort (none, mild, moderate, severe), and the time of occurrence. The symptoms were:

- stomach queasiness/nausea
- heartburn
- sense of fullness/bloated feeling
- belching
- bitter or acid taste in mouth
- passing gas/wind
- stomach pain/cramps
- other symptoms

The subjects were instructed to take 30 mL of the test medication when symptoms first occurred and to repeat the dose every 30 to 60 minutes, if needed, up to eight doses. The test medication (bismuth subsalicylate) and the placebo were prepared as white, opaque suspensions identical in flavor and viscosity. However, Berkowitz did not mention the concentration of the bismuth subsalicylate preparation. Subjects recorded the time the dose was taken and the degree of relief obtained (none, poor, good, excellent).

Ninety-one of the 132 subjects developed symptoms that required medication, with 43 taking bismuth subsalicylate and 48 taking placebo. Comparison of the two groups showed no significant demographic or baseline differences. The number of subjects and the percent of 91 total subjects reporting the symptoms were as follows:

- stomach queasiness/nausea - 50 (55%)
- heartburn - 48 (53%)
- sense of fullness/bloated feeling - 66 (73%)
- belching - 50 (55%)
- bitter or acid taste in mouth - 18 (20%)
- passing gas/wind - 30 (33%)
- stomach pain/cramps - 17 (19%)

The number of symptoms reported is greater than the number of subjects because subjects reported more than one symptom. Berkowitz performed a statistical analysis of the four relief categories for each symptom and for overall relief. Berkowitz found that bismuth subsalicylate was significantly more effective than placebo for each category except bitter/acid taste. When the analysis was done using (1) Two relief categories (none and poor counted as failure, and good and excellent counted as success) and (2) time to good or excellent relief for each symptom, Berkowitz found that bismuth subsalicylate was significantly more effective and provided significantly faster relief than placebo for relief of nausea, fullness, heartburn, belching, and overall relief. There was no statistical difference in relief of stomach pain/cramps, passing gas, and bitter/acid taste. FDA finds that, although all data are not clearly shown in this study, the results support that bismuth subsalicylate is effective in relieving nausea, heartburn, fullness, and belching. FDA notes that the medical definitions of flatulence, eructation, and bloating are defined using the word gas. While "fullness" is not defined in *Stedman's Medical Dictionary* (Ref. 10) or in *Dorland's Illustrated Medical Dictionary* (Ref. 11), Berkowitz combined the term "fullness" with the term "bloating," which refers to abdominal distention from swallowing air or from intestinal gas, and showed that bismuth subsalicylate relieved fullness and bloating.

FDA notes that, in evaluating the consumer study of 285 subjects (Ref. 5) (47 FR 43540 at 43545), the Panel noted that 96 percent of the subjects had at least one of the symptoms of gas (fullness), heartburn (or acid indigestion), or nausea, and that 56

percent [the highest percentage] reported gas as one of their symptoms. Nonetheless, the Panel used the term "fullness" (and not "gas") in its proposed indication for overindulgence drug products containing bismuth subsalicylate (47 FR 43540 at 43558). FDA believes that the Panel also found that bismuth subsalicylate relieves gas due to overindulgence in food and drink, but chose to use the word "fullness" instead in its recommended indications statement. FDA also points out that its current indications statement for OTC antiflatulent drug products containing simethicone in § 332.30(b)(2) states: "(Select one of the following: 'Alleviates' or 'Relieves') (select one or more of the following: 'bloating,' 'pressure,' 'fullness,' or 'stuffed feeling') 'commonly referred to as gas'." Thus, FDA already acknowledges that the term "fullness" encompasses the term "gas."

As the comment noted, the combination of bismuth subsalicylate and simethicone is subject to FDA's combination drug policy (see section II of this document). However, FDA notes that a bismuth subsalicylate-simethicone combination is different than the antacid-simethicone combination that the comment discussed. Simethicone is a monograph ingredient (see § 332.10) for antiflatulent use (to relieve fullness and bloating commonly referred to as gas). Bismuth subsalicylate is not included in the antacid monograph but based on the information and analysis in this document has an antigas (antiflatulent) effect when relieving symptoms of overindulgence in food and drink. This analysis and finding are new information that the comment did not have when it proposed a bismuth subsalicylate-simethicone combination product.

FDA's regulation in § 330.10(a)(4) sets forth the standard for determining whether a combination drug product may be generally recognized as safe and effective and not misbranded. Section 330.10(a)(4)(iv) states that "an OTC drug may combine two or more safe and effective active ingredients and may be generally recognized as safe and effective when each active ingredient makes a contribution to the claimed effect(s) * * *." FDA's "General Guidelines for OTC Drug Combination Products, September 1978" ["Combination Product Guidelines"] (Ref. 1) state that Category I active ingredients from the same therapeutic category ["antiflatulent" in this case] that have the same mechanism of action may be combined in selected circumstances to treat the same symptoms if:

- The combination meets the OTC combination policy in all respects;
- the combination offers some advantage over the active ingredients used alone; and
- the combination is, on a benefit-risk basis, equal to or better than each of the active ingredients used alone at its therapeutic dose.

The "Combination Product Guidelines" (Ref. 1) list similar factors in assessing combination drug products with active ingredients from the same therapeutic category that have different mechanisms of action.

FDA does not have any data on the antigas mechanism of action of bismuth subsalicylate to determine if it is the same or different from that of simethicone. FDA also has not received any data to date comparing the antigas effectiveness of a combination of the two ingredients versus either individual ingredient. Further, FDA is not aware of any combination product containing bismuth subsalicylate and simethicone having been marketed. Therefore, FDA needs data from clinical studies showing that the combination of bismuth subsalicylate and simethicone is equal to or better than [offers some advantage over] each of the individual active ingredients used alone at its therapeutic dose for this antigas use. FDA recommends that anyone interested in conducting such studies submit a protocol and meet with the agency before starting the studies. FDA will evaluate the other data (Refs. 2, 3, and 4) that the comment provided to support this combination product when the clinical effectiveness studies are submitted to FDA.

IV. FDA's Proposed Amendment of the Tentative Final Monograph

Based on the Newsom (Refs. 7 and 9) and Berkowitz (Ref. 8) studies, FDA has tentatively determined that bismuth subsalicylate is safe and effective for OTC use for the relief of upset stomach associated with belching and gas due to overindulgence in food and drink. FDA proposes to amend the definition of "upset stomach due to overindulgence in food and drink" proposed in § 357.903 to add the symptoms "belching" and "gas" and to amend the indications statement for bismuth subsalicylate proposed in § 357.950(b)(2) to add "belching" and "gas" as two additional symptoms that manufacturers may select to include in the labeling of these products.

V. Analysis of Impacts

FDA has examined the impacts of this proposed rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation) in any one year.

FDA believes that this proposed rule is consistent with the principles set out in Executive Order 12866 and in these two statutes. The proposed rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order. The Unfunded Mandates Reform Act of 1995 does not require FDA to prepare a statement of costs and benefits for this proposed rule, because the proposed rule is not expected to result in any 1-year expenditure that would exceed $100 million adjusted for inflation. The current inflation adjusted statutory threshold is about $110 million.

The purpose of this proposed rule is to expand an indications statement for OTC overindulgence drug products that contain bismuth subsalicylate as their active ingredient. The proposal provides manufacturers the option of including two additional symptoms in their product's indications statement. As this additional labeling is optional, manufacturers may elect to implement it whenever they revise product labeling or may elect not to include the additional information at all. FDA is unable to state exactly how many bismuth subsalicylate products have an overindulgence claim because these products may be marketed with other claims (e.g., for diarrhea) and not have an overindulgence claim. FDA's Drug Listing System (DLS) identifies 334 OTC drug products that contain bismuth subsalicylate and are marketed for use

as an antidiarrheal. Some of these products may also have a claim for overindulgence or may want to include a claim for overindulgence. Because these products could be marketed with an overindulgence claim, FDA is counting all such products as potentially affected by this proposed rule. However, because any relabeling resulting from this proposed rule is completely voluntary and can be done when manufacturers are ordering new product labeling, FDA considers any costs resulting from this proposed rule to be negligible. FDA recognizes that frequent labeling redesigns are a recognized cost of doing business in the OTC drug industry. Manufacturers that make voluntary market-driven changes to their labeling can usually do so at a nominal cost. FDA recognizes benefits to both manufacturers and consumers from this proposed labeling change. Manufacturers will have two additional uses for these products to promote to consumers, and consumers will be able to use a single product instead of two products (one for overindulgence and one for gas) to relieve their symptoms resulting from overindulgence in food and drink. FDA did not consider other labeling alternatives.

This analysis shows that FDA has considered the burden to small entities. Therefore, FDA certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities. No further analysis is required under the Regulatory Flexibility Act (5 U.S.C. 605(b)).

VI. Paperwork Reduction Act of 1995

FDA tentatively concludes that the labeling proposed in this document is not subject to review by the Office of Management and Budget because they do not constitute a "collection of information" under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Rather, the proposed labeling is a "public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)).

VII. Environmental Impact

FDA has determined under 21 CFR 25.31(a) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, FDA tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement has not been prepared.

IX. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Three copies of all written comments are to be submitted. Individuals submitting written comments or anyone submitting electronic comments may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

X. Proposed Effective Date

FDA is proposing that any final rule that may be issued based on this proposal be included in the future FM for OTC orally administered drug products for relief of symptoms associated with overindulgence in food and drink and have the same effective date as that FM.

XI. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**), under Docket No. 1982N–0166 unless otherwise noted, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. FDA, "General Guidelines for OTC Drug Combination Products, September 1978," Division of Dockets Management, Docket No. 1978D–0322.

2. The Procter & Gamble Co., "*In-vitro* Foam Reducing Capacity Test: Pepto-Bismol With Simethicone," in C12.

3. Lukacovic, M. F. and K. J. Watters, "Dog Bioavailability Study With Pentagastrin—Pepto-Bismol With Simethicone, PBDB #14," The Procter & Gamble Co., in C12, 1992.

4. Lukacovic, M. F. and K. J. Watters, "Rat Gastric Lesion Study–Pepto-Bismol With Simethicone. EtOH Study—ANTR #53," The Procter & Gamble Co., in C12, 1991.

5. Comment 31–11370, Division of Dockets Management, Docket No. 1978N–0263.

6. "Study #PD 0292–07," The Procter & Gamble Co., in C12.

7. Newsom, J. H., "Evaluation of Bismuth Subsalicylate in Relieving Symptoms of Indigestion," OTC Vol. 170208 (pp. 15–17).

8. Berkowitz, J. M., "Bismuth Subsalicylate in Excessive Alcohol/Food Intake," OTC Vol. 170208 (pp. 11–15).

9. Hailey, F. J. and J. H. Newsom, "Evaluation of Bismuth Subsalicylate in Relieving Symptoms of Indigestion," *Archives of Internal Medicine*, 144:269–272, 1984.

10. *Stedman's Medical Dictionary*, 25th ed., Williams & Wilkins, Baltimore, MD, s.v. "indigestion," 1990.

11. *Dorland's Illustrated Medical Dictionary*, 28th ed., W. B. Saunders Co., Philadelphia, PA, 1994.

List of Subjects in 21 CFR Part 357

Labeling, Over-the-counter drugs, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 357, as proposed in the **Federal Register** of December 24, 1991 (56 FR 66742), be amended as follows:

PART 357—MISCELLANEOUS INTERNAL DRUG PRODUCTS FOR OVER–THE–COUNTER HUMAN USE

1. The authority citation for 21 CFR part 357 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

2. Section 357.903 is amended by revising paragraph (a) to read as follows:

§ 357.903 Definitions.

* * * * *

(a) *Upset stomach due to overindulgence in food and drink.* A condition that occurs as a result of overindulgence in food and drink and consists of a group of symptoms that includes heartburn, nausea, fullness, belching, and gas.

* * * * *

3. Section 357.950 is amended by revising paragraph (b)(2) to read as follows:

§ 357.950 Labeling of drug products for the relief of symptoms of upset stomach due to overindulgence in food and drink.

* * * * *

(b) * * *

(2) "For the relief of upset stomach associated with" (select one or more of the following: "nausea," "heartburn," "fullness," "belching," and "gas") "due to overindulgence in food and drink."

* * * * *

Dated: December 15, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–154 Filed 1–4–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–117969–00]

RIN 1545–BD76

Statutory Mergers and Consolidations

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Amendment of previously proposed regulations and notice of public hearing.

SUMMARY: This document amends previously proposed regulations published in the **Federal Register** on January 24, 2003 (REG–126485–01, 2003–9 I.R.B. 542, 68 FR 3477) by cross-reference to temporary regulations. Those regulations define the term *statutory merger or consolidation* as that term is used in section 368(a)(1)(A). This notice of proposed rulemaking affects corporations engaging in mergers and consolidations and their shareholders. It is being issued concurrently with proposed regulations under sections 358, 367, and 884. (*See* REG–125628–01 in the proposed rulemaking section of this issue of the **Federal Register**).

DATES: Written and electronic comments and requests to speak and outlines of topics to be discussed at the public hearing scheduled for May 19, 2005, to be held in the IRS Auditorium (7th floor) must be received by April 28, 2005.

ADDRESSES: Send submissions to CC:PA:LPD:PR (REG–117969–00), Room 5203, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG–117969–00), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC, or sent electronically, via the IRS Internet site at *http://www.irs.gov/regs* or via the Federal eRulemaking Portal at *http://www.regulations.gov* (IRS–REG–117969–00). The public hearing will be held in the IRS Auditorium (7th floor), Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Vincent Daly, (202) 622–7770; concerning submissions, the hearing, or placement on the building access list to attend the hearing, Robin Jones, (202) 622–7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background and Explanation of Provisions

Before 1934, the term *merger*, as used in the reorganization provisions, included statutory mergers as well as other combinations of corporate entities. In 1934, congress amended the definition of a reorganization to provide separately for *statutory mergers or consolidations* and for the other types of transactions previously included in the definition of a *merger*. There is no indication in the legislative history of the 1934 changes to the definition of reorganization that Congress intended to exclude transactions effected under foreign law.

In 1935, Treasury regulations interpreted the term *statutory merger* under the revised provision to mean a merger or consolidation effected pursuant to the corporation laws of a State or Territory or the District of Columbia. The requirement that the transaction be effected under domestic law remains in place, with minor variations. The Treasury Department and IRS believe that this interpretation is reasonable; nevertheless, the Treasury Department and IRS believe that a reexamination is warranted in light of the purposes of the statute and changes in domestic and foreign law since 1935.

The states have revised their laws to offer a greater variety of business entities and greater flexibility in effecting business combinations. Accordingly, the Treasury Department and IRS thought it advisable to define a merger or consolidation functionally, to supplement the reference to State law. Accordingly, the Treasury Department and IRS developed and proposed such a functional definition in 2003. See Notice of Proposed Rulemaking (REG–126485–01, 2003–9 I.R.B. 542, 68 FR 3477), cross-referencing temporary regulations (TD 9038, 2003–9, I.R.B. 524, 68 FR 3384) (January 24, 2003).

Many foreign jurisdictions now have merger or consolidation statutes that operate in material respects like those of the states, *i.e.*, all assets and liabilities move by operation of law. The Treasury Department and IRS believe that transactions affected pursuant to these statutes should be treated as reorganizations if they satisfy the functional criteria applicable to transactions under domestic statutes.

This document proposes a revised definition of a statutory merger or consolidation. The previously proposed definition of a statutory merger required that it be a transaction effected "pursuant to the laws of the United States or a State or the District of Columbia." See REG–126485–01 (2003–9 I.R.B. 542, 68 FR 3477). The new proposed definition contained in this document replaces the quoted language with "pursuant to the statute or statutes necessary to effect the merger or consolidation." This proposed change would allow a transaction effected pursuant to the statutes of a foreign jurisdiction or of a United States possession to qualify as a statutory merger or consolidation under section 368(a)(1)(A), provided it otherwise qualifies as a reorganization. The phrase *statute or statutes* is not intended to prevent transactions effected pursuant to legislation from qualifying as mergers or consolidations where such legislation is supplemented by administrative or case law.

This notice of proposed rulemaking also proposes to remove § 1.368–2(b)(1)(iii) of the previously proposed regulations. That section imposes limitations on the use of disregarded entities in statutory mergers or consolidations when certain entities are not organized under the laws of the United States or a State or the District of Columbia.

Although this document revises the terms of the proposed definition of a statutory merger or consolidation for purposes of section 368, the provisions of the temporary regulations will remain in effect until this proposal is incorporated in temporary or final regulations after notice and comment.

Section 1.368–2(b)(1)(B)(iv), *Examples 1* and *2* in the previously proposed regulations each specified that one of the parties to the transaction described in the example "is not treated as owning any assets of an entity that is disregarded as an entity separate from its owner for Federal tax purposes." The results in those examples would be the same in each case whether or not a party to the transaction held such assets. See

§ 1.368–2(b)(1)(B)(iv), *Example 3* in the previously proposed regulations. To avoid any possible implication to the contrary, the Treasury Department and IRS propose removal of the sentence specifying that condition from each example. The Treasury Department and IRS are continuing to study other comments received on the earlier proposed regulations.

A notice of proposed rulemaking proposing amendments to the regulations under sections 358, 367, and 884 (including special rules for determining basis and holding period in certain transactions involving one or more foreign corporations) is being published simultaneously with the publication of this notice of proposed rulemaking. See REG–125628–01 in the proposed rulemaking section of this issue of the **Federal Register**.

Proposed Effective Date

These regulations are proposed to apply to transactions occurring after the date final regulations are published in the **Federal Register**.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations. Because the regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Internal Revenue Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written comments (a signed original and eight (8) copies) or electronic comments that are submitted timely to the IRS. The IRS and Treasury Department specifically request comments on the clarity of the proposed regulations and on how they can be made easier to understand. All comments will be available for public inspection and copying.

A public hearing has been scheduled for May 19, 2005 beginning at 10 a.m. in the IRS Auditorium (7th floor), Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC. Due to building security procedures, visitors must enter at the Constitution Avenue entrance. In addition, all visitors must present photo identification to enter the building. Because of access restrictions, visitors will not be admitted beyond the immediate entrance area more than 30 minutes before the hearing starts. For information about having your name placed on the building access list to attend the hearing, see the **FOR FURTHER INFORMATION CONTACT** portion of this preamble.

The rules of 26 CFR 601.601 (a)(3) apply to the hearing. Persons who wish to present oral comments must submit written or electronic comments and an outline of the topics to be discussed and the time to be devoted to each topic (asigned original and eight (8) copies) by April 29, 2005. A period of 10 minutes will be allotted to each person for making comments. An agenda showing the scheduling of the speakers will be prepared after the deadline for receiving outlines has passed. Copies of the agenda will be available free of charge at the hearing.

Drafting Information

The principal author of these regulations is Vincent Daly, Office of the Associate Chief Counsel (Corporate). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 continues to read, in part, as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 2. Paragraph (b)(1) of § 1.368–2 as proposed on January 24, 2003, at 68 FR 3477, is proposed to be revised to read as follows:

§ 1.368–2 Definition of terms.

* * * * *

(b)(1)(i) *Definitions.* The following definitions apply for purposes of this paragraph (b)(1):

(A) *Disregarded entity.* A disregarded entity is a business entity (as defined in § 301.7701–2(a) of this chapter) that is disregarded as an entity separate from its owner for Federal tax purposes. Examples of disregarded entities include a domestic single member limited liability company that does not elect to be classified as a corporation for Federal tax purposes, a corporation (as defined in § 301.7701–2(b) of this chapter) that is a qualified REIT subsidiary (within the meaning of section 856(i)(2)), and a corporation that is a qualified subchapter S subsidiary (within the meaning of section 1361(b)(3)(B)).

(B) *Combining entity.* A combining entity is a business entity that is a corporation (as defined in § 301.7701–2(b) of this chapter) that is not a disregarded entity.

(C) *Combining unit.* A combining unit is composed solely of a combining entity and all disregarded entities, if any, the assets of which are treated as owned by such combining entity for Federal tax purposes.

(ii) *Statutory merger or consolidation generally.* For purposes of section 368(a)(1)(A), a statutory merger or consolidation is a transaction effected pursuant to the statute or statutes necessary to effect the merger or consolidation, in which transaction, as a result of the operation of such statute or statutes, the following events occur simultaneously at the effective time of the transaction—

(A) All of the assets (other than those distributed in the transaction) and liabilities (except to the extent satisfied or discharged in the transaction) of each member of one or more combining units (each a transferor unit) become the assets and liabilities of one or more members of one other combining unit (the transferee unit); and

(B) The combining entity of each transferor unit ceases its separate legal existence for all purposes; provided, however, that this requirement will be satisfied even if, under applicable law, after the effective time of the transaction, the combining entity of the transferor unit (or its officers, directors, or agents) may act or be acted against, or a member of the transferee unit (or its officers, directors, or agents) may act or be acted against in the name of the combining entity of the transferor unit, provided that such actions relate to assets or obligations of the combining entity of the transferor unit that arose, or relate to activities engaged in by such entity, prior to the effective time of the transaction, and such actions are not inconsistent with the requirements of paragraph (b)(1)(ii)(A) of this section.

(iii) *Examples.* The following examples illustrate the rule of paragraph (b)(1) of this section. In each of the examples, except as otherwise provided, each of V, Y, and Z is a C corporation. X is a limited liability company. Except

as otherwise provided, X is wholly owned by Y and is disregarded as an entity separate from Y for Federal tax purposes. The examples are as follows:

Example 1. Divisive transaction pursuant to a merger statute. (i) Under State W law, Z transfers some of its assets and liabilities to Y, retains the remainder of its assets and liabilities, and remains in existence following the transaction. The transaction qualifies as a merger under State W corporate law.

(ii) The transaction does not satisfy the requirements of paragraph (b)(1)(ii)(A) of this section because of all the assets and liabilities of Z, the combining entity of the transferor unit, do not become the assets and liabilities of Y, the combining entity and sole member of the transferee unit. In addition, the transaction does not satisfy the requirements of paragraph (b)(1)(ii)(B) of this section because the separate legal existence of Z does not cease for all purposes. Accordingly, the transaction does not qualify as a statutory merger or consolidation under section 368(a)(1)(A).

Example 2. Merger of a target corporation into a disregarded entity in exchange for stock of the owner. (i) Under State W law, Z merges into X. Pursuant to such law, the following events occur simultaneously at the effective time of the transaction: All of the assets and liabilities of Z become the assets and liabilities of X and Z's separate legal existence ceases for all purposes. In the merger, the Z shareholders exchange their stock of Z for stock of Y.

(ii) The transaction satisfies the requirements of paragraph (b)(1)(ii) of this section because the transaction is effected pursuant to State W law and the following events occur simultaneously at the effective time of the transaction: All of the assets and liabilities of Z, the combining entity and sole member of the transferor unit, become the assets and liabilities of one or more members of the transferee unit that is comprised of Y, the combining entity of the transferee unit, and X, a disregarded entity the assets of which Y is treated as owning for Federal tax purposes, and Z ceases its separate legal existence for all purposes. Accordingly, the transaction qualifies as a statutory merger or consolidation for purposes of section 368(a)(1)(A).

Example 3. Merger of a target S corporation that owns a QSub into a disregarded entity. (i) The facts are the same as in *Example 2*, except that Z is an S corporation and owns all of the stock of U, a QSub.

(ii) The deemed formation by Z of U pursuant to § 1.1361–5(b)(1) (as a consequence of the termination of U's QSub election) is disregarded for Federal income tax purposes. The transaction is treated as a transfer of the assets of U to X, followed by X's transfer of these assets to U in exchange for stock of U. See § 1.1361–5(b)(3), *Example 9*. The transaction will, therefore, satisfy the requirements of paragraph (b)(1)(ii) of this section because the transaction is effected pursuant to State W law and the following events occur simultaneously at the effective time of the transaction: all of the the assets and liabilities of Z and U, the sole members of the transferor unit, become the assets and liabilities of one or more members of the transferee unit that is comprised of Y, the combining entity of the transferee unit, and X, a disregarded entity the assets of which Y is treated as owning for Federal tax purposes, and Z ceases its separate legal existence for all purposes. Moreover, the deemed transfer of the assets of U in exchange for U stock does not cause the transaction to fail to qualify as a statutory merger or consolidation. See section 368(a)(2)(C). Accordingly, the transaction qualifies as a statutory merger or consolidation for purposes of section 368(a)(1)(A).

Example 4. Triangular merger of a target corporation into a disregarded entity. (i) The facts are the same as in *Example 2*, except that V owns 100 percent of the outstanding stock of Y and, in the merger of Z into X, the Z shareholders exchange their stock of Z for stock of V. In the transaction, Z transfers substantially all of its properties to X.

(ii) The transactions is not prevented from qualifying as a statutory merger or consolidation under section 368(a)(1)(A), provided the requirements of section 368(a)(2)(D) are satisfied. Because the assets of X are treated for Federal tax purposes as the assets of Y, Y will be treated as acquiring substantially all of the properties of Z in the merger for purposes of determining whether the merger satisfies the requirements of section 368(a)(2)(D). As a result, the Z shareholders that receive stock of V will be treated as receiving stock of a corporation that is in control of Y, the combining entity of the transferee unit that is the acquiring corporation for purposes of section 368(a)(2)(D). Accordingly, the merger will satisfy the requirements of section 368(a)(2)(D).

Example 5. Merger of a target corporation into a disregarded entity owned by a partnership. (i) The facts are the same as in *Example 2*, except that Y is organized as a partnership under the laws of State W and is classified as a partnership for Federal tax purposes.

(ii) The transaction does not satisfy the requirements of paragraph (b)(1)(ii)(A) of this section. All of the assets and liabilities of Z, the combining entity and sole member of the transferor unit, do not become the assets and liabilities of one or more members of a transferee unit because neither X nor Y qualifies as a combining entity. Accordingly, the transaction cannot qualify as a statutory merger or consolidation for purposes of section 368(a)(1)(A).

Example 6. Merger of a disregarded entity into a corporation. (i) Under State W law, X merges into Z. Pursuant to such law, the following events occur simultaneously at the effective time of the transaction: All of the assets and liabilities of X (but not the assets and liabilities of Y other than those of X) become the assets and liabilities of Z and X's separate legal existence ceases for all purposes.

(ii) The transaction does not satisfy the requirements of paragraph (b)(1)(ii)(A) of this section because all of the assets and liabilities of a transferor unit do not become the assets and liabilities of one or more members of the transferee unit. The transaction also does not satisfy the requirements of paragraph (b)(12)(ii)(B) of this section because X does not qualify as a combining entity. Accordingly, the transaction cannot qualify as a statutory merger or consolidation for purposes of section 368(a)(1)(A).

Example 7. Merger of a corporation into a disregarded entity in exchange for interests in the disregarded entity. (i) Under State W law, Z merges into X. Pursuant to such law, the following events occur simultaneously at the effective time of the transaction: All of the assets and liabilities of Z become the assets and liabilities of X and Z's separate legal existence ceases for all purposes. In the merger of Z into X, the Z shareholders exchange their stock of Z for interests in X so that, immediately after the merger, X is not disregarded as an entity separate from Y for Federal tax purposes. Following the merger, pursuant to § 301.7701–3(b)(1)(i) of this chapter, X is classified as a partnership for Federal tax purposes. (ii) The transaction does not satisfy the requirements of paragraph (b)(1)(ii)(A) of this section because immediately after the merger X is not disregarded as an entity separate from Y and, consequently, all of the assets and liabilities of Z, the combining entity of the transferor unit, do not become the assets and liabilities of one or more members of a transferee unit. Accordingly, the transaction cannot qualify as a statutory merger or consolidation for purposes of section 368(a)(1)(A).

Example 8. Merger transaction preceded by distribution. (i) Z operates two unrelated businesses, Business P and Business Q, each of which represents 50 percent of the value of the assets of Z. Y desires to acquire and continue operating Business P, but does not want to acquire Business Q. Pursuant to a single plan, Z sells Business Q for cash to parties unrelated to Z and Y in a taxable transaction, and then distributes the proceeds of the sale pro rata to its shareholders. Then, pursuant to State W law, Z merges into Y. Pursuant to such law, the following events occur simultaneously at the effective time of the transaction: All of the assets and liabilities of Z related to Business P become the assets and liabilities of Y and Z's separate legal existence ceases for all purposes. In the merger, the Z shareholders exchange their Z stock for Y stock.

(ii) The transaction satisfies the requirements of paragraph (b)(1)(ii) of this section because the transaction is effected pursuant to State W law and the

following events occur simultaneously at the effective time of the transaction: All of the assets and liabilities of Z, the combining entity and sole member of the transferor unit, become the assets and liabilities of Y, the combining entity and sole member of the transferee unit, and Z ceases its separate legal existence for all purposes. Accordingly, the transaction qualifies as a statutory merger or consolidation for purposes of section 368(a)(1)(A).

Example 9. Transaction effected pursuant to foreign statutes. (i) Z and Y are entities organized under the laws of Country Q and classified as corporations for Federal tax purposes. Z and Y combine. Pursuant to statutes of Country Q the following events occur simultaneously: All of the assets and liabilities of Z become the assets and liabilities of Y and Z's separate legal existence ceases for all purposes.

(ii) The transaction satisfies the requirements of paragraphs (b)(1)(ii) of this section because the transaction is effected pursuant to statutes of Country Q and the following events occur simultaneously at the effective time of the transaction: All of the assets and liabilities of Z, the combining entity of the transferor unit, become the assets and liabilities of Y, the combining entity and sole member of the transferee unit, and Z ceases its separate legal existence for all purposes. Accordingly, the transaction qualifies as a statutory merger or consolidation for purposes of section 368(a)(1)(A).

(iv) *Effective dates.* This paragraph (b)(1) applies to transactions occurring after the date these regulations are published as final regulations in the **Federal Register**. For rules regarding statutory mergers or consolidations on or after January 24, 2003, and before these regulations are published as final regulations in the **Federal Register**, see § 1.368–2T(b)(1). For rules regarding statutory mergers or consolidations before January 24, 2003, see § 1.368–2(b)(1) as it applies before January 24, 2003 (see 26 CFR part 1, revised April 1, 2002).

* * * * *

Mark E. Matthews,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 05–202 Filed 1–4–05; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–125628–01]

RIN 1545–BA65

Revision of Income Tax Regulations Under Sections 358, 367, 884, and 6038B Dealing With Statutory Mergers or Consolidations Under Section 368(a)(1)(A) Involving One or More Foreign Corporations

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking and notice of public hearing.

SUMMARY: This document contains proposed regulations amending the income tax regulations under various provisions of the Internal Revenue Code (Code) to account for statutory mergers and consolidations under section 368(a)(1)(A) (including reorganizations described in section 368(a)(2)(D) and (E)) involving one or more foreign corporations. These proposed regulations are issued concurrently with proposed regulations (REG–117969–00) that would amend the definition of a reorganization under section 368(a)(1)(A) to include certain statutory mergers or consolidations effected pursuant to foreign law.

DATES: Written and electronic comments and requests to speak and outlines of topics to be discussed at the public hearing scheduled for May 19, 2005, at 10 a.m. must be received by April 28, 2005.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–125628–01), room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG–125628–01), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC, or sent electronically, via the IRS Internet site at: *http://www.irs.gov/regs* or via the Federal eRulemaking Portal at *http://www.regulations.gov* (IRS and REG–125628–01). The public hearing will be held in the Auditorium, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Robert W. Lorence, Jr., (202) 622–3860; concerning submissions, the hearing, or placement on the building access list to attend the hearing, Guy Traynor, (202) 622–7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in this notice of proposed rulemaking has been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act (44 U.S.C. 3507(d)). Comments on the collection of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, SE:W:CAR:MP:T:T:SP Washington, DC 20224. Comments on the collection of information should be received no later than March 7, 2005. Comments are specifically requested concerning:

Whether the proposed collection of information is necessary for the proper performance of the functions of the IRS, including whether the information will have practical utility;

The accuracy of the estimated burden associated with the proposed collection of information (see below);

How the quality, utility, and clarity of the information to be collected may be enhanced;

How the burden of complying with the proposed collection of information can be minimized, including through the application of automated collection techniques or other forms of information technology; and

Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

The collection of information in this proposed regulation is in § 1.367(a)–3(d)(2)(vi)(B)(*1*)(*ii*). This information is required to inform the IRS of a domestic corporation that is claiming an exception from the application of section 367(a) and (d) to certain transfers of property to a foreign corporation that is re-transferred by the foreign corporation to a domestic corporation controlled by the foreign corporation. The information is in the form of a statement attached to the domestic corporation's U.S. income tax return for the year of the transfer certifying that if the foreign corporation disposes of the stock of the domestic controlled corporation with a tax avoidance purpose, the domestic corporation will file an income tax return (or amended return, as the case may be) reporting gain. The collection of

information is mandatory. The likely respondents are domestic corporations.

Estimated total annual reporting burden: 50 hours.

Estimated average annual burden hours per respondent: 1 hour.

Estimated number of respondents: 50.

Estimated annual frequency of responses: on occasion.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Background

Section 368(a)(1)(A) defines a reorganization to include a statutory merger or consolidation (A reorganization). For transactions completed before January 24, 2003, regulations under section 368(a)(1)(A) provided that a reorganization was a merger or consolidation effected pursuant to the corporation law of the United States or a State or Territory or the District of Columbia. See 1.368–2(b)(1), as in effect before January 24, 2003.

On January 24, 2003, the IRS and the Treasury Department issued proposed regulations (REG–126485–01, 2003–9 I.R.B. 542, 66 FR 57400) and temporary regulations (TD 9038, 2003–9 I.R.B. 524, 68 FR 3384), revising the definition of a statutory merger or consolidation. The proposed and temporary regulations define a statutory merger or consolidation in a manner intended to ensure that those transactions are not divisive in nature. Accordingly, the regulations generally require that all the assets and liabilities of the merged corporation (other than assets distributed or liabilities discharged in the transaction) are transferred to the acquiring corporation and that the separate legal identity of the merged corporation ceases to exist in the transaction.

Pursuant to a notice of proposed rulemaking (proposed section 368 regulations) published contemporaneously with this document, the IRS and Treasury are proposing further revisions to the definition of a statutory merger or consolidation to take into account those transactions effected pursuant to foreign law. The proposed section 368 regulations amend the 2003 proposed regulations and provide that an A reorganization may occur, if certain conditions are satisfied, pursuant to the laws of a foreign jurisdiction, including a U.S. possession.

In light of this change, this document contains proposed amendments to the regulations under certain international Code provisions (sections 367, 884, and 6038B) to account for statutory mergers and consolidations involving one or more foreign corporations. Current international tax regulations are premised on an A reorganization being limited to a statutory merger or consolidation involving domestic corporations effected pursuant to domestic law. See, *e.g.*, Rev. Rul. 57–465 (1957–2 C.B. 250). As a result, conforming changes must be made to these international tax regulations to ensure that they apply appropriately to statutory mergers and consolidations effected pursuant to foreign law. The proposed regulations also modify the section 367(a) and (b) regulations to address several other related issues.

Explanation of Provisions

A. Basis and Holding Period Rules

The proposed regulations provide basis and holding period rules for certain transactions involving foreign corporations with section 1248 shareholders in order to preserve relevant section 1248 amounts. A section 1248 shareholder is a U.S. person that satisfies the ownership requirements of section 1248(a) with respect to a foreign corporation. Section 1248(a) applies to a U.S. person that owns stock (directly, indirectly, or constructively) with 10 percent or more of the voting power in the foreign corporation at any time during the 5-year period ending on the sale or exchange of the stock when the foreign corporation was a controlled foreign corporation (CFC). Gain recognized by a section 1248 shareholder on the sale or exchange of stock of the foreign corporation is included in gross income as a dividend to the extent of the earnings and profits of the foreign corporation that are attributable to the stock sold or exchanged and that were accumulated while the stock was held by the U.S. person when the foreign corporation was a CFC (the section 1248 amount).

The IRS and Treasury believe that it is important to preserve section 1248 amounts in certain nonrecognition exchanges of foreign corporation stock. Preservation of section 1248 amounts is a function of the holding period and basis in the stock of the foreign corporation being exchanged. One of the underlying policies of section 367(b) is the preservation of the potential application of section 1248 in connection with certain nonrecognition exchanges. H. Rep. No. 94–658, 94th Cong., 1st Sess., at 242 (Nov. 12, 1975). These proposed regulations provide basis and holding period rules to preserve section 1248 amounts in the context of certain section 354 exchanges and certain triangular reorganizations.

The basis and holding period rules of the proposed regulations also apply to a foreign corporate shareholder of a foreign corporation that is a party to the reorganization, provided that the foreign corporate shareholder has at least one U.S. person that is a section 1248 shareholder with respect to the foreign corporate shareholder and to the foreign corporation. This rule is necessary to preserve application of section 964(e) to the foreign corporate shareholder with respect to lower-tier foreign corporations. Under section 964(e), if a CFC sells or exchanges stock in another foreign corporation, gain recognized on the sale or exchange is included in the income of the CFC as a dividend to the same extent that it would have been included under section 1248(a) if the CFC were a U.S. person. Such dividend income may be treated as subpart F income that is included in the income of U.S. shareholders of the CFC.

1. Section 354 Exchanges

The proposed regulations apply to certain section 354 exchanges involving foreign corporations, including exchanges of multiple blocks of stock. The proposed regulations preserve the bases and holding periods in different blocks of stock in certain foreign target corporations by requiring the exchanging shareholder to establish the particular shares of stock that were received in exchange for shares of a particular block of target stock. If the exchanging shareholder cannot establish the particular shares of target stock that were received for shares of a particular block of stock, then the shareholder must designate which shares of stock were received in exchange for shares of a particular block of stock, provided that the designation is consistent with the terms of the exchange. These tracing methods are used to determine the resulting tax consequences when stock received in a nonrecognition exchange is subsequently sold or otherwise exchanged. If the exchanging shareholder cannot establish, and does not designate, the particular shares received, the shareholder is treated as selling or otherwise exchanging a share received in a nonrecognition exchange

for a share that was purchased or acquired at the earliest time.

The IRS and Treasury recently published proposed section 358 regulations (REG–116564–03) that determine the basis of stock or securities received in section 354 exchanges (proposed section 358 regulations). The proposed section 358 regulations generally provide that the basis of each share of stock or security received in an exchange to which section 354, 355, or 356 applies will be the same as the basis of the share of stock or security exchanged therefor. For these purposes, the determination of which share of stock or security is received in exchange for a particular share of stock or security is made in accordance with the terms of the exchange or distribution.

These proposed regulations apply the principles of the proposed section 358 regulations to certain exchanges of stock of a foreign corporation by either a section 1248 shareholder, or a foreign corporate shareholder where at least one U.S. person is a section 1248 shareholder with respect to such foreign corporate shareholder and to the foreign corporation whose shares are exchanged (collectively and individually, section 367(b) shareholder), to ensure the preservation of section 1248 amounts. The proposed regulations also include specific guidance on the shareholder's holding period in the stock received in the section 354 exchange. The proposed regulations do not, however, apply to distributions described in section 355.

Consistent with the proposed section 358 regulations, the proposed regulations hereunder would not apply to section 351 exchanges or to exchanges to which both section 351 and section 354 (or section 356) apply, if, in addition to stock being received, other property is received or liabilities are assumed. This limitation is intended to prevent a conflict between the rules for determining basis in a section 351 exchange (including the application of section 357(c)) and the rules proposed in this document. The IRS and Treasury are considering approaches for the preservation of section 1248 amounts in section 351 transactions in which liabilities are assumed or other property is received, and comments are requested in this regard.

In addition, the IRS and Treasury are considering developing specific rules for situations in which stock of the foreign acquiring corporation is not issued in the exchange (for example, when the exchanging shareholder owns all the stock of the foreign acquiring corporation). One possible approach may be for each existing share of stock in that corporation to be divided into portions to account for the different basis and holding periods of the stock of the foreign acquiring corporation and the stock of the acquired corporation in order to preserve section 1248 amounts. Comments are requested regarding this approach or possible alternative approaches.

2. Triangular Reorganizations

The proposed regulations provide special basis and holding period rules for triangular reorganizations where the merging or surviving corporation is a foreign corporation with a section 367(b) shareholder. These rules apply to reorganizations described in section 368(a)(1)(A) and (a)(2)(D) (forward triangular merger) and to parenthetical section 368(a)(1)(C) reorganizations. In these transactions, the surviving corporation (S) acquires substantially all the assets of the acquired corporation (T), and the T shareholders exchange their T stock for stock of the corporation (P) that is in control (within the meaning of section 368(c)) of S. These rules also apply to reorganizations described in section 368(a)(1)(A) and (a)(2)(E) (reverse triangular merger). In a reverse triangular merger, S, a controlled subsidiary of P, merges into T, the surviving corporation, and the T shareholders exchange their T stock for stock of P.

Under current regulations, in a forward triangular merger or a parenthetical C reorganization, P's basis in its S stock is adjusted as if P had acquired the T assets directly from T in a section 362(b) exchange and then had transferred the T assets to S in a transaction in which P's basis in S stock is determined under section 358. See § 1.358–6(c)(1) (commonly referred to as the "over-the-top" basis rules). Under current regulations, in a reverse triangular merger, P's basis in the T stock it receives immediately after the transaction is equal to its basis in its S stock immediately before the transaction adjusted as if T had merged into S in a forward triangular merger and the over-the-top basis rules had applied. See § 1.358–6(c)(2). If a reverse triangular merger also qualifies as a section 351 transfer or a section 368(a)(1)(B) reorganization, P can determine its basis in its S stock either by using the over-the-top basis rules as described in the prior sentence or by treating P as if it had acquired the T stock from the former shareholders of T in a transaction in which basis is determined under section 362(b) (carryover stock basis).

The IRS and Treasury are concerned that, in certain exchanges involving foreign corporations, application of the over-the-top basis rules would not properly preserve the section 1248 or 964(e) amounts with respect to the stock of S or T. The proposed regulations provide that, in determining the stock basis of the surviving corporation in certain triangular reorganizations, outside stock basis will be used instead of inside asset basis pursuant to § 1.358–6(c). For example, in the case of a forward triangular merger (or a parenthetical C reorganization), where P is a domestic corporation, S is a foreign corporation, T is a foreign corporation, and T has a section 1248 shareholder, the basis and holding period in the T stock, not the T assets, are used to determine P's basis in the S stock. The same rules apply to certain reverse triangular mergers, where S merges into T with T surviving. In that case, P's basis in the T stock immediately after the transaction would reflect the basis and holding period of the T stock instead of the T assets.

Under this stock basis approach for triangular reorganizations, the proposed regulations provide for a divided basis and holding period in each share of stock in the surviving corporation to reflect the relevant section 1248 amounts in the S stock and T stock. In particular, each share of S stock in a forward triangular merger, and each share of T stock in a reverse triangular merger, where P is a section 367(b) shareholder immediately after the transaction, is divided into portions reflecting the basis and holding period of the S stock and the T stock before the transaction. However, the proposed regulations contain a *de minimis* exception to this rule. Under this exception, if the value of the S stock immediately before the transaction is *de minimis* (for example, where S is a corporation formed to facilitate the transaction), then each share of the surviving corporation is not divided; instead, the basis of the S stock is added to the basis of the stock of the surviving corporation held by P. The value of the S stock would be *de minimis* for this purpose if it is less than 1 percent of the value of the surviving corporation (S or T) immediately after the transaction.

If there are two or more blocks of stock in T or S held by a section 367(b) shareholder immediately before the transaction, then each share of the surviving corporation (S or T) is further divided to account for each block of stock. If two or more blocks of stock are held by one or more shareholders that are not section 367(b) shareholders, then shares in these blocks are aggregated into one divided portion for basis purposes. If none of the S or T shareholders is a section 367(b)

shareholder, then the over-the-top basis rules of § 1.358–6 apply instead of the rules in these proposed regulations.

The proposed regulations provide special rules when stock of the surviving corporation has a divided basis and holding period. Earnings and profits accumulated prior to the reorganization are attributed to a divided portion of a share of stock based on the block of stock whose basis and holding period the divided portion reflects. Post-reorganization earnings and profits are attributed to each divided share of stock pursuant to section 1248 and the regulations thereunder. The amount of earnings and profits attributed to a divided share of stock pursuant to section 1248 are further attributed to a divided portion of such share of stock based on its fair market value in relation to the other divided portions. Finally, shares of stock are no longer divided into separate portions if section 1248 or 964(e) becomes inapplicable to a subsequent sale or exchange of the stock.

The special basis rules in these proposed regulations apply to all triangular reorganizations where T has at least one section 367(b) shareholder, even if such shareholders own less than a controlling interest in T. The IRS and Treasury are considering whether the current basis rules of § 1.358–6 should apply in cases where section 367(b) shareholders do not own a substantial percentage of the stock of T, or whether taxpayers should be permitted to elect to apply the current basis rules under § 1.358–6 to determine P's basis in the stock of the surviving corporation (S or T), provided that all section 367(b) shareholders of T include in income the section 1248 amounts with respect to the stock exchanged. Comments are requested in this regard.

The use of stock basis to determine P's basis in the surviving corporation also presents administrative concerns when a portion of the stock of T is widely held. In the case of a reorganization described in section 368(a)(1)(B), which presents similar issues, Rev. Proc. 81–70 (1980–2 C.B. 729) provides that statistical sampling techniques, if appropriate, are permitted to determine the basis of stock received by the acquiring corporation. In this regard, the IRS and Treasury recently have requested comments whether Rev. Proc. 81–70 should be revised to reflect changes in the marketplace since its publication. See Notice 2004–44 (2004–28 I.R.B. 32). Comments are requested on expanding this guidance to apply under the proposed regulations, for example in cases where blocks of T stock are held by persons that are not section 367(b) shareholders and such shares are aggregated into a single divided portion for basis and holding period purposes.

B. Exceptions to the Application of Section 367(a)

Under section 367(a), a U.S. person recognizes gain, but not loss, on the transfer of property to a foreign corporation in an exchange described in section 351, 354, 356, or 361, unless an exception applies. Section 367(a), however, does not apply to a section 354 exchange by a U.S. person of: (1) Stock of a foreign corporation in a section 368(a)(1)(E) reorganization; or (2) stock of a domestic or foreign corporation for stock of a foreign corporation in an asset reorganization described in section 368(a)(1)(C), (D), or (F) that is not treated as an indirect stock transfer under § 1.367(a)–3(a).

The proposed regulations amend § 1.367(a)-3(a) so that this exception to the application of section 367(a) also applies to A reorganizations (including forward and reverse triangular mergers). In addition, the proposed regulations clarify that § 1.367(a)-3(a) applies to exchanges described in section 356, as well as in section 354. Section 356 applies to an exchange that would qualify as a section 354 exchange except for the fact that money or other property is received in the exchange.

Taxpayers have questioned why the exception to the application of section 367(a) in § 1.367(a)-3(a) includes exchanges of stock but not exchanges of securities in section 368(a)(1)(E) reorganizations and certain asset reorganizations. The IRS and Treasury believe that it is appropriate to provide comparable treatment for exchanges of securities in this context. Accordingly, Notice 2005–6 (2005–5 IRB), published contemporaneously with these proposed regulations, announces that the IRS and Treasury intend to amend § 1.367(a)-3(a) to apply the exception from section 367(a) to exchanges of stock or securities. Notice 2005–6 provides that the applicable date of the amendment will be January 5, 2005.

The proposed regulations also provide rules concerning the application of section 367(a) to reverse triangular mergers, where stock of P, a corporation that controls the merging corporation S, is treated as transferred (along with any other property of S) to the surviving corporation T in a section 361 transfer. If S is a domestic corporation and T is a foreign corporation, section 367(a) applies to the transfer by S of the P stock to T, unless an exception applies.

The IRS and Treasury believe that, if the stock of P is provided to S pursuant to the plan of reorganization, the section 361 transfer of the P stock from S to T should not be subject to section 367(a), and the proposed regulations so provide. If P does not provide its stock to S pursuant to the plan of reorganization, then the P stock will be treated as property of S and the transfer of such stock will be subject to section 367(a).

The IRS and Treasury intend to amend the regulations under section 6038B to conform with the changes made in these regulations.

C. Concurrent Application of Section 367(a) and (b)

The proposed regulations modify the current application of section 367(a) and (b) to transactions that require the inclusion in income of the all earnings and profits amount under section 367(b). Section 1.367(a)-3(b)(2) provides rules for the concurrent application of section 367(a) and (b) to transfers of stock of a foreign corporation. This may occur, for example, when a U.S. shareholder exchanges stock of a foreign corporation (foreign acquired corporation) for stock of another foreign corporation (foreign acquiring corporation). See § 1.367(a)-3(b)(1). It may also occur when an acquiring corporation (foreign or domestic) acquires the assets of a foreign acquired corporation, and the U.S. shareholder exchanges stock of the foreign acquired corporation for stock of the foreign parent of the acquiring corporation in a triangular reorganization.

The U.S. person's exchange of stock of the foreign acquired corporation for stock of either the foreign acquiring corporation or the foreign parent is subject to section 367(a). See § 1.367(a)-3(b) and (d). If the exchanging U.S. shareholder owns 5 percent or more (by vote or value) of the stock of the foreign acquiring corporation or the foreign parent immediately after the exchange, the shareholder recognizes gain, if any, under section 367(a), unless the shareholder enters into a gain recognition agreement as provided in § 1.367(a)-8. If the exchanging shareholder is not a 5-percent shareholder, then the exchanging shareholder does not recognize gain, if any, on the exchange.

The U.S. shareholder's exchange described above also may be subject to section 367(b). If the exchanging U.S. shareholder is a section 1248 shareholder of the foreign acquired corporation, and the stock of the foreign acquiring corporation (or its foreign parent corporation) is not stock in a corporation that is a CFC as to which the U.S. shareholder is a section 1248

shareholder immediately after the exchange, then the exchanging shareholder must include in income the section 1248 amount with respect to the stock exchanged. See § 1.367(b)–4. If, instead, a domestic acquiring corporation acquires the assets of a foreign acquired corporation, and the U.S. shareholder exchanges stock of the foreign acquired corporation for stock of the foreign parent of the acquiring corporation in a triangular reorganization, then the exchanging shareholder must include in income the all earnings and profits amount with respect to the stock of the acquired corporation. See § 1.367(b)–3. Unlike the section 1248 amount, the all earnings and profits amount is not limited by the shareholder's gain inherent in the stock of the foreign acquired corporation.

In cases where section 367(a) and (b) apply concurrently to a transaction, existing § 1.367(a)–3(b)(2) provides that section 367(b) will not apply if the transfer is taxable under section 367(a). If the transfer is taxable under section 367(a), the exchanging U.S. shareholder will recognize gain inherent in the exchanged stock (subject to recharacterization as dividend income under section 1248). If the transfer is not taxable under section 367(a), because the exchanging U.S. shareholder either is not a 5-percent shareholder or enters into a gain recognition agreement, then section 367(b) applies and the exchange is subject to either § 1.367(b)–3 or 1.367(b)–4 at the shareholder level.

Questions with respect to the concurrent application of section 367(a) and (b) have arisen in situations that otherwise would require inclusion of the all earnings and profits amount under § 1.367(b)–3. If the all earnings and profits amount is greater than the section 367(a) gain with respect to the stock of the foreign acquired corporation, under current law the exchanging shareholder effectively may elect to be taxed on the lesser amount of gain under section 367(a) simply by failing to file a gain recognition agreement. In that case, section 367(b) would not apply and the shareholder would avoid inclusion in income of the greater all earnings and profits amount.

The ability to elect to recognize the lesser gain inherent in the stock exchanged in such cases is inconsistent with the policies of section 367(b) that apply to inbound transactions, including preventing conversion of tax deferral into tax forgiveness and ensuring that the domestic acquiring corporation's section 381 carryover basis reflects an after-tax amount. Accordingly, the IRS and Treasury believe that the all earnings and profits amount provisions under § 1.367(b)–3 should not operate electively in these cases. The proposed regulations require that, for exchanges subject to § 1.367(b)–3 and section 367(a), section 367(b) would apply before section 367(a). In that case, inclusion of the all earnings and profits amount would increase the exchanging shareholder's stock basis for purposes of computing the shareholder's gain under section 367(a). Thus, if the all earnings and profits amount exceeds the inherent gain in the exchanged stock, gain is not recognized under section 367(a). If the transaction does not involve inclusion of the all earnings and profits amount (for example, if § 1.367(b)–4 applies), the existing ordering rules continue to apply.

D. Parenthetical Section 368(a)(1)(B) Reorganizations

In a parenthetical reorganization under section 368(a)(1)(B), if a U.S. shareholder exchanges stock of an acquired corporation for voting stock of a foreign corporation that controls (within the meaning of section 368(c)) the acquiring corporation, the U.S. shareholder is treated as making an indirect transfer of stock of the acquired corporation to the foreign controlling corporation in a transfer subject to section 367(a). See § 1.367(a)–3(d)(1)(iii). This result occurs even if the acquiring corporation is domestic. If the U.S. shareholder owns five percent or more (by vote or value) of the stock of the foreign controlling corporation, the shareholder must recognize gain inherent in the exchanged stock, unless a gain recognition agreement is filed. A gain recognition agreement filed with respect to the transfer may be triggered (and gain on the initial transfer of stock will be recognized) if the foreign controlling corporation disposes of the stock of the acquiring corporation, or the acquiring corporation disposes of the stock of the acquired corporation, within 5 years of the initial transfer. See § 1.367(a)–3(d)(2)(ii).

The proposed regulations revise the indirect stock transfer rules to include triangular section 368(a)(1)(B) reorganizations in which a U.S. shareholder exchanges stock of the acquired corporation for voting stock of a domestic corporation that controls a foreign acquiring corporation. In such a case, the gain recognition agreement may be triggered if the domestic controlling corporation disposes of the stock of the foreign acquiring corporation, or the foreign acquiring corporation disposes of the stock of the acquired corporation, within 5 years of the initial transfer.

E. Transfers of Assets Following Certain Asset Reorganizations

If a U.S. shareholder exchanges stock or securities of an acquired corporation for stock or securities of a foreign acquiring corporation in a reorganization described in section 368(a)(1)(C), and the foreign acquiring corporation transfers all or part of the assets of the acquired corporation to a subsidiary controlled (within the meaning of section 368(c)) by the foreign acquiring corporation in a transaction described in section 368(a)(2)(C), the U.S. shareholder is treated, for purposes of section 367(a), as transferring the stock of the acquired corporation to the foreign acquiring corporation to the extent of the assets transferred to the controlled subsidiary. § 1.367(a)–3(d)(1)(v). Section 368(a)(2)(C) provides that a transaction otherwise qualifying as a reorganization under section 368(a)(1)(A), (B), (C), and (G) will not be disqualified because all or part of the assets or stock acquired in the transaction are transferred to a corporation controlled by the acquiring corporation.

On August 16, 2004, the IRS and Treasury issued proposed regulations under § 1.368–2(k) that permit assets or stock acquired in any reorganization under section 368(a)(1) to be transferred to a corporation controlled by the acquiring corporation without disqualifying the reorganization. Prior to these proposed regulations, the IRS and Treasury issued Rev. Rul. 2002–85 (2002–2 C.B. 986) which extended this treatment to section 368(a)(1)(D) reorganizations. Notice 2002–77 (2002–2 C.B. 997) issued contemporaneously with Rev. Rul. 2002–85, provided that § 1.367(a)–3(d)(1)(v) would be amended to treat transactions described in Rev. Rul. 2002–85 as indirect stock transfers, if the transfer of assets by the acquiring corporation to its controlled subsidiary occurred pursuant to the plan of reorganization.

The effect of the proposed regulations under § 1.368–2(k) is to permit transfers of assets or stock to a controlled subsidiary in reorganizations not specifically identified or mentioned in section 368(a)(2)(C) (section 368(a)(1)(D) and (F) reorganizations). The proposed regulations amend the indirect stock transfer rules to conform to the changes in the section 368 regulations. As a result, the proposed regulations provide that the transfer of assets to a controlled subsidiary subsequent to an asset reorganization under section 368(a)(1) would constitute an indirect transfer of

stock, provided the transfer of assets by the foreign acquiring corporation to its controlled subsidiary occurs as part of the same transaction.

F. Indirect Transfers Involving a Change in Domestic or Foreign Status of Acquired Corporation

As indicated above, under existing § 1.367(a)–3(d)(1)(v), a U.S. shareholder of an acquired corporation is treated as transferring the stock of the acquired corporation to the foreign acquiring corporation to the extent of the assets transferred to the controlled subsidiary. Thus, if the acquired corporation is foreign, the U.S. shareholder is treated as transferring stock of a foreign corporation to the foreign acquiring corporation in a transaction that is subject to the § 1.367(a)–3(b) stock transfer rules. If the acquired corporation is domestic, the U.S. shareholder is treated as transferring stock of a domestic corporation to the foreign acquiring corporation in a transaction that is subject to § 1.367(a)–3(c). This deemed transfer of domestic stock prevails even if the controlled subsidiary is foreign. Similar rules apply to parenthetical C reorganizations.

Some commentators have suggested that the determination of whether domestic or foreign stock is deemed transferred should be based on the status of the controlled subsidiary, rather than the status of the acquired corporation. Under this approach, if the acquired corporation were domestic and the controlled subsidiary were foreign, the U.S. shareholders would be deemed to transfer foreign corporation stock subject to § 1.367(a)–3(b), rather than domestic corporation stock subject to § 1.367(a)–3(c). The IRS and Treasury believe that, consistent with the framework of the current regulations, it is appropriate for the rules to continue to apply based on the stock that is owned and exchanged by the U.S. person in the transaction (rather than on the stock of the controlled subsidiary). The IRS and Treasury are considering the application of §§ 1.367(a)–3(b), 1.367(a)–3(c), and 1.367(a)–8 to situations where the foreign acquiring corporation transfers assets of the acquired corporation to multiple controlled subsidiaries (including both domestic and foreign subsidiaries), comments are requested in this regard.

G. Coordination of the Indirect Stock Transfer Rules and the Asset Transfer Rules

In the case of an indirect stock transfer that also involves a transfer of assets by a domestic corporation to a foreign corporation, § 1.367(a)–3(d)(2)(vi) generally provides that section 367(a) and (d) apply to the transfer of assets prior to application of the indirect stock transfer rules. However, section 367(a) does not apply to such transfers to the extent that the foreign acquiring corporation transfers the assets received in the asset transfer to a domestic corporation controlled (within the meaning of section 368(c)) by the foreign acquiring corporation in a transfer described in section 368(a)(2)(C) or in a transfer described in section 351, provided the domestic transferee's basis in the assets is no greater than the basis that the domestic acquired corporation had in such assets. The initial asset transfer to the foreign corporation is not subject to section 367(a) in such cases because the assets re-transferred to the domestic corporation remain subject to U.S. corporate tax.

The IRS and Treasury are concerned that asset reorganizations subject to this coordination rule may be used to facilitate corporate inversion transactions. An inversion generally involves a U.S. multinational corporation reincorporating outside the United States for tax purposes (either as a foreign corporation or as a subsidiary of a new foreign corporation). The IRS and Treasury also are concerned that the coordination rule might be used to facilitate divisive transactions. The proposed regulations address both of these concerns by modifying the scope of the coordination rule.

The revised coordination rule operates as follows. Section 367(a) and (d) generally apply to the transfer of assets to a foreign corporation even if the foreign corporation transfers all or part of the assets received to a controlled domestic corporation. This general rule, however, is subject to two exceptions which do not require income recognition under section 367(a) and (d) on the transfer of assets to the foreign corporation to the extent that assets are re-transferred to the domestic controlled corporation.

The first exception applies if the domestic acquired corporation is controlled (within the meaning of section 368(c)) by 5 or fewer domestic corporations, appropriate basis adjustments as provided in section 367(a)(5) are made to the stock of the foreign acquiring corporation, and any other conditions provided in regulations under section 367(a)(5) are satisfied. Although there currently are no regulations under section 367(a)(5), this exception will incorporate any conditions or limitations in future regulations once published.

In cases where the first exception does not apply, the second exception applies if the following two conditions are satisfied: (1) The indirect transfer of stock of the domestic acquired corporation satisfies the requirements of § 1.367(a)–3(c)(1)(i), (ii), and (iv), and (c)(6); and (2) the domestic acquired corporation attaches a statement (described below) to its tax return for the taxable year of the transfer.

The statement that the domestic acquired corporation files must certify that, if the foreign acquiring corporation disposes of any stock of the domestic controlled corporation with a principal purpose of avoiding U.S. tax that would have been imposed on the domestic acquired corporation had it disposed of the re-transferred assets, the domestic acquired corporation will amend its return for the year of the initial transaction and recognize gain (described below). The disposition of stock is presumed to have a principal purpose of tax avoidance if the disposition occurs within 2 years of the transfer. The presumption may be rebutted, however, if the domestic acquired corporation (or the foreign acquiring corporation on its behalf) demonstrates to the satisfaction of the Commissioner that the transaction did not have a principal purpose of tax avoidance.

If the domestic acquired corporation recognizes gain pursuant to the statement, it is treated as if, immediately prior to the exchange, it had transferred the re-transferred assets, including any intangible assets, directly to a domestic corporation in exchange for stock of the corporation in a transaction that is treated as a section 351 exchange, and immediately sold the stock to an unrelated party at fair market value in a sale in which it recognizes gain, if any, but not loss. For purposes of this rule, the deemed transfer to a domestic corporation is treated as a section 351 exchange regardless of whether all the requirements for nonrecognition under section 351 are otherwise satisfied. Treating the domestic acquired corporation as recognizing gain on the disposition of stock, rather than assets, is intended to approximate the consequences that would have resulted had the domestic acquired corporation transferred the assets to a corporation and sold the stock received in such transfer prior to the outbound reorganization. In addition, this treatment is consistent with other provisions that address divisive transactions. See, *e.g.*, section 355(e) and § 1.367(e)–(2)(b)(2)(iii).

The basis that the foreign acquiring corporation has in the stock of the

domestic controlled corporation is increased by the amount of gain recognized by the domestic acquired corporation under these rules immediately prior to its disposition; however, the basis of the re-transferred assets held by the domestic controlled corporation will not be increased by such gain. Finally, the anti-abuse provision under § 1.367(d)–1T(g)(6) will not apply to intangible property included in the re-transferred assets.

H. Application of Section 367(b) Regulations to Certain Triangular Reorganizations

Section 367(b) applies to exchanges under sections 332, 351, 354, 355, 356, and 361 (except to the extent described in section 367(a)(1)) in which the status of a foreign corporation as a corporation for tax purposes is necessary for application of the relevant nonrecognition provisions. Except as provided in regulations, under section 367(b) a foreign corporation that is a party to such an exchange is considered to be a corporation for tax purposes, and therefore the parties involved in the transaction are eligible for nonrecognition treatment.

Section 1.367(b)–4 applies to acquisitions by a foreign corporation (the foreign acquiring corporation) of the stock or assets of another foreign corporation (the foreign acquired corporation) in certain nonrecognition exchanges (a section 367(b) exchange). Consistent with section 1248, § 1.367(b)–4(b)(1)(i) addresses exchanges by a section 1248 shareholder (or, in certain cases, a CFC shareholder that has a section 1248 shareholder), and generally requires such a shareholder to include in income its section 1248 amount as a result of a section 367(b) exchange, if immediately after the exchange (i) the stock received in the exchange is not stock in a corporation that is a controlled foreign corporation as to which the section 1248 shareholder described above is a section 1248 shareholder, or (ii) the foreign acquiring corporation or the foreign acquired corporation (if any, such as in a transaction described in section 368(a)(1)(B) or 351), is not a controlled foreign corporation as to which the section 1248 shareholder described above is a section 1248 shareholder.

Therefore, in a triangular reorganization (such as a triangular reorganization described in section 368(a)(1)(C)) that is within the scope of § 1.367(b)–4, a section 367(b) shareholder must include in income the section 1248 amount if, for example, it receives stock of a domestic corporation in exchange for its stock in a controlled foreign corporation. This is the case because, immediately after the exchange, the section 367(b) shareholder does not hold stock in a corporation that is a controlled foreign corporation as to which such shareholder is a section 367(b) shareholder.

Pursuant to the basis rules contained in this proposed regulation under § 1.367(b)–13, the section 1248 amount with respect to the stock of the foreign acquired corporation that is exchanged can be properly preserved in the stock of a foreign corporation owned by a domestic corporation when the section 367(b) shareholder receives stock of the domestic corporation in a triangular reorganization. Consequently, the proposed regulations provide that a section 367(b) shareholder receiving stock of a domestic corporation in a triangular reorganization is not required to include in income the section 1248 amount under § 1.367(b)–4(b)(1)(i), provided that the domestic corporation, immediately after the exchange, is a section 1248 shareholder of the surviving corporation (or in the case of a parenthetical section 368(a)(1)(B) reorganization, of the acquired corporation) that is itself a controlled foreign corporation.

I. Application of Section 367(b) Regulations to Certain Outbound Reorganizations

If a domestic corporation is a section 1248 shareholder with respect to a foreign corporation and transfers the stock in such foreign corporation to another foreign corporation in a section 361 transfer, the domestic corporation must include in income the section 1248 amount, if any, with respect to the stock of the transferred foreign corporation. See section 1248(f)(1) and § 1.367(b)–4(b)(2)(ii), *Example 4*.

Taxpayers have commented that this rule may result in income inclusions in some cases where the section 1248 amount could be preserved, such that a current inclusion may not be necessary or appropriate. The IRS and Treasury are considering the application of section 367(a)(5) and section 1248(f)(1) to such transactions, in conjunction with § 1.367(b)–13 of these regulations, to preserve section 1248 amounts, and comments are requested in this regard. The IRS and Treasury also are considering, and request comments, on situations in which there are multiple shareholders (including minority shareholders) of the domestic corporation; multiple assets (including appreciated and depreciated assets being transferred as part of the section 361 transfer); and liabilities being assumed in connection with the transaction.

J. Nonrecognition Transactions Under the FIRPTA and PFIC Provisions

Section 897(a) generally treats gain or loss from the disposition of a U.S. real property interest by a nonresident alien individual or a foreign corporation as gain or loss that is effectively connected with the conduct of a trade or business within the United States. Sections 897(d) and (e) provide rules that apply section 897 in the context of distributions and nonrecognition exchanges of U.S. real property interests. Temporary regulations were issued under sections 897(d) and (e) providing guidance on the application of section 897 to certain corporate transactions involving U.S. real property interests. See § 1.897–5T, 1.897–6T, and Notice 89–85 (1989–2 C.B. 403). These rules do not specifically address A reorganizations because such regulations were based on A reorganizations being limited to statutory mergers between domestic corporations. The IRS and Treasury intend to revise these regulations to reflect A reorganizations and welcome comments on revisions that are necessary to apply these regulations to A reorganizations, as well as comments on other issues under the regulations.

Section 1291(f) provides authority to issue regulations concerning the exchange of stock in a passive foreign investment company (PFIC) in a nonrecognition transaction. Proposed regulations were published in the **Federal Register** (57 FR 11047) on April 1, 1992, providing rules for the disposition of PFIC stock by U.S. shareholders in nonrecognition exchanges. See § 1.1291–6 of the proposed regulations. The application of these proposed regulations is based on A reorganizations being limited to statutory mergers between domestic corporations. The IRS and Treasury intend to revise these proposed regulations to reflect A reorganizations and welcome comments on revisions that are necessary in this regard, as well as comments on other issues under these regulations.

Proposed Effective Date

Except as otherwise specified, these regulations are proposed to apply to transactions occurring after the date these regulations are published as final regulations in the **Federal Register**.

Special Analyses

The IRS and the Treasury Department have determined that this notice of proposed rulemaking is not a significant

regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment pursuant to that Order is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and that because this regulation does not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Code, this regulation will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written comments (a signed original and eight (8) copies) or electronic comments that are submitted timely to the IRS. The IRS and Treasury Department specifically request comments on the clarity of the proposed regulations and on how they can be made easier to understand. All comments will be available for public inspection and copying.

A public hearing has been scheduled for May 19, 2005, beginning at 10 a.m. in the Auditorium, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC. Due to building security procedures, visitors must enter at the Constitution Avenue entrance. In addition, all visitors must present photo identification to enter the building. Because of access restrictions, visitors will not be admitted beyond the immediate entrance area more than 30 minutes before the hearing starts. For information about having your name placed on the building access list to attend the hearing, see the **FOR FURTHER INFORMATION CONTACT** portion of this preamble.

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Persons who wish to present oral comments must submit written or electronic comments and an outline of the topics to be discussed and the time to be devoted to each topic (a signed original and eight (8) copies) by April 28, 2005. A period of 10 minutes will be allotted to each person for making comments. An agenda showing the scheduling of the speakers will be prepared after the deadline for receiving outlines has passed. Copies of the agenda will be available free of charge at the hearing.

Drafting Information

The principal author of these regulations is Robert W. Lorence, Jr., of the Office of Associate Chief Counsel (International). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes. Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 continues to read, in part, as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 2. In section 1.358–1, paragraph (a) is amended by adding a sentence at the end of the paragraph to read as follows:

§ 1.358–1 Basis to distributes.

(a) * * * In the case of certain section 354 or 356 exchanges of stock in a foreign corporation, § 1.367(b)–13 applies instead of the rules of § 1.358–2.

* * * * *

Par. 3. In § 1.358–6, paragraph (e) is amended by adding a sentence at the end of the paragraph to read as follows:

§ 1.358–6 Stock basis in certain triangular reorganizations.

* * * * *

(e) * * * For certain triangular reorganizations where the surviving corporation (S or T) is foreign, see § 1.367(b)–13.

* * * * *

Par. 4. Section 1.367(a)–3 is amended as follows:

1. In paragraph (a), remove the third and fourth sentences, and add five sentences in their place.
2. Revise paragraph (b)(2)(i).
3. Revise paragraph (c)(5)(vi).
4. In paragraph (d)(1), introductory text, first sentence, add the parenthetical "(or in a domestic corporation in control of a foreign acquiring corporation in a triangular section 368(a)(1)(B) reorganization)" after the words "for stock or securities in a foreign corporation".
5. In paragraph (d)(1), introductory text, remove the last sentence and add three sentences in its place.
6. In paragraph (d)(1)(i), remove the last sentence and add a sentence in its place.
7. In paragraph (d)(1)(ii), add a sentence at the end of the paragraph.
8. Paragraph (d)(1)(iii) is revised.
9. In paragraph (d)(1)(iv), remove the language "*Example 7*" and add "*Example 8*" in its place, and remove "*Example 11*" and add "*Example 14*" in its place.
10. Revise paragraph (d)(1)(v).
11. Revise paragraphs (d)(2)(i) and (ii).
12. In paragraph (d)(2)(iv), last sentence, remove the language "*Example 4*" and add "*Examples 5* and *5A*" in its place.
13. Revise paragraph (d)(2)(v)(C).
14. Redesignate paragraph (d)(2)(v)(D) as paragraph (d)(2)(v)(F).
15. Add new paragraphs (d)(2)(v)(D) and (E).
16. Revise paragraph (d)(2)(vi).
17. In paragraph (d)(3), redesignate the examples as follows and add the following new examples:

Redesignate	As	Add
Example 12	*Example 16*	
		Example 15.
Examples 11 and *11A*	*Examples 14* and *14A*	
Examples 10 and *10A*	*Examples 13* and *13A*	
Example 9	*Example 12*	
		Examples 10 and *11.*
Example 8	*Example 9*	

Redesignate	As	Add
Examples 7, 7A, 7B, and *7C*	*Examples 8, 8A, 8B,* and *8C*	
Examples 6 and *6A*	*Examples 7* and *7A*	
Examples 5, 5A, and *5B*	*Examples 6, 6A,* and *6B*	
		Examples 6C and *6D.*
Example 4	*Example 5*	
		Example 5A.
Example 3	*Example 4*	
Example 2	*Example 3*	
		Example 2.

18. In paragraph (d)(3), newly designated *Example 6A*, paragraph (i), the first and last sentences are revised.

19. In paragraph (d)(3), newly designated *Example 6B* and *Example 9* are revised.

20. In paragraph (d)(3), for each of the newly designated Examples listed in the first column, replace the language in the second column with the language in the third column:

Redesignated examples	Remove	Add
Example 6A, paragraph (i), first sentence	*Example 5*	*Example 6.*
Example 7, paragraph (i)	*Example 5*	*Example 6.*
Example 7A, paragraph (i) and paragraph (ii), penultimate sentence	*Example 6*	*Example 7.*
Example 8, paragraph (i)	*Example 5*	*Example 6.*
Example 8A, paragraph (i)	*Example 7*	*Example 8.*
Example 8B, paragraph (i)	*Example 7*	*Example 8.*
Example 8C, paragraph (i)	*Example 7*	*Example 8.*
Example 12, paragraph (i), third sentence	*Example 9*	*Example 12.*
Example 13A, paragraph (i) and paragraph (ii), first sentence	*Example 10*	*Example 13.*
Example 14A, paragraph (i)	*Example 11*	*Example 14.*

22. In paragraph (e)(1), remove the first sentence and add two sentences in its place.

The revisions and additions are as follows:

§ 1.367(a)–3 Treatment of transfers of stock or securities to foreign corporations.

* * * * *

(a) * * * However, if, in an exchange described in section 354 or 356, a U.S. person exchanges stock of a foreign corporation in a reorganization described in section 368(a)(1)(E), or a U.S. person exchanges stock of a domestic or foreign corporation for stock of a foreign corporation pursuant to an asset reorganization that is not treated as an indirect stock transfer under paragraph (d) of this section, such section 354 or 356 exchange is not a transfer to a foreign corporation subject to section 367(a). See paragraph (d)(3), *Example 16*, of this section. For purposes of this section, an asset reorganization is defined as a reorganization described in section 368(a)(1) involving a transfer of assets under section 361. If, in a transfer described in section 361, a domestic merging corporation transfers stock of a controlling corporation to a foreign surviving corporation in a reorganization described in sections 368(a)(1)(A) and (a)(2)(E), such section 361 transfer is not subject to section 367(a) if the stock of the controlling corporation is provided to the merging corporation by the controlling corporation pursuant to the plan of reorganization; a section 361 transfer of other property, including stock of the controlling corporation not provided by the controlling corporation pursuant to the plan of reorganization, by the domestic merging corporation to the foreign surviving corporation pursuant to such a reorganization is subject to section 367(a). For special basis and holding period rules involving foreign corporations that are parties to certain reorganizations under section 368(a)(1), see § 1.367(b)–13. * * *

(b) * * *

(2) * * *

(i) *In general.* A transfer of foreign stock or securities described in section 367(a) and the regulations thereunder as well as in section 367(b) and the regulations thereunder shall be subject concurrently to sections 367(a) and (b) and the regulations thereunder, except as provided in paragraph (b)(2)(i)(A) or (B) of this section. See paragraph (d)(3), *Example 11*, of this section.

(A) If a foreign corporation transfers assets to a domestic corporation in a transaction to which § 1.367(b)–3(a) and

(b) and the indirect stock transfer rules of paragraph (d) of this section apply, then the section 367(b) rules shall apply prior to the section 367(a) rules. See paragraph (d)(3), *Example 15*, of this section. This paragraph (b)(2)(i)(A) applies only to transactions occurring after the date these regulations are published as final regulations in the **Federal Register**.

(B) Except as provided in paragraph (b)(2)(i)(A) of this section, section 367(b) and the regulations thereunder shall not apply if the foreign corporation is not treated as a corporation under section 367(a)(1). See paragraph (d)(3), *Example 14*, of this section.

* * * * *

(c) * * *

(5) * * *

(vi) *Transferee foreign corporation.* Except as provided in paragraph (d)(1)(iii)(B) of this section, the transferee foreign corporation shall be the foreign corporation that issues stock or securities to the U.S. person in the exchange.

* * * * *

(d) * * *

(1) * * * For examples of the concurrent application of the indirect stock transfer rules under section 367(a) and the rules of section 367(b), see paragraph (d)(3), *Examples 14* and *15* of this section. For purposes of this paragraph (d), if a corporation acquiring assets in a reorganization described in section 368(a)(1) transfers all or a portion of such assets to a corporation controlled (within the meaning of section 368(c)) by the acquiring corporation as part of the same transaction, the subsequent transfer of assets to the controlled corporation will be referred to as a controlled asset transfer. See section 368(a)(2)(C).

(i) * * * See paragraph (d)(3), *Example 1* of this section for an example of a reorganization described in sections 368(a)(1)(A) and (a)(2)(D) involving domestic acquired and acquiring corporations, and see paragraph (d)(3), *Example 10* of this section for an example involving a domestic acquired corporation and a foreign acquiring corporation.

(ii) * * * See paragraph (d)(3), *Example 2* of this section for an example of a reorganization described in sections 368(a)(1)(A) and (a)(2)(E) involving domestic acquired and acquiring corporations, and see paragraph (d)(3), *Example 11* of this section for an example involving a domestic acquired corporation and a foreign acquiring corporation.

(iii) *Triangular reorganizations described in section 368(a)(1)(B).*—(A) A U.S. person exchanges stock of the acquired corporation for voting stock of a foreign corporation that is in control (as defined in section 368(c)) of the acquiring corporation in a reorganization described in section 368(a)(1)(B). See paragraph (d)(3), *Example 5* of this section.

(B) A U.S. person exchanges stock of the acquired corporation for voting stock of a domestic corporation that is in control (as defined in section 368(c)) of a foreign acquiring corporation in a reorganization described in section 368(a)(1)(B).

(*1*) For purposes of paragraphs (b) and (c) of this section, the foreign acquiring corporation is considered to be the transferee foreign corporation even though the U.S. transferor receives stock of the domestic controlling corporation in the exchange.

(*2*) If stock of a foreign acquired corporation is exchanged for the voting stock of a domestic corporation in control of a foreign acquiring corporation, then the exchange will be subject to the rules of paragraph (b) of this section. If the exchanging shareholder is a section 1248 shareholder with respect to the foreign acquired corporation, the indirect transfer will be subject to sections 367(a) and (b) concurrently. For the application of section 367(b) to the exchange, see §§ 1.367(b)–4 and 1.367(b)–13(c).

(*3*) If stock of a domestic acquired corporation is exchanged for the voting stock of a domestic corporation in control of a foreign acquiring corporation, then the exchange will be subject to the rules of paragraph (c) of this section.

(*4*) For purposes of applying the gain recognition agreement provisions of paragraph (d)(2) of this section and § 1.367(a)–8, the domestic controlling corporation will be treated as the transferee foreign corporation. Thus, a disposition of foreign acquiring corporation stock by the domestic controlling corporation, or a disposition of acquired corporation stock by the foreign acquiring corporation, will trigger the gain recognition agreement. See paragraph (d)(3), *Example 5A* of this section.

(*5*) This paragraph (d)(1)(iii)(B) applies only to transactions occurring after the date these regulations are published as final regulations in the **Federal Register**.

* * * * *

(v) *Transfers of assets to subsidiaries in certain section 368(a)(1) reorganizations.* A U.S. person exchanges stock or securities of a corporation (the acquired corporation) for stock or securities of a foreign acquiring corporation in an asset reorganization (other than a triangular section 368(a)(1)(C) reorganization described in paragraph (d)(1)(iv) of this section or a reorganization described in sections 368(a)(1)(A) and (a)(2)(D) or (a)(2)(E) described in paragraphs (d)(1)(i) or (ii) of this section) that is followed by a controlled asset transfer. In the case of a transaction described in this paragraph (d)(1)(v) in which some but not all of the assets of the acquired corporation are transferred in a controlled asset transfer, the transaction shall be considered to be an indirect transfer of stock or securities subject to this paragraph (d) only to the extent of the assets so transferred. The remaining assets shall be treated as having been transferred in an asset transfer rather than an indirect stock transfer, and such asset transfer shall be subject to the other provisions of section 367, including sections 367(a)(1), (3), and (5), and (d) if the acquired corporation is a domestic corporation. See paragraph (d)(3), *Examples 6A* and *6B* of this section.

* * * * *

(2) * * *

(i) *Transferee foreign corporation.* Except as provided in paragraph (d)(1)(iii)(B) of this section, the transferee foreign corporation shall be the foreign corporation that issues stock or securities to the U.S. person in the exchange.

(ii) *Transferred corporation.* The transferred corporation shall be the acquiring corporation, except as provided in this paragraph (d)(2)(ii). In the case of a triangular section 368(a)(1)(B) reorganization described in paragraph (d)(1)(iii) of this section, the transferred corporation shall be the acquired corporation. In the case of an indirect stock transfer described in paragraph (d)(1)(i), (ii), or (iv) of this section followed by a controlled asset transfer, or an indirect stock transfer described in paragraph (d)(1)(v) of this section, the transferred corporation shall be the controlled corporation to which the assets are transferred. In the case of successive section 351 transfers described in paragraph (d)(1)(vi) of this section, the transferred corporation shall be the corporation to which the assets are transferred in the final section 351 transfer. The transferred property shall be the stock or securities of the transferred corporation, as appropriate under the circumstances.

* * * * *

(v) * * *

(C) In the case of an asset reorganization followed by a controlled asset transfer, as described in paragraph (d)(1)(v) of this section, the assets of the acquired corporation that are transferred to the corporation controlled by the acquiring corporation;

(D) In the case of a triangular reorganization described in section 368(a)(1)(C) followed by a controlled asset transfer, or a reorganization described in sections 368(a)(1)(A) and (a)(2)(D) followed by a controlled asset transfer, the assets of the acquired corporation including those transferred to the corporation controlled by the acquiring corporation;

(E) In the case of a reorganization described in sections 368(a)(1)(A) and (a)(2)(E) followed by a controlled asset transfer, the assets of the acquiring corporation including those transferred to the corporation controlled by the acquiring corporation; and

* * * * *

(vi) *Coordination between asset transfer rules and indirect stock transfer rules*— (A) *General rule.* If, pursuant to any of the transactions described in paragraph (d)(1) of this section, a U.S. person transfers (or is deemed to transfer) assets to a foreign corporation in an exchange described in section 351 or 361, the rules of section 367, including sections 367(a)(1), (a)(3), and (a)(5), as well as section 367(d), and the regulations thereunder shall apply prior to the application of the rules of this section.

(B) *Exceptions.* (*1*) If a transaction is described in paragraph (d)(2)(vi)(A) of this section, sections 367(a) and (d) shall not apply to the extent a domestic corporation (domestic acquired corporation) transfers its assets to a foreign corporation (foreign acquiring corporation) in an asset reorganization, and such assets (re-transferred assets) are transferred to a domestic corporation (domestic controlled corporation) controlled (within the meaning of section 368(c)) by the foreign acquiring corporation as part of the same transaction, provided that the domestic controlled corporation's basis in such assets is no greater than the basis that the domestic acquired corporation had in such assets and the conditions contained in either of the following paragraphs are satisfied:

(*i*) The domestic acquired corporation is controlled (within the meaning of section 368(c)) by 5 or fewer domestic corporations, appropriate basis adjustments as provided in section 367(a)(5) are made to the stock of the foreign acquiring corporation, and any other conditions as provided in regulations under section 367(a)(5) are satisfied. For purposes of determining whether the domestic acquired corporation is controlled by 5 or fewer domestic corporations, all members of the same affiliated group within the meaning of section 1504 shall be treated as 1 corporation.

(*ii*) The requirements of paragraphs (c)(1)(i), (ii), and (iv), and (c)(6) of this section are satisfied with respect to the indirect transfer of stock in the domestic acquired corporation, and the domestic acquired corporation attaches a statement described in paragraph (d)(2)(vi)(C) of this section to its U.S. income tax return for the taxable year of the transfer.

(*2*) Sections 367(a) and (d) shall not apply to transfers described in paragraph (d)(1)(vi) of this section where a U.S. person transfers assets to a foreign corporation in a section 351 exchange, to the extent that such assets are transferred by such foreign corporation to a domestic corporation in another section 351 exchange, but only if the domestic transferee's basis in the assets is no greater than the basis that the U.S. transferor had in such assets.

(C) *Required statement.* The statement required by paragraph (d)(2)(vi)(B)(*1*)(*ii*) of this section shall be entitled "Required Statement under § 1.367(a)–3(d) for Assets Transferred to a Domestic Corporation" and shall be signed under penalties of perjury by an authorized officer of the domestic acquired corporation and by an authorized officer of the foreign acquiring corporation. The required statement shall contain a certification that, if the foreign acquiring corporation disposes of any stock of the domestic controlled corporation in a transaction described in paragraph (d)(2)(vi)(D) of this section, the domestic acquired corporation shall recognize gain as described in paragraph (d)(2)(vi)(E)(*1*) of this section. The domestic acquired corporation (or the foreign acquiring corporation on behalf of the domestic acquired corporation) shall file a U.S. income tax return (or an amended U.S. tax return, as the case may be) for the year of the transfer reporting such gain.

(D) *Gain recognition transaction.* (*1*) A transaction described in this paragraph (d)(2)(vi)(D) is one where a principal purpose of the transfer by the domestic acquired corporation is the avoidance of U.S. tax that would have been imposed on the domestic acquired corporation on the disposition of the re-transferred assets. A transfer may have a principal purpose of tax avoidance even though the tax avoidance purpose is outweighed by other purposes when taken together.

(*2*) For purposes of paragraph (d)(2)(vi)(D)(*1*) of this section, a transaction is deemed to have a principal purpose of tax avoidance if the foreign acquiring corporation disposes of any stock of the domestic controlled corporation (whether in a recognition or non-recognition transaction) within 2 years of the transfer. The rule in this paragraph (d)(2)(vi)(D)(*2*) shall not apply if the domestic acquired corporation (or the foreign acquiring corporation on behalf of the domestic acquired corporation) demonstrates to the satisfaction of the Commissioner that the avoidance of U.S. tax was not a principal purpose of the transaction.

(E) *Amount of gain recognized and other matters.* (*1*) In the case of a transaction described in paragraph (d)(2)(vi)(D) of this section, solely for purposes of this paragraph (d)(2)(vi)(E), the domestic acquired corporation shall be treated as if, immediately prior to the transfer, it transferred the re-transferred assets, including any intangible assets, directly to a domestic corporation in exchange for stock of such domestic corporation in a transaction that is treated as a section 351 exchange, and immediately sold such stock to an unrelated party for its fair market value in a sale in which it shall recognize gain, if any (but not loss). Any gain recognized by the domestic acquired corporation pursuant to this paragraph (d)(2)(vi)(E) will increase the basis that the foreign acquiring corporation has in the stock of the domestic controlled corporation immediately before the transaction described in paragraph (d)(2)(vi)(D) of this section, but will not increase the basis of the re-transferred assets held by the domestic controlled corporation. Section 1.367(d)–1T(g)(6) shall not apply with respect to any intangible property included in the re-transferred assets described in the preceding sentence.

(*2*) If additional tax is required to be paid as a result of a transaction described in paragraph (d)(2)(vi)(D) of this section, then interest must be paid on that amount at rates determined under section 6621 with respect to the period between the date prescribed for filing the domestic acquired corporation's income tax return for the year of the transfer and the date on which the additional tax for that year is paid.

(F) *Examples.* For illustrations of the rules in paragraph (d)(2)(vi) of this section, see paragraph (d)(3), *Examples 6B, 6C, 6D, 9,* and *13A* of this section.

(G) *Effective dates.* Paragraph (d)(2)(vi) of this section applies only to transactions occurring after the date these regulations are published as final

regulations in the **Federal Register**. See § 1.367(a)–3(d)(2)(vi), as contained in 26 CFR part 1 revised as of April 1, 2004, for transactions occurring on or after July 20, 1998, until the date these regulations are published as final regulations in the **Federal Register**.

(3) * * *

Example 2. Section 368(a)(1)(A)/(a)(2)(E) reorganization—(i) *Facts.* The facts are the same as in *Example 1*, except that Newco merges into W and Newco receives stock of W which it distributes to F in a reorganization described in sections 368(a)(1)(A) and (a)(2)(E). Pursuant to the reorganization, A receives 40 percent of the stock of F in an exchange described in section 354.

(ii) *Result.* The consequences of the transfer are similar to those described in *Example 1*. Pursuant to paragraph (d)(1)(ii) of this section, the reorganization is subject to the indirect stock transfer rules. F is treated as the transferee foreign corporation, and W is treated as the transferred corporation. Provided that the requirements of paragraph (c)(1) of this section are satisfied, including the requirement that A enter into a five-year gain recognition agreement as described in § 1.367(a)–8, A's exchange of W stock for F stock under section 354 will not be subject to section 367(a)(1).

* * * * *

Example 5A. Triangular section 368(a)(1)(B) reorganization—(i) *Facts.* The facts are the same as in *Example 5*, except that F is a domestic corporation and S is a foreign corporation.

(ii) *Result.* U's exchange of Y stock for stock of F, a domestic corporation in control of S, the foreign acquiring corporation, is treated as an indirect transfer of Y stock to a foreign corporation under paragraph (d)(1)(iii) of this section. U's exchange of Y stock for F stock will not be subject to section 367(a)(1) provided that all of the requirements of paragraph (c)(1) are satisfied, including the requirement that U enter in a five-year gain recognition agreement. In satisfying the 50 percent or less ownership requirements of paragraph (c)(1)(i) and (ii) of this section, U's indirect ownership of S stock (through its direct ownership of F stock) will determine whether the requirement of paragraph (c)(1)(i) is satisfied and will be taken into account in determining whether the requirement of paragraph (c)(1)(ii) is satisfied. (See paragraph (c)(4)(iv)). For purposes of applying the gain recognition agreement provisions of paragraph (d)(2) of this section and § 1.367(a)–8, F is treated as the transferee foreign corporation. The gain recognition agreement would be triggered if F sold all or a portion of the stock of S, or if S sold all or a portion of the stock of Y.

* * * * *

Example 6A. Section 368(a)(1)(C) reorganization followed by a controlled asset transfer—(i) *Facts.* The facts are the same as in *Example 6*, except that the transaction is structured as a section 368(a)(1)(C) reorganization, followed by a controlled asset transfer, and R is a foreign corporation. * * * F then contributes Businesses B and C to R in a controlled asset transfer. * * *

* * * * *

Example 6B. Section 368(a)(1)(C) reorganization followed by a controlled asset transfer to a domestic controlled corporation—(i) *Facts.* The facts are the same as in Example 6A, except that R is a domestic corporation.

(ii) *Result.* As in *Example 6A*, the outbound transfer of the Business A assets to F is not affected by the rules of this paragraph (d) and is subject to the general rules under section 367. However, the Business A assets qualify for the section 367(a)(3) active trade or business exception. The Business B and C assets are part of an indirect stock transfer under this paragraph (d) but must first be tested under sections 367(a) and (d). The Business B assets qualify for the active trade or business exception under section 367(a)(3); the Business C assets do not. However, pursuant to paragraph (d)(2)(vi)(B) of this section, the Business C assets are not subject to section 367(a) or (d), provided that the basis of the Business C assets in the hands of R is no greater than the basis of the assets in the hands of Z, and appropriate basis adjustments are made pursuant to section 367(a)(5) to the stock of F held by V. (In this case, no adjustments are required because, pursuant to section 358, V takes a basis of $30 in the stock of F, which is equal to V's proportionate share of the basis in the assets of Z ($30) transferred to F.) V also is deemed to make an indirect transfer of stock under the rules of paragraph (d). To preserve non-recognition treatment under section 367(a), V must enter into a 5-year gain recognition agreement in the amount of $50, the amount of the appreciation in the Business B and C assets, as the transfer of such assets by Z was not taxable under section 367(a)(1) and constituted an indirect stock transfer.

Example 6C. Section 368(a)(1)(C) reorganization followed by a controlled asset transfer to a domestic controlled corporation—(i) *Facts.* The facts are the same as in *Example 6B*, except that Z is owned by individuals, none of whom qualify as five-percent target shareholders with respect to Z within the meaning of paragraph (c)(5)(iii) of this section. The following additional facts are present. No U.S. persons that are either officers or directors of Z own any stock of F immediately after the transfer. F is engaged in an active trade or business outside the United States that satisfies the test set forth in paragraph (c)(3) of this section.

(ii) *Result.* The transfer of the Business A assets is not affected by the rules of this paragraph (d). However, the transfer of such assets is subject to gain recognition under section 367(a)(1), because the section 367(a)(3) active trade or business exception is inapplicable pursuant to section 367(a)(5). The Business B and C assets are part of an indirect stock transfer under this paragraph (d) but must first be tested under sections 367(a) and (d). The transfer of the Business B assets (which otherwise would satisfy the section 367(a)(3) active trade or business exception) generally is subject to section 367(a)(1) pursuant to section 367(a)(5). The transfer of the Business C assets generally is subject to sections 367(a)(1) and (d). However, pursuant to paragraph (d)(2)(vi)(B) of this section, the transfer of the Business B and C assets is not subject to sections 367(a)(1) and (d), provided the basis of the Business B and C assets in the hands of R is no greater than the basis in the hands of Z and certain other requirements are satisfied. Since Z is not controlled within the meaning of section 368(c) by 5 or fewer domestic corporations, the indirect transfer of Z stock must satisfy the requirements of paragraphs (c)(1)(i), (ii), and (iv), and (c)(6) of this section, and Z must attach a statement described in paragraph (d)(2)(vi)(C) of this section to its U.S. income tax return for the taxable year of the transfer. In general, the statement must contain a certification that, if F disposes of the stock of R (in a recognition or nonrecognition transaction) and a principal purpose of the transfer is the avoidance of U.S. tax that would have been imposed on Z on the disposition of the Business B and C assets transferred to R, then Z (or F on behalf of Z) will file a return (or amended return as the case may be) recognizing gain ($50), as if, immediately prior to the reorganization, Z transferred the Business B and C assets to a domestic corporation in exchange for stock in a transaction treated as a section 351 exchange and immediately sold such stock to an unrelated party for its fair market value. A transaction is deemed to have a principal purpose of U.S. tax avoidance if F disposes of R stock within two years of the transfer, unless Z (or F on behalf of Z) can rebut the presumption to the satisfaction of the Commissioner. See paragraph (d)(2)(vi)(D)(*2*) of this section. With respect to the indirect transfer of Z stock, the requirements of paragraphs (c)(1)(i), (ii), and (iv) of this section are satisfied. Thus, assuming Z attaches the statement described in paragraph (d)(2)(vi)(C) of this section to its U.S. income tax return and satisfies the reporting requirements of (c)(6) of this section, the transfer of Business B and C assets is not subject to section 367(a) or (d).

Example 6D. Section 368(a)(1)(C) reorganization followed by a controlled asset transfer to a domestic controlled corporation—(i) *Facts.* The facts are the same as in *Example 6C*, except that the Z shareholders receive 60 percent of the F stock in exchange for their Z stock in the reorganization.

(ii) *Result.* The requirement of paragraph (c)(1)(i) of this section is not satisfied because the Z shareholders that are U.S. persons do not receive 50 percent or less of the total voting power and the total value of the stock of F in the transaction. Accordingly, Z shareholders that are U.S. persons are subject to section 367(a)(1) on their exchange of Z stock for F stock pursuant to the reorganization. For the same reason, the conditions of paragraph (d)(2)(vi)(B)(*1*)(*ii*) of this section are not met. Accordingly, the transfer of Business B and C assets is subject to sections 367(a)(1) and (d), even though such assets are re-transferred to R, a domestic corporation. As in *Example 6C*, the transfer of Business A assets, which is not affected by the rules of paragraph (d) of this section, is

subject to gain recognition under sections 367(a)(1) and (5).

* * * * *

Example 9. Concurrent application with a controlled asset transfer—(i) *Facts.* The facts are the same as in *Example 8,* except that R transfers the Business A assets to M, a wholly owned domestic subsidiary of R, in a controlled asset transfer. In addition, V's basis in its Z stock is $90.

(ii) *Result.* Pursuant to paragraph (d)(2)(vi)(B) of this section, sections 367(a) and (d) do not apply to Z's transfer of the Business A assets to R, because such assets are re-transferred to M, a domestic corporation, provided that the basis of the Business A assets in the hands of M is no greater than the basis of the assets in the hands of Z, and certain other requirements are satisfied. Because Z is controlled (within the meaning of section 368(c)) by V, a domestic corporation, appropriate basis adjustments must be made pursuant to section 367(a)(5) to the stock of F held by V. (In this case, no adjustments are required because, pursuant to section 358, V takes a basis of $90 in the stock of F, which is less than V's proportionate share of the basis in the assets of Z ($100) transferred to R.) Section 367(a)(1) does not apply to Z's transfer of its Business B assets to R (which are not re-transferred to M) because such assets qualify for an exception to gain recognition under section 367(a)(3). With respect to the indirect transfer of Z stock, such transfer is not subject to gain recognition under section 367(a)(1) if the requirements of paragraph (c) of this section are satisfied, including the requirement that V enter into a 5-year gain recognition agreement and comply with the requirements of § 1.367(a)–8 with respect to the gain ($100) realized on the Z stock. Under paragraphs (d)(2)(i) and (ii) of this section, the transferee foreign corporation is F and the transferred corporation is M. Pursuant to paragraph (d)(2)(iv) of this section, a disposition by F of the stock of R, or a disposition by R of the stock of M, will trigger the gain recognition agreement. To determine whether an asset disposition constitutes a deemed disposition of the transferred corporation's stock under the rules of § 1.367(a)–8(e)(3)(i), both the Business A assets in M and the Business B assets in R must be considered.

Example 10. Concurrent application in section 368(a)(1)(A)/(a)(2)(D) reorganization—(i) *Facts.* The facts are the same as in *Example 8,* except that R acquires all of the assets of Z in a reorganization described in sections 368(a)(1)(A) and (a)(2)(D). Pursuant to the reorganization, V receives 30 percent of the stock of F in a section 354 exchange.

(ii) *Result.* The consequences of the transaction are similar to those in *Example 8.* The assets of Businesses A and B that are transferred to R must be tested under section 367(a) prior to the consideration of the indirect stock transfer rules of this paragraph (d). The Business B assets qualify for the active trade or business exception under section 367(a)(3). Because the Business A assets do not qualify for the exception, Z must recognize $40 of gain under section 367(a) on the transfer of Business A assets to R. Because V and Z file a consolidated return, V's basis in the stock of Z is increased from $100 to $140 as a result of Z's $40 gain. V's indirect transfer of Z stock will be taxable under section 367(a) unless V enters into a gain recognition agreement in the amount of $60 ($200 value of Z stock less $140 adjusted basis) and the other requirements of paragraph (c)(1) of this section are satisfied.

Example 11. Section 368(a)(1)(A)/(a)(2)(E) reorganization—(i) *Facts.* F, a foreign corporation, owns all the stock of D, a domestic corporation. V, a domestic corporation, owns all the stock of Z, a foreign corporation. V has a basis of $100 in the stock of Z which has a fair market value of $200. D is an operating corporation with assets valued at $100 with a basis of $60. In a reorganization described in sections 368(a)(1)(A) and (a)(2)(E), D merges into Z, and V exchanges its Z stock for 55 percent of the outstanding F stock.

(ii) *Result.* Under paragraph (d)(1)(ii) of this section, V is treated as making an indirect transfer of Z stock to F. V's exchange of Z stock for F stock will be taxable under section 367(a) (and section 1248 will be applicable) if V fails to enter into a 5-year gain recognition agreement in accordance with the requirements of § 1.367(a)–8. Under paragraph (b)(2) of this section, if V enters into a gain recognition agreement, the exchange will be subject to the provisions of section 367(b) and the regulations thereunder as well as section 367(a). Under § 1.367(b)–4(b) of this chapter, however, no income inclusion is required because both F and Z are controlled foreign corporations with respect to which V is a section 1248 shareholder immediately after the exchange. Under paragraphs (d)(2)(i) and (ii) of this section, the transferee foreign corporation is F, and the transferred corporation is Z (the acquiring corporation). If F disposes (within the meaning of § 1.367(a)–8(e)) of all (or a portion) of Z stock within the 5-year term of the agreement (and V has not made a valid election under § 1.367(a)–8(b)(1)(vii)), V is required to file an amended return for the year of the transfer and include in income, with interest, the gain realized but not recognized on the initial section 354 exchange. To determine whether Z (the transferred corporation) disposes of substantially all of its assets, the assets of Z immediately prior to the transaction are taken into account, pursuant to paragraph (d)(2)(v)(B) of this section. Because D is owned by F, a foreign corporation, section 367(a)(5) precludes any assets of D from qualifying for nonrecognition under section 367(a)(3). Thus, D recognizes $40 of gain on the transfer of its assets to Z under section 367(a)(1).

* * * * *

Example 15. Concurrent application of indirect stock transfer rules and section 367(b)— (i) *Facts.* F, a foreign corporation, owns all of the stock of Newco, a domestic corporation. P, a domestic corporation, owns all of the stock of FC, a foreign corporation. P's basis in the stock of FC is $50 and the value of FC stock is $100. The all earnings and profits amount with respect to the FC stock held by P is $60. See § 1.367(b)–2(d). In a reorganization described in sections 368(a)(1)(A) and (a)(2)(D) (and paragraph (d)(1)(i) of this section), Newco acquires all of the properties of FC, and P exchanges its stock in FC for 20 percent of the stock in F.

(ii) *Result.* Because a domestic corporation, Newco, acquires the assets of a foreign corporation, FC, in an asset reorganization to which § 1.367(b)–3(a) and (b) and the indirect stock rules of paragraph (d) of this section apply, the section 367(b) rules apply before the section 367(a) rules apply. See § 1.367(a)–3(b)(2)(i)(A). Under the rules of section 367(b), P must include in income the all earnings and profits amount of $60 with respect to its FC stock. See § 1.367(b)–3. Although P's exchange of FC stock for F stock under section 354 is an indirect stock transfer, no gain is recognized under section 367(a), because P's basis in the FC stock is increased by the amount ($60) included in income under the rules of section 367(b). See § 1.367(b)–2(e)(3)(ii). Alternatively, if P's all earnings and profits amount were $30, then the amount of the income inclusion and basis adjustment under the rules of section 367(b) would be $30, and the amount of gain subject to section 367(a)(1) would be $20 unless P entered into a 5-year gain recognition agreement in accordance with § 1.367(a)–8.

* * * * *

(e) * * *

(1) *In general.* Except as provided in paragraphs (b)(2)(i)(A), (d)(1)(iii)(B), and (d)(2)(vi)(G), or in this paragraph (e), the rules in paragraphs (a), (b), and (d) of this section apply to transfers occurring on or after July 20, 1998. The rules in paragraphs (a) and (d) of this section, as they apply to section 368(a)(1)(A) reorganizations (including reorganizations described in section 368(a)(2)(D) or (E)) involving a foreign acquiring or acquired corporation, apply only to transfers occurring after the date these regulations are published as final regulations in the **Federal Register**.

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Par. 5. Section 1.367(a)–8 is amended as follows:

1. In paragraphs (c)(2) and (d), remove the words "district director" and add "Director of Field Operations" in their place.

2. In paragraph (e)(1)(i), a sentence is added after the first sentence.

The addition reads as follows:

§ 1.367(a)–8 Gain recognition agreement requirements.

* * * * *

(e) * * *

(1) * * *

(i) * * * It also includes an indirect disposition of the stock of the transferred corporation as described in § 1.367(a)–3(d)(2)(iv). * * *

* * * * *

Par. 6. In § 1.367(b)–1(a), remove the third and fourth sentences and add a sentence in their place to read as follows:

§ 1.367(b)–1 Other transfers.

(a) * * * For rules coordinating the concurrent application of sections 367(a) and (b), including the extent to which section 367(b) does not apply if the foreign corporation is not treated as a corporation under section 367(a), see § 1.367(a)–3(b)(2)(i). * * *

* * * * * *

Par. 7. In § 1.367(b)–3(b)(3)(ii), revise paragraph (i) of *Example 5* to read as follows:

§ 1.367(b)–3 Repatriation of foreign corporate assets in certain nonrecognition transactions.

* * * * * *

(b) * * *
(3) * * *
(ii) * * *

Example 5—(i) *Facts.* DC1, a domestic corporation, owns all of the outstanding stock of FC1, a foreign corporation. FC1 owns all of the outstanding stock of FC2, a foreign corporation. The all earnings and profits amount with respect to the FC2 stock owned by FC1 is $20. In a reorganization described in section 368(a)(1)(A), DC2, a domestic corporation unrelated to FC1 or FC2, acquires all of the assets and liabilities of FC2 pursuant to a State W merger. FC2 receives DC2 stock and distributes such stock to FC1. The FC2 stock held by FC1 is canceled, and FC2 ceases its separate legal existence.

* * * * * *.

Par. 8. Section 1.367(b)–4 is amended as follows.

1. Paragraph (a) is revised.

2. Redesignate paragraph (b)(1)(ii) as paragraph (b)(1)(iii), and add new paragraph (b)(1)(ii).

3. In newly designated paragraph (b)(1)(iii), after *Example 3*, add *Examples 3A* and *3B*.

The revisions and additions read as follows:

§ 1.367(b)–4 Acquisition of foreign corporate stock or assets by a foreign corporation in certain nonrecognition transactions.

(a) *Scope.* This section applies to an acquisition by a foreign corporation (the foreign acquiring corporation) of the stock or assets of a foreign corporation (the foreign acquired corporation) in an exchange described in section 351 or a reorganization described in section 368(a)(1). In the case of a reorganization described in sections 368(a)(1)(A) and (a)(2)(E), this section applies if stock of the foreign surviving corporation is exchanged for stock of a foreign corporation in control of the merging corporation; in such a case, the foreign surviving corporation is treated as a foreign acquired corporation for purposes of this section. A foreign corporation that undergoes a reorganization described in section 368(a)(1)(E) is treated as both the foreign acquired corporation and foreign acquiring corporation for purposes of this section. See § 1.367(a)–3(b)(2) for transactions subject to the concurrent application of this section and section 367(a).

(b) * * *

(1) * * *

(ii) *Exception.* In the case of a triangular reorganization described in section 368(a)(1)(B) or (C), or a reorganization described in sections 368(a)(1)(A) and (a)(2)(D) or (E), an exchange is not described in paragraph (b)(1)(i) of this section if the stock received in the exchange is stock of a domestic corporation and, immediately after the exchange, such domestic corporation is a section 1248 shareholder of the acquired corporation (in the case of a triangular section 368(a)(1)(B) reorganization) or the surviving corporation (in the case of a reorganization described in sections 368(a)(1)(A) and (a)(2)(D) or (E)) and such acquired or surviving corporation is a controlled foreign corporation. See paragraph (b)(1)(iii) of this section, *Example 3B* for an illustration of this rule.

(iii) * * *

Example 3A. (i) *Facts.* The facts are the same as in *Example 3*, except that FC1 merges into FC2 in a reorganization described in sections 368(a)(1)(A) and (a)(2)(E). Pursuant to the reorganization, DC exchanges its FC2 stock for stock of FP.

(ii) *Result.* The result is similar to the result in *Example 3*. The transfer is an indirect stock transfer subject to section 367(a). See § 1.367(a)–3(d)(1)(ii). Accordingly, DC's exchange of FC2 stock for FP stock will be taxable under section 367(a) (and section 1248 will be applicable) if DC fails to enter into a gain recognition agreement. If DC enters into a gain recognition agreement, the exchange will be subject to the provisions of section 367(b) and the regulations thereunder, as well as section 367(a). If FP and FC2 are controlled foreign corporations as to which DC is a (direct or indirect) section 1248 shareholder immediately after the reorganization, then paragraph (b)(1)(i) of this section does not apply to require inclusion in income of the section 1248 amount and the amount of the gain recognition agreement is the amount of gain realized on the indirect stock transfer. If FP or FC2 is not a controlled foreign corporation as to which DC is a (direct or indirect) section 1248 shareholder immediately after the exchange, then DC must include in income the section 1248 amount ($20) attributable to the FC2 stock that DC exchanged. Under these circumstances, the gain recognition agreement would be the amount of gain realized on the indirect transfer, less the $20 section 1248 income inclusion.

Example 3B. (i) *Facts.* The facts are the same as *Example 3*, except that USP, a domestic corporation, owns the controlling interest (within the meaning of section 368(c)) in FC1 stock. FC2 merges into FC1 in a reorganization described in sections 368(a)(1)(A) and (a)(2)(D). Pursuant to the reorganization, DC exchanges its FC2 stock for USP stock.

(ii) *Result.* Because DC receives stock of a domestic corporation, USP, in the section 354 exchange, the transfer is not an indirect stock transfer subject to section 367(a). Accordingly, the exchange will be subject only to the provisions of section 367(b) and the regulations thereunder. Under paragraph (b)(1)(ii)(A) of this section, because the stock received is stock of a domestic corporation (USP) and, immediately after the exchange, USP is a section 1248 shareholder of FC1 (the acquiring corporation) and FC1 is a controlled foreign corporation, the exchange is not described in paragraph (b)(1)(i) of this section and DC includes no amount in its gross income. See § 1.367(b)–13(b) and (c) for the basis and holding period rules applicable to this transaction, which cause USP's adjusted basis and holding period in the stock of FC1 after the transaction to reflect the basis and holding period that DC had in its FC2 stock.

* * * * * *

Par. 9. In § 1.367(b)–6, paragraph (a)(1), add a sentence to the end to read as follows:

§ 1.367(b)–6 Effective dates and coordination rules.

(a) * * *

(1) * * * The rules of §§ 1.367(b)–3 and 1.367(b)–4, as they apply to reorganizations described in section 368(a)(1)(A) (including reorganizations described in section 368(a)(2)(D) or (E)) involving a foreign acquiring or foreign acquired corporation, apply only to transfers occurring after the date these regulations are published as final regulations in the **Federal Register**.

* * * * * *

Par. 10. Section 1.367(b)–13 is added to read as follows:

§ 1.367(b)–13 Special rules for determining basis and holding period.

(a) *Scope and definitions*—(1) *Scope.* This section provides special basis and holding period rules for certain transactions involving the acquisition of property by a foreign acquiring corporation in nonrecognition exchanges. Special rules apply to determine the basis and holding period of stock in a foreign corporation received by certain shareholders in a section 354 or 356 exchange. In addition, special rules apply to determine the basis and holding period of stock of certain foreign surviving corporations held by a controlling corporation whose stock is issued in an exchange under section 354 or 356 in a triangular reorganization. This section

applies to transactions that are subject to section 367(b) as well as section 367(a), including transactions concurrently subject to sections 367(a) and (b).

(2) *Definitions.* For purposes of this section, the following definitions apply:

(i) A foreign acquired corporation is a foreign corporation whose stock or assets are acquired by a foreign corporation in a reorganization described in section 368(a)(1). In a reverse triangular merger, where T is a foreign corporation, T is treated as a foreign acquired corporation. A foreign corporation that undergoes a reorganization described in section 368(a)(1)(E) is treated as a foreign acquired corporation.

(ii) A block of stock has the meaning provided in § 1.1248–2(b).

(iii) A triangular reorganization is a reorganization described in § 1.358–6(b)(2)(i), (ii), or (iii) (but not a reorganization described in § 1.358–6(b)(2)(iv)). A triangular C reorganization, a forward triangular merger, and a reverse triangular merger each is a reorganization described in § 1.358–6(b)(2)(i), (ii), or (iii), respectively. For purposes of triangular reorganizations—

(A) P is a corporation that is a party to a reorganization that is in control (within the meaning of section 368(c)) of another party to the reorganization and whose stock is transferred pursuant to the reorganization;

(B) S is a corporation that is a party to the reorganization and that is controlled by P; and

(C) T is a corporation that is another party to the reorganization.

(b) *Determination of basis and holding period for exchanges of foreign stock*—(1) *Application.* Except as provided in paragraph (b)(4) of this section, this paragraph (b) applies to a shareholder that exchanges stock of a foreign acquired corporation in an exchange under section 354 or 356 for stock of a controlled foreign corporation, if—

(i) Immediately before the exchange either such shareholder is a section 1248 shareholder with respect to the foreign acquired corporation, or such shareholder is a foreign corporation and a United States person is a section 1248 shareholder with respect to both such foreign corporation and the foreign acquired corporation; and

(ii) The exchange is not described in § 1.367(b)–4(b)(1)(i), (2)(i), or (3).

(2) *Basis and holding period rules*—(i) If a shareholder surrenders a share of stock in an exchange under the terms of section 354 or 356, the basis and holding period of each share of stock received in the exchange shall be the same as the basis and holding period of the allocable portion of the share or shares of stock exchanged therefor, as adjusted under § 1.358–1 (such that the section 1248 amount of each share of stock exchanged is preserved in the share or shares of stock received). If more than one share of stock is received in exchange for one share of stock, the basis of the share of stock surrendered shall be allocated to the shares of stock received in the exchange in proportion to the fair market value of the shares of stock received. If one share of stock is received in respect of more than one share of stock or a fraction of a share of stock is received, the basis of the shares of stock surrendered must be allocated to the share of stock received, or a fraction thereof received, in a manner that reflects, to the greatest extent possible, that a share of stock is received in respect of shares of stock acquired on the same date and at the same price. The provisions of this paragraph may be applied, to the extent possible, on the basis of blocks of stock.

(ii) If a shareholder that purchased or acquired shares of stock in a corporation on different dates or at different prices exchanges such shares of stock under the terms of section 354 or 356, and the shareholder is not able to identify which particular share or shares of stock (or portion of a share of stock) is received in exchange for a particular share or shares of stock, the shareholder may designate which share or shares of stock is received in exchange for a particular share or shares of stock, provided that such designation is consistent with the terms of the exchange or distribution. The designation must be made on or before the first date on which the basis of a share of stock received is relevant. The basis of a share received, for example, is relevant when such share is sold or otherwise transferred. The designation will be binding for purposes of determining the Federal tax consequences of any sale or transfer of a share received. If the shareholder fails to make a designation, then the shareholder will not be able to identify which share is sold or transferred for purposes of determining the basis of property sold or transferred under section 1012 and § 1.1012–1(c) and, instead, will be treated as selling or transferring the share received in respect of the earliest share purchased or acquired. See paragraph (e), *Example 1* of this section for an illustration of this paragraph (b).

(3) In the case of a triangular reorganization, this paragraph (b) applies only to the exchange of T stock for P stock by T shareholders. See paragraph (c) of this section to determine the basis and holding period of stock of the surviving corporation (S or T) held by P immediately after a triangular reorganization.

(4) Paragraphs (b)(1) through (3) of this section shall not apply to determine the basis of a share of stock received by a shareholder in an exchange described in both section 351 and section 354 or 356, if, in connection with the exchange, the shareholder exchanges property for stock in an exchange to which neither section 354 nor 356 applies or liabilities of the shareholder are assumed.

(c) *Determination of basis and holding period for triangular reorganizations*—(1) *Application.* In the case of a triangular reorganization, this paragraph (c) applies, if—

(i) In the case of a reverse triangular merger—

(A) Immediately before the transaction, either P is a section 1248 shareholder with respect to S, or P is a foreign corporation and a United States person is a section 1248 shareholder with respect to both P and S; and

(B) P's exchange of S stock is not described in § 1.367(b)–3(a) and (b) or in § 1.367(b)–4(b)(1)(i), (2)(i), or (3); or

(ii)(A) Immediately before the transaction, a shareholder of T is either a section 1248 shareholder with respect to T or a foreign corporation and a United States person is a section 1248 shareholder with respect to both such foreign corporation and T; and

(B) With respect to at least one of the exchanging shareholders described in paragraph (c)(1)(ii)(A) of this section, the exchange of T stock is not described in § 1.367(b)–3(a) and (b) or in § 1.367(b)–4(b)(1)(i), (2)(i), or (3).

(2) *Basis and holding period rules.* In the case of a triangular reorganization described in this paragraph (c), each share of stock of the surviving corporation (S or T) held by P must be divided into portions attributable to the S stock and the T stock immediately before the exchange. See paragraph (e) of this section, *Examples 2* through 5 for illustrations of this rule.

(i) *Portions attributable to S stock*—(A) In the case of a forward triangular merger or a triangular C reorganization, the basis and holding period of the portion of each share of surviving corporation stock attributable to the S stock is the basis and holding period of such share of stock immediately before the exchange.

(B) In the case of a reverse triangular merger, the basis and holding period of the portion of each share of surviving corporation stock attributable to the S stock is the basis and the holding period

immediately before the exchange of a proportionate amount of the S stock to which the portion relates. If P is a shareholder described in paragraph (c)(1)(i)(A) of this section with respect to S, and P exchanges two or more blocks of S stock pursuant to the transaction, then each share of the surviving corporation (T) attributable to the S stock must be further divided into separate portions to account for the separate blocks of stock in S.

(C) If the value of S stock immediately before the triangular reorganization is less than one percent of the value of the surviving corporation stock immediately after the triangular reorganization, then P may determine its basis in the surviving corporation stock by applying the rules of paragraph (c)(2)(ii) of this section to determine the basis and holding period of the surviving corporation stock attributable to the T stock, and then increasing the basis of each share of surviving corporation stock by the proportionate amount of P's aggregate basis in the S stock immediately before the exchange (without dividing the stock of the surviving corporation into separate portions attributable to the S stock).

(ii) *Portions attributable to T stock*—(A) If any exchanging shareholder of T stock is described in paragraph (c)(1)(ii) of this section, the basis and holding period of the portion of each share of stock in the surviving corporation attributable to the T stock is the basis and holding period immediately before the exchange of a proportionate amount of the T stock to which such portion relates. If any exchanging shareholder of T stock is described in paragraph (c)(1)(ii) of this section, and such shareholder exchanges two or more blocks of T stock pursuant to the transaction, then each share of surviving corporation stock attributable to the T stock must be further divided into separate portions to account for the separate blocks of T stock.

(B) If no exchanging shareholder of T stock is described in paragraph (c)(1)(ii) of this section, the rules of § 1.358–6(c) apply to determine the basis of the portion of each share of the surviving corporation attributable to T immediately before the exchange.

(d) *Special rules applicable to divided shares of stock*—(1) *In general*—(i) Shares of stock in different blocks can be aggregated into one divided portion for basis purposes, if such shares immediately before the exchange are owned by one or more shareholders that are—

(A) Neither section 1248 shareholders with respect to the corporation nor foreign corporate shareholders; or

(B) Foreign corporate shareholders, provided that no United States persons are section 1248 shareholders with respect to both such foreign corporate shareholders and the corporation.

(ii) For purposes of determining the amount of gain realized on the sale or exchange of stock that has a divided portion pursuant to paragraph (c) of this section, any amount realized on such sale or exchange will be allocated to each divided portion of the stock based on the relative fair market value of the stock to which the portion is attributable at the time the portions were created.

(iii) Shares of stock will no longer be required to be divided if section 1248 or section 964(e) would not apply to a disposition or exchange of such stock.

(2) *Pre-exchange earnings and profits.* All earnings and profits (or deficits) accumulated by a foreign corporation before the reorganization and attributable to a share (or block) of stock for purposes of section 1248 are attributable to the divided portion of stock with the basis and holding period of that share (or block). See § 1.367(b)–4(d).

(3) *Post-exchange earnings and profits.* Any earnings and profits (or deficits) accumulated by the surviving corporation subsequent to the reorganization are attributed to each divided share of stock pursuant to section 1248 and the regulations thereunder. The amount of earnings and profits (or deficits) attributable to a divided share of stock is further attributed to the divided portions of such share of stock based on the relative fair market value of each divided portion of stock.

(e) *Examples.* The rules of this section are illustrated by the following examples:

Example 1. (i) *Facts.* US1 is a domestic corporation that owns all the stock of FT, a foreign corporation with 100 shares of stock outstanding. Each share of FT stock is valued at $10x. Because US1 acquired the stock of FT at two different dates, US1 owns two blocks of FT stock for purposes of section 1248. The first block consists of 60 shares. The shares in the first block have a basis of $300x ($5x per share), a holding period of 10 years, and $240x ($4x per share) of earnings and profits attributable to the shares for purposes of section 1248. The second block consists of 40 shares. The shares in the second block have a basis of $600x ($15x per share), a holding period of 2 years, and $80x ($2x per share) of earnings and profits attributable to the shares for purposes of section 1248. US2, a domestic corporation, owns all of the stock of FP, a foreign corporation, which owns all of the stock of FS, a foreign corporation. FT merges into FS with FS surviving in a reorganization described in section 368(a)(1)(A). Pursuant to the reorganization, US1 receives 50 shares of FS stock with a value of $1,000x for its FT stock in an exchange that qualifies for nonrecognition under section 354.

(ii) *Basis and holding period determination*—(A) US1 is a section 1248 shareholder of FT immediately before the exchange and exchanges its FT stock for stock of a controlled foreign corporation (FS) as to which US1 is a section 1248 shareholder immediately after the exchange. US1 is not required to include income under § 1.367(b)-4(b) with respect to the exchange. Accordingly, the basis and holding period of the FS stock received by US1 is determined pursuant to paragraph (b) of this section.

(B) Pursuant to paragraph (b) of this section, 30 shares of the FS stock received by US1 in the reorganization (valued at $20x per share and exchanged for US1's first block of 60 shares of FT stock) have a basis of $300x ($10x per share), a holding period of 10 years, and $240x of earnings and profits ($8x per share) attributable to such shares for purposes of section 1248. In addition, 20 shares of the FS stock (valued at $20 per share and exchanged for US1's second block of 40 shares of FT stock) have a basis of $600x ($30x per share), a holding period of 2 years, and $80x of earnings and profits ($4x per share) attributable to such shares for purposes of section 1248.

(iii) *Subsequent Disposition.* Assume, subsequent to the exchange, US1 disposes of 20 shares of FS stock. On or before the date of the disposition when the basis of the F1 shares received by US1 becomes relevant, US1 can designate the 20 shares from the first block, the second block, or from any combination of shares in both blocks.

Example 2. (i) *Facts.* The facts are the same as in *Example 1*, except that US1 receives 50 shares of FP stock (instead of FS stock) with a value of $1,000x in exchange for its FT stock. Accordingly, the merger of FT into FS qualifies as forward triangular merger, and immediately after the exchange US1 is a section 1248 shareholder with respect to FP and FS. Additionally, prior to the transaction, FP owned two blocks of FS stock. Each block consisted of 10 shares with a value of $200x ($20x per share). The shares in the first block had a basis of $50x ($5x per share), a holding period of 10 years, and $50x ($5x per share) of earnings and profits attributable to such shares for purposes of section 1248. The shares in the second block had a basis of $100x ($10x per share), a holding period of 5 years, and $20x ($2x per share) of earnings and profits attributable to such shares for purposes of section 1248.

(ii) *Basis and holding period determination.* (A) The basis and holding period of the FP shares received by US1 in the exchange are determined pursuant to paragraph (b) of this section and are identical to the results in *Example 1.*

(B)(*1*) US1 is a section 1248 shareholder of FT immediately before the transaction. Moreover, US1 is not required to include income under § 1.367(b)–3(b) or 1.367(b)–4(b) as described in paragraph (c)(2) of this section. Accordingly, the basis and holding period of the FS stock held by FP immediately after the triangular reorganization is determined pursuant to paragraph (c) of this section.

(2) Pursuant to paragraph (c) of this section, each share of FS stock is divided into portions attributable to the basis and holding period of the FS stock held by FP immediately before the exchange (the FS portion) and the FT stock held by US1 immediately before the exchange (the FT portion). The basis and holding period of the FS portion is the basis and holding period of the FS stock held by FP immediately before the exchange. Thus, each share of FS stock in the first block has a portion with a basis of $5x, a value of $20x, a holding period of 10 years, and $5x of earnings and profits attributable to such portion for purposes of section 1248. Each share of FS stock in the second block has a portion with a basis of $10x, a value of $20x, a holding period of 5 years, and $2x of earnings and profits attributable to such portion for purposes of section 1248.

(3) Because the exchanging shareholder of FT stock (US1) is a section 1248 shareholder, the holding period and basis of the FT portion is the holding period and the proportionate amount of the basis of the FT stock immediately before the exchange to which such portion relates. Further, because US1 exchanged two blocks of FT stock, the FT portion must be divided into two separate portions attributable to the two blocks of FT stock. Thus, each share of FS stock will have a second portion with a basis of $15x ($300x basis / 20 shares), a value of $30x ($600x value / 20 shares), a holding period of 10 years, and $12x of earnings and profits ($240x / 20 shares) attributable to such portion for purposes of section 1248. Each share of FS stock will have a third portion with a basis of $30x ($600x basis / 20 shares), a value of $20x ($400x value / 20 shares), a holding period of 2 years, and $4x of earnings and profits ($80x / 20 shares) attributable to such portion for purposes of section 1248.

(iii) Assume, immediately after the transaction, FP disposes of a share of FS stock from the first block. When FP disposes of any share of its FS stock, it is treated as disposing of each divided portion of such share. With respect to the first portion (attributable to the FS stock), FP recognizes a gain of $15x ($20x value − $5x basis), $5x of which is treated as a dividend under section 1248. With respect to the second portion (attributable to the first block of FT stock), FP recognizes a gain of $15x ($30x value − $15x basis), $12x of which is treated as a dividend under section 1248. With respect to the third portion (attributable to the second block of FT stock), FP recognizes a capital loss of $10x ($20x value − $30x basis).

(iv) Assume further, immediately after the transaction, FP also disposes of a share of stock from the second block of FS stock. With respect to the first portion (attributable to the FS stock), FP recognizes a gain of $10x ($20x value − $10x basis), $2x of which is treated as a dividend under section 1248. With respect to the second portion (attributable to the first block of FT stock), FP recognizes a gain of $15x ($30x value − $15x basis), $12x of which is treated as a dividend under section 1248. With respect to the third portion (attributable to the second block of FT stock), FP recognizes a capital loss of $10x ($20x value − $30x basis).

Example 2A. (i) *Facts.* The facts are the same as in *Example 2*, except that FS merges into FT with FT surviving in a reverse triangular merger. Pursuant to the merger, US1 receives FP stock with a value of $1,000x in exchange for its FT stock, and FP receives 10 shares of FT stock with a value of $1,400x in exchange for its FS stock. Immediately after the exchange, US1 is a section 1248 shareholder with respect to FP and FT.

(ii) *Basis and holding period determination*—(A) The basis and holding period of the FP shares received by US1 and the stock of the surviving corporation held by FP are the same as in *Example 2*, except that each share of the surviving corporation (FT, instead of FS) will be divided into four portions instead of three portions. Because FP exchanges two blocks of FS stock, the FS portion must be divided into two separate portions attributable to the two blocks of FS stock. Because US1 exchanges two blocks of FT stock, the FT portion must be divided into two separate portions attributable to the two blocks of FT stock.

(B) Thus, each share of the surviving corporation (FT) will have a first portion (attributable to the first block of FS stock) with a basis of $5x ($50x / 10 shares), a value of $20x ($200x / 10 shares), a holding period of 10 years, and $5x of earnings and profits ($50x / 10 shares) attributable to such portion for purposes of section 1248. Each share of FT stock will have a second portion (attributable to the second block of FS stock) with a basis of $10x ($100x / 10 shares), a value of $20x ($200x / 10 shares), a holding period of 5 years, and $2x of earnings and profits ($20x / 10 shares) attributable to such portion for purposes of section 1248. Moreover, each share of FT stock will have a third portion (attributable to the first block of FT stock) with a basis of $30x ($300x basis / 10 shares), a value of $60x ($600x value / 10 shares), a holding period of 10 years, and $24x of earnings and profits ($240x / 10 shares) attributable to such portion for purposes of section 1248. Lastly, each share of FT stock will have a fourth portion (attributable to the second block of FT stock) with a basis of $60x ($600x basis / 10 shares), a value of $40x ($400x value / 10 shares), a holding period of 2 years, and $8x of earnings and profits ($80x / 10 shares) attributable to such portion for purposes of section 1248.

Example 3. (i) *Facts.* USP, a domestic corporation, owns all the stock of FS, a foreign corporation with 10 shares of stock outstanding. Each share of FS stock has a value of $10x, a basis of $5x, a holding period of 10 years, and $7x of earnings and profits attributable to such share for purposes of section 1248. FP, a foreign corporation, owns the stock of FT, another foreign corporation. FP and FT do not have any section 1248 shareholders. FT has assets with a value of $100x, a basis of $50x, and no liabilities. The FT stock held by FP has a value of $100x and a basis of $75x. FT merges into FS with FS surviving in a forward triangular merger. Pursuant to the reorganization, FP receives USP stock with a value of $100x in exchange for its FT stock.

(ii) *Basis and holding period determination*—(A) Because USP is a section 1248 shareholder of FS immediately before the transaction, the basis and holding period of the FS stock held by USP immediately after the triangular reorganization is determined pursuant to paragraph (c) of this section.

(B) Pursuant to paragraph (c) of this section, each share of FS stock is divided into portions attributable to the basis and holding period of the FS stock held by USP immediately before the exchange (the FS portion) and the basis of FT's net assets (the FT portion) immediately before the exchange. The basis of FT's net assets (and not FT stock) is used to determine the FT portion because FT does not have a section 1248 shareholder immediately before the transaction. As a result, the rules of § 1.358–6(c) apply to determine the basis of the FT portion of each share of FS stock. The basis and holding period of the FS portion is the basis and holding period of the FS stock held by USP immediately before the exchange. Thus, each share of FS stock has a portion with a basis of $5x, a value of $10x, and a holding period of 10 years. The basis of the FT portion is the basis of the FT assets to which such portion relates. Thus, each share of FS stock has a second portion with a basis of $5x ($50x basis in FT's assets / 10 shares) and a value of $10x ($100x value of FT's assets / 10 shares). All of FS's earnings and profits prior to the transaction ($70x) is attributed solely to the FS portion in each share of FS stock. The FS portion of each share of FS stock has earnings and profits of $7x ($70x / 10 shares) attributable to such portion for purposes of section 1248. As a result of each share of stock being divided into portions, the basis of the FS stock is not averaged with the basis of the FT assets to increase the section 1248 amount with respect to the stock of the surviving corporation (FS).

Example 4. (i) *Facts.* US, a domestic corporation, owns all of the stock of FT, a foreign corporation. The FT stock held by US constitutes a single block of stock with a value of $1,000x, a basis of $600x, and holding period of 5 years. USP, a domestic corporation, forms FS, a foreign corporation, pursuant to the plan of reorganization and capitalizes it with $10x of cash. FS merges into FT with FT surviving in a reverse triangular merger and a reorganization described in section 368(a)(1)(B). Pursuant to the reorganization, US receives USP stock with a value of $1,000x in exchange for its FT stock, and USP receives 10 shares of FT stock with a value of $1,010x in exchange for its FS stock.

(ii) *Basis and holding period determination.* (A) U.S. and USP are section 1248 shareholders of FT and FS, respectively, immediately before the transaction. Neither US nor USP is required to include income under § 1.367(b)–3(b) or 1.367(b)–4(b) as described in paragraph (c)(2) of this section. The basis and holding period of the FT stock held by USP is determined pursuant to paragraph (c) of this section.

(B) Pursuant to paragraph (c) of this section, because the exchanging shareholder of FT stock (US) is a section 1248

shareholder of FT, each share of the surviving corporation (FT) has a proportionate amount of the basis and holding period of the FT stock immediately before the exchange to which such share relates. Thus, the portion of each share of FT stock attributable to the FT stock has a basis of $60x ($600x basis / 10 shares), a value of $100x ($1,000x value / 10 shares), and a holding period of 5 years. Because the value of FS stock immediately before the triangular reorganization ($10x) is less than one percent of the value of the surviving corporation (FT) immediately after the triangular reorganization ($1,010x), USP may determine its basis in the stock of the surviving corporation (FT) by increasing the basis of each share of FT stock by the proportionate amount of USP's aggregate basis in the FS stock immediately before the exchange (without dividing each share of FT stock into separate portions to account for FS and FT). If USP so elects, USP's basis in each share of FT stock is increased by $1x ($10x basis in FS stock / 10 shares). As a result, each share of FT stock has a basis of $61x, a value of $101x, and a holding period of 5 years.

Example 5. (i) *Facts.* U.S., a domestic corporation, owns all of the stock of FT, a foreign corporation. The FT stock held by U.S. constitutes one block of stock with a basis of $170x, a value of $200x, a holding period of 5 years, and $10x of earnings and profits attributable to such stock for purposes of section 1248. FP, a foreign corporation, owns all the stock of FS, a foreign corporation. FS has 10 shares of stock outstanding. No United States person is a section 1248 shareholder with respect to FP or FS. The FS stock held by FP has a value of $100x and a basis of $50x ($5x per share). FT merges into FS with FS surviving in a forward triangular merger. Pursuant to the merger, U.S. receives FP stock with a value of $200x for its FT stock in an exchange that qualifies for non-recognition under section 354. FP is a controlled foreign corporation and U.S. is a section 1248 shareholder with respect to FP and FS immediately after the exchange.

(ii) *Basis and holding period determination.* (A) Because U.S. is a section 1248 shareholder of FT immediately before the transaction, and U.S. is not required to include income under §§ 1.367(b)–3(b) and 1.367(b)–4(b) as described in paragraph (c)(2) of this section, the basis and holding period of the FS stock held by FP immediately after the triangular reorganization is determined pursuant to paragraph (c) of this section.

(B) Pursuant to paragraph (c) of this section, each share of FS stock is divided into portions attributable to the basis and holding period of the FS stock held by FP immediately before the exchange (the FS portion) and the FT stock held by U.S. immediately before the exchange (the FT portion). The basis and holding period of the FS portion is the basis and holding period of the FS stock held by FP immediately before the exchange. Thus, each share of FS stock has a portion with a basis of $5x and a value of $10x. Because the exchanging shareholder of FT stock (U.S.) is a section 1248 shareholder of FT, the basis and holding period of the FT portion is the proportionate amount of the basis and the holding period of the FT stock immediately before the exchange to which such portion relates. Thus, each share of FS stock will have a second portion with a basis of $17x ($170x basis/10 shares), a value of $20x ($200x value/10 shares), a holding period of 5 years, and $1x of earnings and profits ($10x earnings and profits/10 shares) attributable to such portion for purposes of section 1248.

(iii) *Subsequent disposition.* (A) Several years after the merger, FP disposes of all of its FS stock in a transaction governed by section 964(e). At the time of the disposition, FS stock has decreased in value to $210x (a post-merger reduction in value of $90x), and FS has incurred a post-merger deficit in earnings and profits of $30x.

(B) Pursuant to paragraph (d)(1)(ii) of this section, for purposes of determining the amount of gain realized on the sale or exchange of stock that has a divided portion, any amount realized on such sale or exchange is allocated to each divided portion of the stock based on the relative fair market value of the stock to which the portion is attributable at the time the portions were created. Immediately before the merger, the value of the FS stock in relation to the value of both the FS stock and the FT stock was one-third ($100x/($100x plus $200x)). Likewise, immediately before the merger, the value of the FT stock in relation to the value of both the FT stock and the FS stock was two-thirds ($200x/$100x plus $200x). Accordingly, one-third of the $210x amount realized is allocated to the FS portion of each share and two-thirds to the FT portion of each share. Thus, the amount realized allocated to the FS portion of each share is $7x (one-third of $210x divided by 10 shares). The amount realized allocated to the FT portion of each share is $14x (two-thirds of $210x divided by 10 shares).

(C) Pursuant to paragraph (d)(3) of this section, any earnings and profits (or deficits) accumulated by the surviving corporation subsequent to the reorganization are attributed to the divided portions of shares of stock based on the relative fair market value of each divided portion of stock. Accordingly, one-third of the post-merger earnings and profits deficit of $30x is allocated to the FS portion of each share and two-thirds to the FT portion of each share. Thus, the deficit in earnings and profits allocated to the FS portion of each share is $1x (one-third of $30x divided by 10 shares). The deficit in earnings and profits allocated to the FT portion of each share is $2x (two-thirds of $30x divided by 10 shares).

(D) When FP disposes of its FS stock, FP is treated as disposing of each divided portion of a share of stock. With respect to the FS portion of each share of stock, FP recognizes a gain of $2x ($7x value − $5x basis), which is not recharacterized as a dividend because a deficit in earnings and profits of $1x is attributable to such portion for purposes of section 1248. With respect to the FT portion of each share of stock, FP recognizes a loss of $3x ($14x value − $17x basis).

(e) *Effective date.* This section applies to exchanges occurring after the date these regulations are published as final regulations in the **Federal Register**.

Par. 11. Section 1.884–2 is amended as follows:

1. Paragraphs (c)(3) through (c)(6)(i)(A) are revised.

2. Paragraphs (c)(6)(i)(B), (C), and (D) are added.

3. Paragraphs (c)(6)(ii) through (f) are revised.

4. Paragraph (g) is amended by adding a sentence at the end.

The revisions and additions read as follows:

§ 1.884–2 Special rules for termination or incorporation of a U.S. trade or business or liquidation or reorganization of a foreign corporation or its domestic subsidiary.

* * * * *

(c)(3) through (c)(6)(i)(A) [Reserved]. For further guidance, see § 1.884–2T(c)(3) through (c)(6)(i)(A).

(c)(6)(i)(B) Shareholders of the transferee (or of the transferee's parent in the case of a triangular reorganization described in section 368(a)(1)(C) or a reorganization described in sections 368(a)(1)(A) and 368(a)(2)(D) or (E)) who in the aggregate owned more than 25 percent of the value of the stock of the transferor at any time within the 12-month period preceding the close of the year in which the section 381(a) transaction occurs sell, exchange or otherwise dispose of their stock or securities in the transferee at any time during a period of three years from the close of the taxable year in which the section 381(a) transaction occurs.

(c)(6)(i)(C) In the case of a triangular reorganization described in section 368(a)(1)(C) or a reorganization described in sections 368(a)(1)(A) and 368(a)(2)(D) or (E), the transferee's parent sells, exchanges, or otherwise disposes of its stock or securities in the transferee at any time during a period of three years from the close of the taxable year in which the section 381(a) transaction occurs.

(c)(6)(i)(D) A corporation related to any such shareholder or the shareholder itself if it is a corporation (subsequent to an event described in paragraph (c)(6)(i)(A) or (B) of this section) or the transferee's parent (subsequent to an event described in paragraph (c)(6)(i)(C) of this section), uses, directly or indirectly, the proceeds or property received in such sale, exchange or disposition, or property attributable thereto, in the conduct of a trade or business in the United States at any time during a period of three years from the date of sale in the case of a disposition of stock in the transferor, or from the close of the taxable year in which the section 381(a) transaction

occurs in the case of a disposition of the stock or securities in the transferee (or the transferee's parent in the case of a triangular reorganization described in section 368(a)(1)(C) or a reorganization described in sections 368(a)(1)(A) and (a)(2)(D) or (E)). Where this paragraph (c)(6)(i) applies, the transferor's branch profits tax liability for the taxable year in which the section 381(a) transaction occurs shall be determined under § 1.884–1, taking into account all the adjustments in U.S. net equity that result from the transfer of U.S. assets and liabilities to the transferee pursuant to the section 381(a) transaction, without regard to any provisions in this paragraph (c). If an event described in paragraph (c)(6)(i)(A), (B), or (C) of this section occurs after the close of the taxable year in which the section 381(a) transaction occurs, and if additional branch profits tax is required to be paid by reason of the application of this paragraph (c)(6)(i), then interest must be paid on that amount at the underpayment rates determined under section 6621(a)(2), with respect to the period between the date that was prescribed for filing the transferor's income tax return for the year in which the section 381(a) transaction occurs and the date on which the additional tax for that year is paid. Any such additional tax liability together with interest thereon shall be the liability of the transferee within the meaning of section 6901 pursuant to section 6901 and the regulations thereunder.

(c)(6)(ii) through (f) [Reserved]. For further guidance, see § 1.884–2T(c)(6)(ii) through (f).

(g) * * * Paragraphs (c)(6)(i)(B), (C), and (D), are applicable for tax years beginning after December 31, 1986, except that such paragraphs are applicable to transactions occurring after the date these regulations are published as final regulations in the **Federal Register** in the case of reorganizations described in sections 368(a)(1)(A) and 368(a)(2)(D) or (E).

Par. 12. In § 1.884–2T, paragraphs (c)(6)(i)(B), (C), and (D) are revised to read as follows:

§ 1.884–2T Special rules for termination or incorporation of a U.S. trade or business or liquidation or reorganization of a foreign corporation or its domestic subsidiary (Temporary).

* * * * *

(c) * * *

(6) * * *

(i) * * *

(B), (C), and (D) [Reserved]. For further guidance, see § 1.884–2(c)(6)(i)(B), (C), and (D).

Mark E. Matthews,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 05–201 Filed 1–4–05; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 31

[REG–152945–04]

RIN 1545–BD96

Flat Rate Supplemental Wage Withholding

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations amending the regulations that provide for the flat rate of withholding applicable to calculating the amount of income tax withholding on supplemental wages. The proposed amendment to the regulations reflects changes in the law made by the Revenue Reconciliation Act of 1993, the Economic Growth and Tax Relief Reconciliation Act of 2001, the Jobs and Growth Tax Relief Reconciliation Act of 2003, and the American Jobs Creation Act of 2004. Under the American Jobs Creation Act of 2004, the optional flat rate for withholding on supplemental wages will generally remain at 25 percent for payments made after December 31, 2004, but may change if income tax rates change. However, the 2004 Act also provides that, after 2004, if an employee receives supplemental wages in excess of one million dollars from an employer in a calendar year, the excess of the supplemental wages over one million dollars is subject to mandatory income tax withholding at the highest income tax rate. The highest income tax rate is currently 35 percent. In determining whether an employer has reached the one million dollar threshold for an employee, supplemental wage payments from all businesses under common control and from agents will be taken into account.

DATES: Written or electronic comments and requests for a public hearing must be received by April 5, 2005.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–152945–04), room 5203, Internal Revenue Service, PO Box 7604, Ben Franklin Station, Washington, DC 20044. Submission may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–152945–04), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC or sent electronically, via the IRS Internet site at *http://www.irs.gov/regs* or via the Federal eRulemaking Portal at *http://www.regulations.gov* (IRS and REG–152945–04).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, A. G. Kelley, (202) 622–6040; concerning submission of comments, Treena Garrett, (202) 622–3401 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

The Employment Tax Regulations distinguish between regular wages paid for a payroll period and supplemental wages for purposes of income tax withholding. Although the regulations do not give a comprehensive definition of the term "supplemental wages," the regulations provide that supplemental wages include "* * * bonuses, commissions, and overtime pay, paid for the same or a different period, or without regard to a particular period." Regulations and revenue rulings have provided other examples. See § 31.3401(a)–1(b)(8)(i)(*b*)(*2*) of the regulations (sick pay paid by an agent of the employer); § 31.3401(a)–4(c) of the regulations (wages paid under reimbursement and other expense allowance arrangements); Rev. Rul. 67–257)1967–2 C.B. 359) (income recognized on exercise of nonqualified stock option); Rev. Rul. 67–131 (1967–1 C.B. 291) (lump sum payment of accumulated annual leave); and Rev. Rul. 66–294 (1966–2 C.B. 459) (lump sum vacation payment, overtime pay, lump sum retroactive pay, sick pay paid separately from regular pay).

Section 31.3402(g)–1 of the regulations provides the current rules for withholding income tax from a payment of supplemental wages. Two procedures have been generally available to the employer with respect to such supplemental wage payments. Under the first procedure (the aggregate procedure), employers calculate the amount of withholding due by aggregating the amount of supplemental wages with the regular wages paid for the current payroll period or for the most recent payroll period this year, and treating the aggregate as if it were a single wage payment for the regular payroll period.

The second procedure for withholding on supplemental wages (the flat rate procedure) allows employers to disregard the amount of regular wages paid to an employee as well as the allowances claimed by an employee on Form W–4, "Employee's Withholding Allowance Certificate," and use a flat percentage rate specified in the regulations in calculating the amount of withholding. This second procedure of withholding on supplemental wages is generally available only if (1) the employer has withheld income tax from regular wages paid the employee, and (2) the supplemental wages are either (a) not paid concurrently with regular wages or (b) separately stated on the payroll records of the employer. See Rev. Rul. 82–200 (1982–2 C.B. 239). Under the current regulations, if the supplemental wage payment satisfies the conditions necessary for use of the flat rate, the decision whether to use the flat rate rather than the aggregate procedure is discretionary with the employer. Section 31.3042(g)–1(a)(2), last modified in 1966, states that, for wages paid after April 30, 1966, the flat percentage rate on supplemental wages is 20 percent. Later statutory changes have changed the applicable rate and the regulation is being amended to reflect those changes.

Section 13273 of Public Law 103–66 (the Revenue Reconciliation Act of 1993; 107 Stat. 542) provides that the rate under section 31.3402(g)–1 "shall not be less than 28 percent." This change was effective for payments made after December 31, 1993., The Conference Report in connection with this change states that the provision "increases the applicable withholding rate on supplemental wage payments to 28 percent." H.R. Rep. No. 103–111, 103d Cong., 1st Sess. 701 (1993).

Section 101(c)(11) of Public Law 107–16 (the Economic Growth and Tax Relief Reconciliation Act of 2001; 115 Stat. 44) amended section 13273 of the Revenue Reconciliation Act of 1993 by striking "28 percent" and inserting "the third lowest rate of tax applicable under section 1(c) of the Internal Revenue Code of 1986." Section 101(d)(2) of Public Law 107–16 provides that the change made by section 101(c)(11) shall apply to "amounts paid after the 60th day after the date of enactment of this Act." Public Law 107–16 was enacted into law on June 7, 2001. The third lowest rate of tax applicable under section 1(c) for purposes of section 13273 of the Revenue Reconciliation Act of 1993 was 27.5 percent. Consequently, the withholding rate for supplemental wages paid after August 6, 2001, and on or before December 31, 2001, was 27.5 percent. For 2002 the third lowest rate of tax applicable under section 1(c) was 27 percent. As a result of the enactment of the Jobs and Growth Tax Relief Reconciliation Act of 2003 (Public Law 108–27) on May 28, 2003, the third lowest rate of tax applicable under section 1(c) of the Internal Revenue Code (Code) for 2003 and 2004 is 25 percent.

Section 904(a) of Public Law 108–357, 118 Stat. 1418 (the American Jobs Creation Act of 2004) provides that, generally, for payments after December 31, 2004, the flat rate for withholding on supplemental wage rate "shall not be less than 28 percent (or the corresponding rate in effect under section 1(i)(2) of the Internal Revenue Code of 1986 for taxable years beginning in the calendar year in which the payment is made)." For 2005, the corresponding rate in effect under section 1(i)(2) is 25 percent.

Section 904(b) of the American Jobs Creation Act of 2004 also established a mandatory flat rate of withholding on supplemental wages to the extent that the employee's total supplemental wages paid by the employer exceed one million dollars during the calendar year. Section 904(b) provides that "[n]otwithstanding subsection (a), if the supplemental wage payment, when added to all such payments previously made by the employer to the employee during the calendar year, exceeds $1,000,000, the rate used with respect to such excess shall be equal to the maximum rate of tax in effect under section 1 of such Code for such taxable years beginning in such calendar year." The maximum rate of tax in effect under section 1 of the Code is currently 35 percent. Section 904(b)(2) also provides that all persons treated as a single employer under subsection (a) or (b) of section 52 of the Code shall be treated as a single employer for purposes of this provision. This new mandatory withholding on supplemental wages in excess of one million dollars is effective with respect to payments made after December 31, 2004.

This provision is described in the Conference Report as follows: "Under the Senate amendment, once annual supplemental wage payments to an employee exceed $1 million, any additional supplemental wage payments to the employee in that year are subject to withholding at the highest income tax rate (35 percent for 2004 and 2005), regardless of any other withholding rules and regardless of the employee's Form W–4." H.R. Rep. No. 108–475 at 785–6 (2004).

This provision for withholding on supplemental wages in excess of one million dollars was originally included as part of S. 2424, 108th Cong., 2d Sess. (2004). The legislative history in connection with S. 2424 provided as follows with respect to the reasons for change: "The Committee believes that because most employees who receive annual supplemental wage payments in excess of $1 million will ultimately be taxed at the highest rate, it is appropriate to raise the withholding rate on such payments so that withholding more closely approximates the ultimate tax liability with respect to these payments." S. Rep. No. 108–266 at 105 (2004).

In a conforming amendment, the 2004 Act repealed section 13273 of the Revenue Reconciliation Act of 1993.

Explanation of Provisions

The proposed regulations change the optional flat rate of withholding on supplemental wages to provide that the 20 percent rate applies only to supplemental wages paid prior to January 1, 1994. The rate of 28 percent applies to supplemental wages paid after December 31, 1993, and on or before August 6, 2001. The Revenue Reconciliation Act of 1993, as amended by the Economic Growth and Tax Relief Reconciliation Act of 2003, provides that the supplemental withholding rate shall not be less than the third lowest rate of tax applicable under section 1(c) for wages paid after August 6, 2001, and before January 1, 2005. Consistent with this amendment, the regulations provide that the rate of 27.5 percent applies to supplemental wages paid after August 6, 2001, and on or before December 31, 2001, the rate of 27 percent applies to wages paid after December 31, 2001, and on or before May 27, 2003, and the rate of 25 percent applies to wages paid after May 27, 2003, and on or before, December 31, 2004. Although the Jobs and Growth Tax Relief Reconciliation Act of 2003 provided that the third lowest rate of tax under section 1(c) after December 31, 2002, would be 25 percent, this provision was not enacted into law until May 28, 2003. Thus, at the time of payments of supplemental wages made after December 31, 2002, and prior to May 28, 2003, the third lowest rate of tax under section 1(c) was 27 percent. This provision is consistent with the general principle that the employment taxation of wage payments is determined based on the rates in effect at the date the wages are paid. *United States* v. *Cleveland Indians Baseball Co.*, 532 U.S. 200 (2001).

To track the statutory language of the American Jobs Creation Act of 2004, the regulation provides that, for wages paid after December 31, 2004, the flat rate for

supplemental wages is generally 28 percent (or the corresponding rate in effect under section 1(i)(2) * * * for taxable years beginning in the calendar year in which the payment is made). Under current law, the corresponding rate in effect under section 1(i)(2) for taxable years beginning in 2005 is 25 percent. Thus, for 2005, the optional flat rate for supplemental wages under $1 million in a given taxable year is 25 percent. The optional flat rate will remain at 25 percent until income tax rates change.[1] However, as described below, a higher mandatory rate applies for withholding on supplemental wages in excess of one million dollars.

The regulation provides that if a supplemental wage payment, together with all other supplemental wage payments paid by an employer to an employee during the calendar year, exceeds one million dollars, the withholding rate on the supplemental wages in excess of one million dollars shall be equal to the maximum rate of tax in effect under section 1 for taxable years beginning in such calendar year. Under current law, the maximum rate of tax in effect for taxable years beginning in 2005 is 35 percent. Thus, in 2005, the mandatory flat rate for supplemental wages in excess of $1 million in a given taxable year is 35 percent. The mandatory rate will remain at 35 percent until income tax rates change.[2]

These proposed regulations also clarify which wages are classified as supplemental wages. Under the proposed regulations, supplemental wages include any payment of wages by an employer that is not regular wages. Regular wages are defined as amounts paid by an employer for a payroll period either at a regular hourly rate or in a predetermined fixed amount. Wages that vary from payroll period to payroll period based on factors other than the amount of time worked, such as commissions, tips, and bonuses, are supplemental wages if they are paid in addition to regular wages. See Rev. Rul. 82–46 (1982–1 C.B. 158). However, if an employee receive only one type of compensation from an employer, that type of compensation will be regular wages even if the type of compensation is something that would normally be classified as supplemental wages. For example, if an employee receives only stock options as compensation from the employer and receives no other wages (including no includible fringe benefits that are wages), then the income on the exercise of the options would generally be regular wages, rather than supplemental wages.

The definitions of supplemental wages and regular wages were developed based on the historical usage of the term in regulations and revenue rulings. Examples are included in the regulations to illustrate the application of the definitions to specific scenarios. The IRS welcomes comments on whether this definition of supplemental wages is appropriate.

When determining whether payments are regular wages or supplemental wages, and furthermore, whether the supplemental wages paid by an employer to an employee in a given taxable year exceed $1 million, an employer (the first employer) must consider wage payments made to the employee by any other person treated as a single employer with the first employer under section 52(a) or 52(b). Furthermore, if an employer enlists a third party to make a payment to an employee on the employer's behalf, the payment will be considered as made by the employer even though it may have been delivered to the employee by the third party.

The new mandatory withholding rate on supplemental wages can apply to a full payment or only a portion of a payment. The maximum rate withholding applies only to the excess of supplemental wages over one million dollars received by an employee from an employer, taking into consideration all payments of supplemental wages made by an employer to an employee. All payments of supplemental wages are considered in determining this threshold regardless of whether the payments were subjected to flat rate withholding. The amount of regular wages paid to the employee has no relevance in determining whether the new mandatory withholding rate applies. Also, if a payment to an employee from an employer is not "wages" as defined under section 3401(a), such payment has no effect on whether the million dollar threshold for mandatory flat rate withholding has been reached.

If a particular supplemental wage payment results in an employee exceeding the million dollar supplemental wage threshold, mandatory flat rate withholding will apply to the extent that the payment together with other supplemental wage payments made to the employee previously during the year is an excess of one million dollars. However, to the extent that such a supplemental wage payment does not exceed one million dollars when combined with the other previous supplemental wage payments, the mandatory flat rate does not apply, and withholding may be calculated on that portion of the payment under the rules generally applicable to other supplemental wage payments.

Withholding on regular wages of the employee will continue to be calculated under the method used by the employer with respect to regular wages after the employee has reached the million dollar supplemental wage threshold.

The regulations also clarify that the mandatory flat rate applies regardless of the withholding method used by the employer with respect to regular wages. The regulations also clarify that mandatory flat rate withholding applies even if the employee receiving the supplemental wages in excess of $1 million has a Form W–4 asserting exempt status pursuant to section 3402(n). Moreover, the regulations also clarify that mandatory flat rate withholding applies to noncash remuneration paid to a retail commission salesperson (section 3402(j)) to the extent that such remuneration constitutes supplemental wages and exceeds $1 million in a given taxable year.

Examples of how the withholding would be calculated under the mandatory flat rate are included in the regulation. Among other things, the examples illustrate that because the higher rate is mandatory, where an employer provides net bonuses (i.e., after withholding) at a specified level, the total of the amount of such net bonuses and the gross up for withholding that are in excess of $1 million of supplemental wages will be subject to the higher rate.

The proposed regulations also clarify that, generally, where an employer has paid an employee supplemental wages that are cumulatively one million dollars or less for a given taxable year, the flat rate of withholding on supplemental wages can be used only if (1) income tax has been withheld from the employee's regular wages and (2) the supplemental wages are either not paid concurrently with regular wages of the employer if paid concurrently with regular wages, are separately stated on the payroll records of the employer.

The proposed regulations do not change the Federal Insurance

[1] Under current law, section 1(i)(2) will not be applicable to taxable years beginning after December 31, 2010, pursuant to the sunset provisions contained in section 901 of the Economic Growth and Tax Relief Reconciliation Act of 2001 (Public Law 107–16; 115 Stat. 150). See also section 107 of Public Law 108–27 (117 Stat. 755). Absent legislative action, the optional flat rate will change to 28 percent in 2011.

[2] Under the sunset provision in section 901 of the Economic Growth and Tax Relief Reconciliation Act of 2001, the mandatory flat rate will change to 39.6 percent for taxable years beginning after December 31, 2010.

Contributions Act (FICA) taxation of wages.

Proposed Effective Date

This regulation will be effective on the date published as a final regulation in the **Federal Register.**

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because the regulation does not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Requests for Public Hearing

Before these proposed regulation are adopted as final regulations, consideration will be given to any written (a signed original and 8 copies) or electronic comments that are submitted timely to the IRS. The IRS and Treasury Department request comments on the clarity of the proposed rules and how they can be made easier to understand. All comments will be available for public inspection and copying. A public hearing may be scheduled if requested in writing by any person that timely submits written comments. If a public hearing is scheduled, notice of the date, time, and place for the public hearing will be published in the **Federal Register.**

Drafting Information

The principal author of these regulations is A. G. Kelley, Office of Division Counsel/Associate Chief Counsel (Tax Exempt and Government Entities). However, other personnel from the IRS and Treasury participated in their development.

List of Subjects in 26 CFR Part 31

Employment taxes, Income taxes.

Proposed Amendment to the Regulations

Accordingly, 26 CFR is proposed to be amended as follows:

PART 31—EMPLOYMENT TAXES AND COLLECTION OF INCOME TAX AT SOURCE

Paragraph 1. The authority citation to part 31 is amended by adding an entry in numerical order to read, as follows:

Authority: 26 U.S.C. 7805 * * *

Section 31.3402(n)–1 also issued under 26 U.S.C. 6011 and 6364. * * *

Par. 2. Section 31.3401(a)–1 is amended by revising paragraph (b)(8)(i)(*b*)(*2*) as follows:

§ 31.3401(a)–1 Wages.

* * * * *

(b) * * *

(8) * * *

(i) * * *

(*b*) * * *

(*2*) Payments made by agents subject to this paragraph are supplemental wages as defined in § 31.3402(g)–1, and are therefore subject to the rules regarding withholding tax on supplemental wages provided in § 31.3402(g)–1. For purposes of those rules, unless the agent is also an agent for purposes of withholding tax from the employees' regular wages, the agent may deem tax to have been withheld form regular wages paid to the employee during the calendar year.

* * * * *

Par. 3 Section 31.3401(a)–4 is amended by revising paragraph (c) to read as follows

§ 31.3401(a)–4 Reimbursements and other expense allowance amounts.

* * * * *

(c) *Withholding rate.* Payments made under reimbursement or other expense allowance arrangements that are subject to income tax withholding are supplemental wages under § 31.3402(g)–1 if paid in addition to regular wages. Accordingly, withholding on such supplemental wages is calculated under the rules provided with respect to supplemental wages in § 31.3402(g)–1.

* * * * *

Par. 4. Section 31.3402(g)–1 is amended by:

(1) Revising paragraph (a).

(2) Adding a sentence at the beginning of paragraph (b)(1).

(3) Revising paragraph (b)(2).

The revisions and addition read as follows:

§ 31.3402(g)–1 Supplemental wage payments.

(a) *In general and withholding applicable with respect to supplemental wages in excess of $1,000,000.* (1)(i) An employee's remuneration may consist of regular wages and supplemental wages. Supplemental wages are all wages paid by an employer that are not regular wages. Supplemental wages include wage payment made without regard to an employee's payroll period, but also may include payments made for a payroll period. Examples of wage payments that are included in supplemental wages, if paid in addition to regular wages, include bonuses, overtime pay, back pay, reported tips, commissions, wages paid under reimbursement or other expense allowance, wages paid as noncash fringe benefits, sick pay paid by a third party as an agent of the employer, amounts that are includible in gross income under section 409A, and income recognized on the exercise of a nonqualified stock option.

(ii) As distinguished form supplemental wages, regular wages are amounts that are paid at a regular hourly, daily, or similar periodic rate (and not an overtime rate) for the current payroll period or at a predetermined fixed determinable amount for the current payroll period. Thus, among other things, wages that vary from payroll period to payroll period (such as commissions, tips, or bonuses) are not regular wages if paid in addition to regular wages. Any overtime pay paid in addition to regular wages would not be included in regular wages. However, if the only wages that an employee receives during a calendar year are bonuses, commissions, tips, or another type of payments that would normally-be classified as supplemental wages if paid in addition to regular wages, then such wages are treated as regular wages. For example, if the only wages an employee receives are commissions paid on a monthly basis, then the payment of the commissions by the employer would be regular wages paid for a monthly payroll period.

(iii) The calculation of the amount of the income tax withholding with respect to supplemental wage payments is provided for under paragraph (a)(2) through (a)(7) of this section.

(2) If a supplemental wage payment, when added to all supplemental wage payments previously made by one employer (as defined in paragraph (a)(3) of this section) to an employee during the calendar year, exceeds $1,000,000, the rate used in determining the amount of withholding on the excess (including any excess which is apportion of a supplemental wage payment) shall be equal to the highest rate of tax applicable under section 1 for such taxable years beginning in such calendar year. This flat rate shall be applied without regard to whether income tax has been withheld from the employee's regular wages, without allowance for the

number of withholding allowances claimed by the employee on Form W–4, "Employee's Withholding Allowance Certificate", without regard to whether the employee has claimed exempt status on Form W–4, and without regard to the withholding method used by the employer.

(3) For purposes of paragraph (a)(2) of this section, including for purposes of determining whether any given payment is a payment of supplemental wages subject to paragraph (a)(2) of the section—

(i) All persons treated as a single employer under subsection (a) to (b) of section 52 shall be treated as one employer; and

(ii) Any payment made to an employee by a third party acting as an agent for the employer (regardless of whether such person shall have been designated as an agent pursuant to section 3504) shall be considered as made by the employer.

(4) To the extent that paragraph (a)(2) of this section does not apply to a supplemental wage payment (or a portion of a payment), the amount of the tax required to be withheld on the supplemental wages when they are paid shall be determined under the rules provided in paragraphs (a)(5) and (6) of this section.

(5)(i) The employer is required to determine withholding upon supplemental wages under this paragraph (a)(5) if paragraph (a)(2) of this section does not apply to the payment or portion of the payment and if paragraph (a)(6) of this section may not be used with respect to the payment. In addition, employers have the option of using this paragraph (a)(5) to calculate withholding with respect to a supplemental wage payment, if paragraph (a)(2) of this section does not apply to the payment, built if paragraph (a)(6) of this section could be used with respect to the payment.

(ii) Provided this procedure applies under paragraph (a)(5)(i) of this section, the supplemental wages. if paid concurrently with wages for payroll period, are aggregated with the wages paid for such payroll period. If not paid concurrently, the supplemental wages are aggregated with the wages paid or to be paid within the same calendar year for the last preceding payroll period or for the current payroll period. The amount of tax to be withheld is determined as if the aggregate of the supplemental wages and the regular wages constituted a single wage payment for the regular payroll period.

(6)(i) The employer may determine withholding upon supplemental wages under this paragraph (a)(6) if three conditions are met—

(A) Paragraph (a)(2) of this section does not apply to the payment or the portion of the payment;

(B) The supplemental wages are either not paid concurrently with regular wages or are separately stated on the payroll records of the employer; and

(C) Income tax has been withheld from the employee's regular wages.

(ii) The determination of the tax to be withheld under paragraph (a)(6)(iii) of this section is made without allowance for exemption and without reference to any payment of regular wages.

(iii) Provided the conditions of paragraph (a)(6)(i) of this section have been met, the employer may determine the tax to be withheld—

(A) From supplemental wages paid after April 30, 1966, and prior to January 1, 1994, by using a flat percentage rate of 20 percent;

(B) From supplemental wages paid after December 31, 1993, and on or before August 6, 2001, by using a flat percentage rate of 28 percent;

(C) From supplemental wages paid after August 6, 2001, and on or before December 31, 2001, by using a flat percentage rate of 27.5 percent;

(D) From supplemental wages paid after December 31, 2001, and on or before May 27, 2003, by using a flat percentage rate of 27 percent;

(E) From supplemental wages paid after May 27, 2003, and on or before December 31, 2004, by using a flat percentage rate of 25 percent; and

(F) From supplemental wages paid after December 31, 2004, by using a flat percentage rate of 28 percent (or the corresponding rate in effect under section 1(i)(2) for taxable years beginning in the calendar year in which the payment is made).

(7) The following examples illustrate this paragraph (a):

Example 1. (i) A is an employee of three entities (X, Y, and Z) that are treated as a single employer under section 52(a) or (b). In year 20XX, A receives regular wages on a monthly payroll periods paid by X for services performed for X, Y, and Z on the third business day of each month. The maximum rate of income tax under section 1 in effect for year 20XX is 35 percent, and the corresponding rate to 28 percent in effect under section 1(i)(2) for taxable years beginning in 20XX is 25 percent. Income tax is withheld from the regular wages of A during the year. A receives only the following supplemental wage payments during 20XX in addition to the regular wages paid by X—

(a) a bonus of $600,000 from X on March 15, 20XX;

(b) a bonus of $2,300,000 from Y on November 15, 20XX; and

(c) a bonus of $10,000 from Z on December 31, 20XX.

(ii) In this *Example 1*, the withholding on the $600,000 payment from X could be determined under either paragraph (a)(5) or (6) of this section because income tax has been withheld from the regular wages of A. If X elects to use the aggregate procedure under paragraph (a)(5) of this section, the amount of withholding on the supplemental wages would be based on aggregating the supplemental wages and the regular wages paid by X either for the current or last payroll period and treating the total of the regular wages paid by X and the $600,000 supplemental wages as a single payment for a regular payroll period. The withholding method used by the employer with respect to regular wages would then be used to calculate the withholding on this single wage payment, and the employer would take into consideration the Form W–4 filed by the employee.

(iii) In this *Example 1*, because the $2,300,000 bonus from Y, together with the regular wages paid by X, is treated as made from one employer, the payment is a supplemental wage payment. To calculate the withholding on the $2,300,000 supplemental wage payment from Y, it would be necessary to take into account that A has already received $600,000 of supplemental wages from X, which is treated as the same employer as Y under section 52(a) or (b). Thus, the withholding on the amount of the payment not in excess of $1,000,000 cumulative supplemental wages would need to be computed separately from the amount of the payment above $1,000,000. With respect to the first component of this supplemental wage payment, equal to $400,000, the withholding could be computed under either paragraph (a)(5) or (a)(6) of this section, because income tax has been withheld from the regular wages of the employee. If Y elected to withhold income tax using paragraph (a)(6) of this section, Y would withhold on the $400,000 component at 25 percent (pursuant to paragraph (a)(6)(ii)(F) of this section), which would result in $100,000 tax withheld. The second component of $1,900,000 would be subject to mandatory income tax withholding at the maximum rate of tax in effect under section 1 for 20XX. The income tax required to be withheld on the second component of this supplemental wage payment would be calculated without regard to the Form W–4 filed by A and would be 35 percent of $1,900,000 or $665,000. The withholding on the first component and the withholding on the second component then would be added together to determine the total income tax withholding on the supplemental wage payment from Y, or $100,000 plus $665,000 ($765,000).

(iv) The bonus paid from Z is also a supplemental wage payment, because Z, together with X, is treated as a single employer. The calculation of the withholding on the supplemental wage payment from Z to A of $10,000 would also be required to take into account that A has received prior supplemental wage payments during the year in excess of one million dollars from X and Y, because Z is treated as the same employer

as X and Y. The income tax required to be withheld on this payment would be 35 percent of $10,000 or $3,500.

Example 2. Employees B and C work for employer M. Each employee receives monthly salaries of $3,000 which are paid on the fifth business day after the end of the month. As a result of the withholding allowances claimed by B, there is no income tax withholding on the regular wages of B paid by M. In contrast, M has withheld income tax from C's regular wages paid by M. Together with the monthly salary check paid on the fifth business day of December, M includes a bonus of $2,000, which is the only supplemental wage payment received by each employee for the calendar year. The bonuses are separately stated on the payroll records of M. M must calculate the income tax withholding required to be made with respect to the bonus paid to B by using the procedure set forth in paragraph (a)(5) of this section. With respect to the bonus paid to C, M has the option of using either the aggregate method provided under paragraph (a)(5) of this section or the optional flat rate provided under paragraph (a)(6) of this section to calculate the income tax withholding due.

Example 3. (i) Employee D works as an employee of Corporation R. Corporations R, S, and T are treated as a single employer under subsection (a) or (b) of section 52. Employee D receives regular wage payments of $200,000 on a monthly basis in 2005 from R and income tax is withheld from those wages. D receives a bonus for his services as an employee from R equal to $3,000,000 on June 30, 2005. Unrelated company U pays D sick pay as an agent of the employer R and such sick pay is supplemental wages pursuant to § 31.3401(a)–1(b)(2). D receives sick pay of $50,000 on October 31, 2005. Corporation T decides to award bonuses to all employees of R, S, and T, and pays a bonus of $100,000 to D on December 31, 2005. D received no other payments from U, P, or T.

(ii) In chronological summary, D receives the following wages other than the regular monthly wages paid by R:

June 30, 2005—$3,000,000 (bonus from R)
October 31, 2005—$50,000 (sick pay from U)
December 31, 2005—$100,000 (bonus from T)

(iii) In this *Example 3*, each payment of wages other than the regular monthly wage payments from R is considered to be supplemental wages for purposes of withholding under § 31.3402(g)–1(a)(2) because, pursuant to § 31.3402(g)–1(a)(3), the payments are treated as made by one employer. The amount of regular wages from R is irrelevant in determining when maximum rate withholding on supplemental wages applies.

(iv) Because income tax has been withheld on the regular wages of the employee, income tax may be withheld on $1,000,000 of the $3,000,000 bonus paid on June 30, 2005, under either paragraph (a)(5) or (6) of this section. If R elects to withhold income tax at the flat rate provided under paragraph (a)(6)(ii)(F), withholding would be calculated at 25 percent of the $1,000,000 portion of the payment, or $250,000.

(v) Income tax withheld on the following supplemental wage payments (or portion of a payment) as follows is required to be calculated at the maximum rate in effect under section 1(c), or 35 percent in 2005—

(A) $2,000,000 of the $3,000,000 bonus paid by R on June 30, 2005;

(B) $50,000, the sick pay paid on October 31, 2005; and

(C) $100,000, the bonus paid by T on December 31, 2005.

Example 4. (i) Employer J has decided it wants to grant its employee B a $1,000,000 net bonus (after withholding). Employer J has withheld income tax from the regular wages of the employee. B has received no other supplemental wage payments during the year. The mandatory flat rate in effect in the year in which the payment is made is 35 percent, and the optional flat rate in effect is 25 percent.

(ii) This *Example 4* requires grossing up the wage payment to determine the gross wages necessary to result in a net payment of $1,000,000. If the employer elected to use the flat rate applicable to supplemental wages, the first $1,000,000 of the wages would be subject to 25 percent withholding. However, any wages above that would be subject to mandatory 35 percent withholding. The withholding applicable to the first $1,000,000 (i.e., $250,000) would thus be required to be grossed-up at a 35 percent rate to determine the gross wage amount above $1,000,000. Thus, the wages above $1,000,000 would be equal to $250,000 divided by .65 (computed by subtracting .35 from 1) or $384,615.38. Thus the total withholding with respect to the payment if Employer J elected the flat rate with respect to the first $1,000,000, would be $384,615.38 and the total supplemental wage payment, taking into account income tax withholding only (and not Federal Insurance Contributions Act taxes), to B would be $1,384,615.38.

(8) For provisions relating to the treatment of wages that are not subject to paragraph (a)(2) of this section and that are paid other than in cash to retail commission salesmen, see § 31,3402(j)–1.

(b) *Special rule where aggregate withholding exemption exceeds wages paid.* (1) This rule applies only if paragraph (a)(2) of this section does not apply to the supplemental wage payment. * * *

(2) The rules prescribed in this paragraph shall, at the election of the employer, be applied in lieu of the rules prescribed in paragraph (a) of this section except that this paragraph shall not be applicable in any case in which the payroll period of the employee is less than one week or if paragraph (a)(2) applies to the supplemental wage payment.

* * * * *

Par. 5. Section 31.3402(j)–1 is amended by adding a new sentence at the beginning of paragraph (a)(2) to read as follows:

§ 31.3402(j)–1 Remuneration other than in cash for service performed by retail commission salesman.

(a) * * *

(2) Section 3402(j) and this section are not applicable with respect to wages paid to the employee that are subject to withholding under section 31.3402(g)–1(a)(2). * * *

* * * * *

Par. 6. Section 31.3402(n)–1 is revised and the authority citation at the end of the section is removed to read as follows:

§ 31.3402(n)–1 Employees incurring no income tax liability.

(a) Notwithstanding any other provision of this subpart (except to the extent a payment of wages is subject to withholding under § 31.3402(g)–1(a)(2)), an employer shall not deduct and withhold any tax under chapter 24 upon a payment of wages made to an employee after April 30, 1970, if there is in effect with respect to the payment a withholding exemption certificate furnished to the employer by the employee which contains statements that—

(1) The employee incurred no liability for income tax imposed under subtitle A of the Internal Revenue Code for his preceding taxable year; and

(2) The employee anticipates that he will incur no liability for income tax imposed under subtitle A for his current taxable year.

(b) To the extent wages are subject to withholding under § 31.3402(g)–1(a)(2), such wages are subject to such income tax withholding regardless of whether a withholding exemption certificate under section 3402(n) and the regulations thereunder has been furnished to the employer.

(c) For purposes of section 3402(n) and this section, an employee is not considered to incur liability for income tax imposed under subtitle A if the amount of such tax is equal to or less than the total amount of credits against such tax which are allowable to him under part iv of subchapter A of chapter 1 of the Internal Revenue Code, other than those allowable under section 31 or 39. For purposes of seciton 3402(n) and this section, "liability for income tax imposed under subtitle A" shall include

liability for a qualified State individual income tax which is treated pursuant to section 6361(a) as if it were imposed by chapter 1 of the Internal Revenue Code. An employee is not considered to incur liability for such a State income tax if the amount of such tax does not exceed the total amount of the credit against such tax which is allowable to him under section 6362(b)(2)(B) or (C) or section 6362(c)(4). For purposes of this section, an employee who files a joint return under section 6013 is considered to incur liability for any tax shown on such return. An employee who is entitled to file a joint return under such section shall not certify that he anticipates that he will incur no liability for income tax imposed by subtitle A for his current taxable year if such statement would not be true in the event that he files a joint return for such year, unless he filed a separate return for his preceding taxable year and anticipates that he will file a separate return for his current taxable year.

(d) For rules relating to invalid withholding exemption certificates, see § 31.3402(f)(2)–1(e), and for rules relating to submission to the Internal Revenue Service of withholding exemption certificates claiming a complete exemption from withholding, see § 31.3402(f)(2)–1(g).

(e) Example 1. Employee A, an unmarried, calendar-year basis taxpayer, files his income tax return for 1970 on April 15, 1971. A has adjusted gross income of $1,200 and is not liable for any tax. He had $180 of income tax withheld during 1970. A anticipates that his gross income for 1971 will be approximately the same amount, and that he will not incur income tax liability for that year. On April 20, 1971, A commences employment and furnishes his employer an exemption certificate stating that he incurred no liability for income tax imposed under subtitle A for 1970, and that he anticipates that he will incur no liability for income tax imposed under subtitle A for 1971. A's employer shall not deduct and withhold on payments of wages made to A on or after April 20, 1971. Under § 31.3402(f)(4)–1(c), unless A files a new exemption certificate with his employer, his employer is required to deduct and withhold upon payments of wages to A made on or after May 1, 1972. Under § 31.3402(f)(3)–1(b), if A had been employed by his employer prior to April 20, 1971, and had furnished his employer a withholding exemption certificate not containing the statements described in § 31.3402(n)–1 proir to furnishing the withholding exemption certificate containing such statements on April 20, 1971, his employer would not be required to give effect to the new certificate with respect to payments of wages made by him prior to July 1, 1971 (the first status determiantion date which occurs at least 30 days after April 20, 1971). However his employer could, if he chose, make the new certificate effective with respect to any payment of wages made on or after April 20 and before July 1, 1971.

Example 2. Assume the facts are the same as in *Example 1* except that for 1970 A has taxable income of $8,000, income tax liability of $1,630, and income tax withheld of $1,700. Although A received a refund of $70 due to income tax withholding of $1,700, he may not state on his exemption certificate that he incurred no liability for income tax imposed by subtitle A for 1970.

Mark E. Matthews,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 05–71 Filed 1–4–05; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD01–04–129]

RIN 1625–AA09

Drawbridge Operation Regulations; Townsend Gut, ME

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to temporarily change the drawbridge operation regulations for the operation of the SR 27 Bridge, at mile 0.7, across Townsend Gut, between Boothbay Harbor and Southport, Maine. This temporary rule would require the bridge to open at specific times between 6 a.m. and 6 p.m., each day, from March 1, 2005, through November 30, 2005. Additionally, this temporary rule would also allow the bridge to remain closed for four periods of four days each between March 1, 2005, and May 26, 2005. This action is necessary to help facilitate rehabilitation construction at the bridge.

DATES: Comments must reach the Coast Guard on or before March 7, 2005.

ADDRESSES: You may mail comments to Commander (obr), First Coast Guard District Bridge Branch, One South Street, Battery Park Building, New York, New York 10004, or deliver them to the same address between 7 a.m. and 3 p.m., Monday through Friday, except, Federal holidays. The telephone number is (212) 668–7165. The First Coast Guard District, Bridge Branch, maintains the public docket for this rulemaking. Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, will become part of this docket and will be available for inspection or copying at the First Coast Guard District, Bridge Branch, 7 a.m. to 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. John W. McDonald Project Officer, First Coast Guard District, (617) 223–8364.

SUPPLEMENTARY INFORMATION:

Request for Comments

We encourage you to participate in this rulemaking by submitting comments or related material. If you do so, please include your name and address, identify the docket number for this rulemaking (CGD01–04–129), indicate the specific section of this document to which each comment applies, and give the reason for each comment. Please submit all comments and related material in an unbound format, no larger than 8½ by 11 inches, suitable for copying. If you would like to know if they reached us, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule in view of them.

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for a meeting by writing to the First Coast Guard District, Bridge Branch, at the address under **ADDRESSES** explaining why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

The SR 27 Bridge has a vertical clearance of 10 feet at mean high water, and 19 feet at mean low water in the closed position. The existing drawbridge operating regulations under 33 CFR 117.5 require the bridge to open on signal at all times.

The bridge owner, Maine Department of Transportation, has requested a temporary rule to allow the bridge to open at specific times of either two or three hour intervals between 6 a.m. and 6 p.m., from March 1, 2005, through November 30, 2005. The purpose of this temporary rule is to help facilitate rehabilitation construction at the bridge. Frequent unscheduled bridge openings would greatly limit the progress of the rehabilitation project.

Under this temporary rule, effective from March 1, 2005, through November 30, 2005, the SR 27 Bridge would operate as follows:

From March 1, 2005, through May 26, 2005, and from September 6, 2005, through November 30, 2005, the draw

would open on signal every three hours at 6 a.m., 9 a.m., 12 p.m., 3 p.m. and 6 p.m., daily. From 6 p.m. to 6 a.m. and on holidays, the draw would open on signal.

From May 27, 2005, through September 5, 2005, the draw would open on signal every two hours at 6 a.m., 8 a.m., 10 a.m., 12 p.m., 2 p.m., 4 p.m., and 6 p.m., daily. From 6 p.m. through 6 a.m. and federal holidays, the draw would open on signal.

In addition, the bridge would also be allowed under this temporary rule to remain closed for four periods of four days each between March 1, 2005, and May 26, 2005. The exact dates of the closures would be set out in the final rule and would be announced in the Local Notice to Mariners and the local newspapers at least ten days prior to implementation.

Discussion of Proposed Rule

This proposed change would amend 33 CFR part 117 by adding a new temporary section 33 CFR 117.T536 from March 1, 2005, through November 30, 2005, that would list the temporary drawbridge operation regulations for the SR 27 Bridge.

The bridge owner requested a temporary regulation to help facilitate a major rehabilitation project at the bridge. Frequent unscheduled bridge openings would greatly limit the progress of the rehabilitation project.

Mariners also may transit an available alternate route around Southport Island during time periods the bridge is closed to vessel traffic.

The Coast Guard believes this rule is reasonable based upon all the above information.

Regulatory Evaluation

This proposed rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not "significant" under the regulatory policies and procedures of the Department of Homeland Security.

We expect the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation, under the regulatory policies and procedures of DHS, is unnecessary.

This conclusion is based on the fact that vessel traffic will still be able to transit through the SR 27 Bridge under a fixed opening schedule.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under section 5 U.S.C. 605(b), that this proposed rule would not have a significant economic impact on a substantial number of small entities.

This conclusion is based on the fact that vessel traffic will still be able to transit through the SR 27 Bridge under a fixed opening schedule.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (*see* **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact us in writing at, Commander (obr), First Coast Guard District, Bridge Branch, 408 Atlantic Avenue, Boston, MA. 02110–3350. The telephone number is (617) 223–8364. The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this proposed rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This proposed rule would not effect a taking of private property or otherwise have taking implications under E.O. 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Energy Effects

We have analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that order because it is not a "significant regulatory action" under Executive Order 12866 and is not likely to have a significant adverse effect

on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this proposed rule under Commandant Instruction M16475.1D, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this proposed rule is categorically excluded, under figure 2–1, paragraph (32)(e), of the Instruction, from further environment documentation because it has been determined that the promulgation of operating regulations or procedures for drawbridges are categorically excluded.

List of Subjects in 33 CFR Part 117

Bridges.

Regulations

For the reasons set out in the preamble, the Coast Guard proposes to amend 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; Department of Homeland Security Delegation No. 0170.1; 33 CFR 1.05–1(g); section 117.255 also issued under the authority of Pub. L. 102–587, 106 Stat. 5039.

2. From March 1, 2005, through November 30, 2005, § 117.T536 is temporarily added to read as follows:

§ 117.T536 Townsend Gut.

The draw of the SR 27 Bridge, mile 0.7, across Townsend Gut shall operate as follows:

(a) From March 1, 2005 through May 26, 2005, and from September 6, 2005 through November 30, 2005, the draw shall open on signal at 6 a.m., 9 a.m., 12 p.m., 3 p.m., and 6 p.m., daily. From 6 p.m. through 6 a.m., and on Federal holidays, the draw shall open on signal.

(b) From May 27, 2005 through September 5, 2005, the draw shall open on signal at 6 a.m., 8 a.m., 10 a.m., 12 p.m., 2 p.m., 4 p.m., and 6 p.m., daily. From 6 p.m. through 6 a.m., and on Federal holidays, the draw shall open on signal.

(c) Between March 1, 2005 and May 26, 2005, the bridge may remain in the closed position for four periods of four days each [dates to be inserted at final rule].

Dated: December 3, 2004.

David P. Pekoske,

Rear Admiral, U.S. Coast Guard, Commander, First Coast Guard District.

[FR Doc. 05–262 Filed 1–4–05; 8:45 am]

BILLING CODE 4910–15–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 04–3877; MB Docket No. 04–436; RM–11112]

Radio Broadcasting Services; Cannelton and Tell City, Indiana

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a Petition for Rule Making filed by Hancock Communications, Inc. "(Petitioner"), licensee of Station WLME(FM), Channel 275C3, Cannelton, Indiana, and Station WTCJ–FM, Channel 289A, Tell City, Indiana. Petitioner requests that Channel 275C3 be reallotted from Cannelton to Tell City and that Station WLME(FM)'s license be modified accordingly. Petitioner also requests that Channel 289A be reallotted from Tell City to Cannelton, Indiana, and that Station WTCJ–FM's license be modified accordingly. The coordinates for proposed Channel 289A at Cannelton are 37–48–13 NL and 86–48–57 WL, with a site restriction of 13.5 kilometers (8.4 miles) southwest of Cannelton. The coordinates for proposed Channel 275C3 at Tell City are 37–50–52 NL and 86–36–18 WL, with a site restriction of 18.4 kilometers (11.4 miles) southeast of Tell City.

Since Petitioner's reallotment proposals comply with the provisions of section 1.420(i) of the Commission's rules, the Commission will not accept competing expressions of interest in the use of Channel 289A at Cannelton, Indiana, or the use of Channel 275C3 at Tell City, Indiana, or require the Petitioner to demonstrate the availability of additional equivalent class channels in those communities.

DATES: Comments must be filed on or before February 10, 2005, and reply comments on or before February 25, 2005.

ADDRESSES: Secretary, Federal Communications Commission, 445 12th Street, SW., Room TW–A325, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner's counsel, as follows: John F. Garziglia, Esq. and Howard J. Barr, Esq., Womble Carlyle Sandridge & Rice, PLLC; 1401 Eye Street, NW., Seventh Floor; Washington, DC 20005.

FOR FURTHER INFORMATION CONTACT: R. Barthen Gorman, Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, MB Docket No. 04–436, adopted December 15, 2004, and released December 20, 2004. The full text of this Commission decision is available for inspection and copying during regular business hours in the FCC's Reference Information Center at Portals II, 445 12th Street, SW., CY–A257, Washington, DC 20554. This document may also be purchased from the Commission's duplicating contractors, Best Copy and Printing, Inc., Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 1–800–378–3160 or *http://www.BCPIWEB.com*.

The provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio, Radio broadcasting.

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334, and 336.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Indiana, is amended by removing Channel 275C3 and adding Channel 289A at Cannelton and by removing Channel 289A and adding Channel 275C3 at Tell City.

Federal Communications Commission.

John A. Karousos,

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. 05–117 Filed 1–4–05; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 229

[Docket No. 041108310–4362–02; I.D. 100104H]

RIN 0648-AS78

List of Fisheries for 2005

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; extension of public comment period.

SUMMARY: On December 2, 2004, the proposed List of Fisheries (LOF) for 2005 under the Marine Mammal Protection Act (MMPA) was published in the Federal Register. NMFS is extending the comment period on this proposed LOF to March 4, 2005.

DATES: Comments must be received by March 4, 2005.

ADDRESSES: Send comments to Chief, Marine Mammal Conservation Division, Attn: List of Fisheries, Office of Protected Resources, NMFS, 1315 East-West Highway, Silver Spring, MD 20910. Comments may also be sent via email to *2005LOF.comments@noaa.gov* or the Federal eRulemaking portal: *http://www.regulations.gov* (Follow instructions for submitting comments).

Comments regarding the burden-hour estimates, or any other aspect of the collection of information requirements contained in the proposed rule, should be submitted in writing to the Chief, Marine Mammal Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Silver Spring, MD 20910 and to David Rostker, OMB, by e-mail at *David_Rostker@omb.eop.gov* or by fax to 202–395–7285.

FOR FURTHER INFORMATION CONTACT: Kristy Long, Office of Protected Resources, 301–713-1401; Kim Thounhurst, Northeast Region, 978–281-9328; Juan Levesque, Southeast Region, 727–570–5312; Cathy Campbell, Southwest Region, 562–980–4060; Brent Norberg, Northwest Region, 206–526–6733; Bridget Mansfield, Alaska Region, 907–586–7642. Individuals who use a telecommunications device for the hearing impaired may call the Federal Information Relay Service at 1–800–877–8339 between 8 a.m. and 4 p.m. Eastern time, Monday through Friday, excluding Federal holidays.

SUPPLEMENTARY INFORMATION: On December 2, 2004, the proposed List of Fisheries for 2005 under the Marine Mammal Protection Act was published in the **Federal Register** (69 FR 70094), NMFS must categorize each commercial fishery on the LOF into one of three categories under the MMPA based on the level of serious injury and mortality of marine mammals that occurs incidental to the fishery. NMFS must publish in the **Federal Register** any necessary changes to the LOF after notice and opportunity for public comment. In the proposed LOF for 2005, NMFS proposed several fishery classification, fishery name, and organizational changes. In particular, NMFS proposed to reclassify the California/Oregon thresher shark/swordfish drift gillnet (≥14 in. mesh) from Category II (occasional incidental mortality and serious injury) to Category I (frequent incidental mortality and serious injury) and to reclassify the Northeast bottom trawl, Mid-Atlantic bottom trawl, and five Alaska fisheries from Category III (remote likelihood of or no known incidental mortality and serious injury) to Category II. The five Alaska fisheries include the following: Bering Sea and Aleutian Islands (BSAI) flatfish trawl, BSAI Greenland turbot longline, BSAI pollock trawl, Bering Sea sablefish pot, and Gulf of Alaska Pacific cod longline. Because the comment period coincides with the holiday season, several commenters have already requested an extension of the comment period to adequately review NMFS' proposed changes to the LOF. In addition, NMFS intends to prepare an environmental assessment on the LOF. Therefore, NMFS is extending the public comment period on the proposed LOF for 2005 from January 3, 2005, to March 4, 2005.

Dated: December 29, 2004.

John Oliver,

Deputy Assistant Administrator for Operations, National Marine Fisheries Service.

[FR Doc. 05–214 Filed 1–4–05; 8:45 am]

BILLING CODE 3510–22–S

Notices

Federal Register
Vol. 70, No. 3
Wednesday, January 5, 2005

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Forest Service

Information Collection; Request for Comments; Locatable Minerals

AGENCY: Forest Service, USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Forest Service is seeking comments from all interested individuals and organizations on the extension of an information collection associated with Locatable Minerals operations on National Forest System lands.

DATES: Comments must be received in writing on or before March 7, 2005 to be assured of consideration. Comments received after that date will be considered to the extent practicable.

ADDRESSES: Comments concerning this notice should be addressed to Director, Minerals and Geology Management, Mail Stop 1126, USDA Forest Service, USDA, P.O. Box 96090, Washington, DC 20090–6090.

Comments also may be submitted via facsimile to (703) 605–1575 or by e-mail to *36cfr228a@fs.fed.us.*

The public may inspect comments received at the Office of Director, Minerals and Geology Management, Forest Service, USDA, 5th Floor, Rosslyn Plaza "C" Building, 1601 North Kent Street, Arlington, VA 22209 during normal business hours. Visitors are encouraged to call (703) 605–4852 to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Sam Hotchkiss, Minerals and Geology Management, at (703) 605–4852. Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 twenty-four hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION:

Title: Locatable Minerals.

OMB Number: 0596–0022.

Expiration Date of Approval: July 31, 2005.

Type of Request: Extension with no revision.

Abstract: This collection of information is necessary to ensure that the environmental impacts associated with locatable mineral operations on National Forest System lands are minimized to the extent practicable. The Forest Service regulations at 36 CFR 228.5 require operators, with some exceptions, to submit a Notice of Intent or a Plan of Operations for conducting locatable minerals operations on National Forest System lands. The information that an operator must provide in a Plan of Operations is set out in 36 CFR 228.4(c), (d), and (e). The content of a Notice of Intent is described in 36 CFR 228.4(a)(2), and the content regarding Cessation of Operations is described in 36 CFR 228.10. Paragraph (g) of 36 CFR 228.4 displays the OMB number assigned to the information collection associated with locatable mineral operations.

Mineral operators notify the authorized Forest Service officer of their intention to conduct a locatable mineral operation on National Forest System lands by filing either a Notice of Intent or a Plan of Operations. No specific format is required for the information collection, but the form, FS–2800–5, Plan of Operations for Mining Activities on National Forest System lands, is available for use by the operators.

A Plan of Operations includes the following information: (1) The name and legal mailing address of operators (and claimants if they are not the operators) and their lessees, assigns, or designees; (2) a map or sketch showing information sufficient to locate the proposed area of operations on the ground, existing and/or proposed roads or access routes to be used in connection with the operations as set forth in 228.12 on access and the approximate location and size of areas where surface resources will be disturbed; and (3) information sufficient to describe the type of operations proposed and how they would be conducted, the type and standard of existing and proposed roads or access routes, the means of transportation used or to be used as set forth in 228.12, the period during which the proposed activity will take place, and measures to be taken to meet the requirements for environmental protection in 36 CFR 228.8.

A Notice of Intent includes the following information: (1) Information sufficient to identify the area involved; (2) the nature of the proposed operation; (3) the route of access to the area of operations; and (4) the method of transport. A Cessation of Operations statement includes verification of intent to maintain structures, equipment, and other facilities; expected reopening date; and an estimate of extended durations of operations.

These collections of information are crucial for protecting surface resources, plants, animals and their habitat, as well as the public safety on National Forest System lands. The collected information will help ensure that the exploration, development, and production of mineral resources are conducted in an environmentally sensitive manner; that these mineral operations are integrated with the planning and management of other resources using the principles of ecosystem management; and, that lands disturbed by minerals operations are reclaimed using the best scientific knowledge and principles and returned to other productive uses.

The following table shows the estimated time it takes an operator for an average Plan of Operations, Notice of Intent, and a Cessation of Operations to gather the appropriate information and put it into a logical order before submitting it to the Forest Service. The table also shows the number of the various types of locatable mineral operations received:

	Plan of operations	Notice of intent	Cessation of operations
Estimate of Annual Burden.	8 hours	2 hours	1 hour.
Type of Respondents.	Mineral Operators.	Mineral Operators.	Mineral Operators.
Estimated Annual Number of Respondents.	736	1,396	19
Estimated Annual Number of Responses per Respondent.	1	1	1

	Plan of operations	Notice of intent	Cessation of operations
Estimated Total Annual Burden on Respondents.	5,888	2,792	19

Comment is invited on: (1) Whether this collection of information is necessary for the stated purposes and the proper performance of the functions of the agency, including whether the information will have practical or scientific utility; (2) the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All comments received in response to this notice, including names and addresses when provided, will be a matter of public record. Comments will be summarized and included in the submission for Office of Management and Budget approval.

Dated: December 28, 2004.

Dave Holland,

Acting Deputy Chief for National Forest System.

[FR Doc. 05–180 Filed 1–4–05; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Forest Service

Wrangell-Petersburg Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Wrangell-Petersburg Resource Advisory Committee (RAC) will meet from 8 a.m. until 5:15 p.m. (or until the conclusion of public testimony) on Friday, January 7, and from 8 a.m. until 9 a.m., Saturday, January 8, 2005, in Wrangell, Alaska. The purpose of this meeting is to review, discuss and potentially recommend for funding proposals received pursuant to Title II, Pub. L. 106–393, H.R. 2389, the Secure Rural Schools and Community Self-Determination Act of 2000, also called the "Payments to States" Act. Public testimony regarding the proposals will also be taken.

DATES: The meeting will be held commencing at 8 a.m. on Friday, January 7, through 9 a.m., Saturday, January 8, 2005.

ADDRESSES: The meeting will be held at the James and Elsie Nolan Center, 1096 Outer Drive, Wrangell, Alaska.

FOR FURTHER INFORMATION CONTACT: Michael Davis, Acting Wrangell District Ranger, P.O. Box 51, Wrangell, AK 99929, phone (907) 874–2323, e-mail *michaeldavis@fs.fed.us.* or Patty Grantham, Petersburg District Ranger, P.O. Box 1328, Petersburg, AK 99833, phone (907) 772–3871, e-mail *pagrantham@fs.fed.us.* Toll-free conference calling is available for this meeting; please call or e-mail for specific information. For further information on RAC history, operations, and the application process, a Web site is available at *http://www.fs.fed.us/payments.* Once in the Web site, follow the links to the Wrangell-Petersburg Resource Advisory Committee.

SUPPLEMENTARY INFORMATION: This meeting will focus on the review and discussion of proposals received by the RAC for funding under Title II of the Payments to States legislation (Pub. L. 106–393), particularly proposals that were of high interest to the committee, but lacked enough information for the committee to act. New information may be introduced concerning these proposals. New proposals (initial reading) may be discussed at this meeting. The committee may make recommendations for project funding at this meeting. A field trip to review proposals proximate to the Wrangell, Alaska, area may take place. The meeting is open to the public. Public input opportunity will be provided and individuals will have the opportunity to address the committee at that time.

Dated: December 27, 2004.

Dennis Neill,

Acting Forest Supervisor.

[FR Doc. 05–113 Filed 1–4–05; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF COMMERCE

International Trade Administration

(A–122–840)

Notice of Correction to Notice of Final Results of Antidumping Duty Administrative Review: Carbon and Certain Alloy Steel Wire Rod from Canada

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: December 22, 2004

FOR FURTHER INFORMATION CONTACT: Daniel O'Brien or David Neubacher, at (202) 482–1376 or (202) 482–5823, respectively; AD/CVD Operations, Office 1, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street & Constitution Avenue, NW, Washington, DC 20230.

CORRECTION:

On November 24, 2004, the Department of Commerce (the Department) published its final results of the antidumping administrative review of the order of carbon and certain alloy steel wire rod (subject merchandise) from Canada for the period April 10, 2002, through September 30, 2003. *See Notice of Final Results of Antidumping Duty Administrative Review: Carbon and Certain Alloy Steel Wire Rod from Canada* 69 FR 68309 (November 24, 2004). Subsequent to the issuance of the final results, we identified an inadvertent error in the **Federal Register.**

In the "Assessment" section of the review notice, the Department indicated that it would "issue appropriate assessment instructions directly to CBP within 15 days of publication of these final results of review." The "within 15 days of publication" description is incorrect in the notice. Section 356.8 of the applicable regulations provides that the Department shall not order liquidation until the "forty–first day after the date of publication of the notice ..." following an administrative review of merchandise exported from Canada or Mexico. Accordingly, the notice should be corrected to indicate that the Department will send assessment instructions to CBP "on or after the 41st day after publication."

This correction is issued and published in accordance with section 777(i) of the Tariff Act of 1930, as amended.

Dated: December 29, 2004.

Barbara E. Tillman,

Acting Assistant Secretary for Import Administration.

[FR Doc. 05–194 Filed 1–4–05; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

A–122–822

Notice of Extension of Time Limit for Final Results of Antidumping Duty Administrative Review: Certain Corrosion–Resistant Carbon Steel Flat Products from Canada

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: January 5, 2005.

FOR FURTHER INFORMATION CONTACT: Sean Carey or Douglas Kirby, AD/CVD Operations, Office 6, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230, telephone: (202) 482–3964 and (202) 482–3782, respectively.

SUPPLEMENTARY INFORMATION:

Background

The Department published the antidumping duty order on certain corrosion–resistant carbon steel flat products (CORE) from Canada on August 19, 1993 (58 FR 44162). Based on timely requests, in accordance with section 751(a) of the Act, on September 30, 2003, the Department initiated an administrative review of the antidumping duty order on CORE from Canada, covering the period August 1, 2002, through July 31, 2003. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews, Request for Revocation in Part and Deferral of Administrative Reviews*, 68 FR 56262 (September 30, 2003). This administrative review was initiated on the following exporters: Continuous Colour Coat, Ltd. ("CCC"), Dofasco Inc. ("Dofasco"), Ideal Roofing Company, Ltd. ("Ideal Roofing"), Impact Steel Canada, Ltd. ("Impact Steel"), Russel Metals Export ("Russel Metals"), Sorevco and Company, Ltd. ("Sorevco"), and Stelco Inc. ("Stelco"). On December 19, 2003, the Department published a rescission, in part, of its administrative review with respect to CCC, Impact Steel, and Ideal Roofing. *See Corrosion–Resistant Carbon Steel Flat Products From Canada: Rescission, in Part, of Antidumping Duty Administrative Review*, 68 FR 70764 (December 19, 2003). On March 30, 2004, the Department published a rescission, in part, of its administrative review with respect to Russell Metals. *See Notice of Rescission, in Part, of Antidumping Duty Administrative Review: Corrosion–Resistant Carbon Steel Flat Products From Canada*, 69 FR 16521 (March 30, 2004).

On April 29, 2004, the Department extended the deadline for the preliminary results of this antidumping duty administrative review from May 2, 2004, until no later than August 30, 2004. *See Notice of Extension of Time Limit for Preliminary Results of Antidumping Duty Administrative Review: Corrosion–Resistant Carbon Steel Flat Products From Canada*, 69 FR 23495 (April 29, 2004). On August 30, 2004, the Department issued the preliminary results on CORE from Canada. *See Certain Corrosion–Resistant Carbon Steel Flat Products from Canada: Preliminary Results of Antidumping Duty Administrative Review*, 69 FR 555138 (September 13, 2004) (*Preliminary Results*).

Extension of Time Limits for Final Results

Section 751(a)(3)(A) of the Act requires the Department to issue the preliminary results of an administrative review within 245 days after the last day of the anniversary month of an antidumping duty order for which a review is requested and issue the final results within 120 days after the date on which the preliminary results are published. However, if it is not practicable to complete the review within the time period, section 751(a)(3)(A) of the Act allows the Department to extend these deadlines to a maximum of 365 days and 180 days, respectively.

The Department recently received case briefs and rebuttal briefs from the interested parties involved in this administrative review. The Department has determined that it is not practicable to complete the review within the statutory time limit due to the need for analysis of certain complex issues, including the treatment of certain U.S. sales and considering whether the Department should accept certain "surface type" product characteristics reported by Dofasco for purposes of the Department's model match and cost reporting methodologies. Therefore, in accordance with section 751(a)(3)(A) of the Act, the Department is extending the time limit for the final results from January 11, 2004, to no later than March 14, 2005, which is the next business day since 180 days from the date of publication of the *Preliminary Results* occurs on a weekend. This notice is issued and published in accordance with section 751(a)(1) of the Act and section 351.213(h)(2) of the Department's regulations.

Dated: December 28, 2004.

Barbara E. Tillman,

Acting Deputy Assistant Secretary for AD/CVD Operations.

[FR Doc. 05–193 Filed 1–4–05; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–831]

Fresh Garlic From the People's Republic of China

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: January 5, 2005.

SUMMARY: In November 2004, the Department of Commerce received three requests to conduct new shipper reviews of the antidumping duty order on fresh garlic from the People's Republic of China. We have determined that these requests meet the statutory and regulatory requirements for the initiation of a new shipper review.

FOR FURTHER INFORMATION CONTACT: Sochieta Moth or Brian Ledgerwood at (202) 482–0168 and (202) 482–3836, respectively, AD/CVD Operations, Office 8, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

The notice announcing the antidumping duty order on fresh garlic from the People's Republic of China (PRC) was published on November 16, 1994. On November 22, 2004, we received a request for a new shipper review from Zhangqui Quingyuan Vegetable Co., Ltd. (Quingyuan). On November 30, 2004, we received requests for new shipper reviews from Shanghai LJ International Trading Co., Ltd. (Shanghai LJ) and Huaiyang Huamei Foodstuff Co., Ltd. (Huamei).

Qingyuan and Huamei certified that they both grew and exported the subject merchandise on which they based their requests for a new shipper review. Shanghai LJ certified that it exported the subject merchandise on which it based its request for a new shipper review, but that it did not grow the subject

merchandise. Specifically, Shanghai LJ certified that Henan Xiancheng Sunny Foodstuff Factory (Sunny Foodstuff) grew the subject merchandise it exported.

Initiation of New Shipper Reviews

Pursuant to 19 CFR 351.214(b)(2)(i), Huamei, Shanghai LJ, and Qingyuan certified that they did not export subject merchandise to the United States during the period of investigation (POI). In addition, pursuant to 19 CFR 351.214(b)(2)(ii)(B), Sunny Foodstuff, the grower of the garlic exported by Shanghai LJ, provided a certification that it did not export the subject merchandise to the United States during the POI.

Pursuant to 19 CFR 351.214(b)(2)(iii)(A), each of the three exporters, Huamei, Shanghai LJ, and Qingyuan, certified that, since the initiation of the investigation, they have never been affiliated with any exporter or producer who exported the subject merchandise to the United States during the POI, including those not individually examined during the investigation. As required by 19 CFR 351.214(b)(2)(iii)(B), each of the above-mentioned companies also certified that their export activities were not controlled by the central government.

In addition to the certifications described above, the companies submitted documentation establishing the following: (1) The date on which they first shipped the subject merchandise for export to the United States and the date on which the subject merchandise was first entered, or withdrawn from warehouse, for consumption; (2) the volume of their first shipment and the volume of subsequent shipments; and (3) the date of their first sale to an unaffiliated customer in the United States.

Pursuant to section 751(a)(2)(B) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.214(d)(1), we are initiating three new shipper reviews for shipments of fresh garlic from the PRC:

(1) Grown and exported by Qingyuan,

(2) Grown and exported by Huamei, and

(3) Grown by Sunny Foodstuffs and exported by Shanghai LJ.

The period of review (POR) is November 1, 2003, through October 31, 2004. *See* 19 CFR 351.214(g)(1)(i)(A). We intend to issue preliminary results of these reviews no later than 180 days from the date of initiation, and final results of these reviews no later than 270 days from the date of initiation. See section 751(a)(2)(B)(iv) of the Act.

Because Qingyuan and Huamei have certified that they both grew and exported the subject merchandise on which they based their request for a new shipper review, we will instruct U.S. Customs and Border Protection (CBP) to allow, at the option of the importer, the posting of a bond or security in lieu of a cash deposit for each entry of the subject merchandise both grown and exported by these companies until the completion of the new shipper reviews. With respect to Shanghai LJ, it has certified that it exported, but did not grow the subject merchandise on which it based its request for a new shipper review. Therefore, until completion of the new shipper reviews, we will instruct CBP to allow, at the option of the importer, the posting of a bond or security in lieu of a cash deposit for entries of subject merchandise grown by Sunny Foodstuffs and exported by Shanghai LJ.

Interested parties that need access to proprietary information in this new shipper review should submit applications for disclosure under administrative protective order in accordance with 19 CFR 351.305 and 351.306.

This initiation and notice are in accordance with section 751(a)(2)(B) of the Act and 19 CFR 351.214 and 351.221(c)(1)(i).

Dated: December 29, 2004.

Barbara E. Tillman,

Acting Deputy Assistant Secretary for Import Administration.

[FR Doc. 05–195 Filed 1–4–05; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Minority Business Development Agency

[Docket No: 041229365–4365–01]

White House Initiative on Asian Americans and Pacific Islanders, President's Advisory Commission on Asian Americans and Pacific Islanders

AGENCY: Minority Business Development Agency, Department of Commerce.

ACTION: Notice of meeting.

SUMMARY: The Minority Business Development Agency (MBDA) publishes this notice to announce that the President's Advisory Commission on Asian Americans and Pacific Islanders (Commission) will be holding a public meeting to seek testimonies from individuals and organizations on ways to provide equal economic opportunities for full participation of Asian American and Pacific Islander businesses in our free market economy where they may be underserved.

DATES: The public meeting will be held on Monday, January 24, 2005, from 8:30 a.m.–5:30 p.m. EST, and Tuesday, January 25, 2004 from 8:30 a.m.–1 p.m. For members of the public who are interested in addressing the Commission, please submit your written requests by January 14, 2005. Requests for special assistance, such as sign language interpretation or other reasonable accommodations, should be submitted to Mr. Erik Wang (See **FOR FURTHER INFORMATION CONTACT**) no later than January 7, 2005.

ADDRESSES: The public meeting will be held on Monday, January 24, 2005 at: National Institute of Standards and Technology, 100 Bureau Drive, Green Auditorium, Gaithersburg, Maryland 20899. And on Tuesday, January 25, 2005 at: Southeast Asia Resource Action Center, 1628 16th Street, NW., Washington, DC 20009. For members of the public who are interested in addressing the Commission, please submit your request to Mr. Erik Wang, Office of the White House Initiative on AAPIs, Herbert C Hoover Building, 1401 Constitution Avenue, NW., Room 5092, Washington, DC 20230, or by fax to (202) 219–8809.

FOR FURTHER INFORMATION CONTACT: For additional information about the Commission or the public meeting, please contact: Mr. Eddy Badrina or Mr. Erik Wang, Office of the White House Initiative on AAPIs, Herbert C Hoover Building, 1401 Constitution Avenue, NW., Room 5092, Washington, DC 20230, Telephone (202) 482–3949.

SUPPLEMENTARY INFORMATION: In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the Commission's intent to conduct a public meeting on January 24 and January 25, 2005. Agenda items will include, but will not be limited to: Testimony from community organizations and individuals; testimony from federal agencies; administrative tasks; upcoming events; and comments from the public.

The purpose of the Commission is to advise and make recommendations to the President on ways to provide equal economic opportunities for full participation of Asian American and Pacific Islander businesses in our free market economy where they may be underserved and thus, improving the quality of life for approximately 14.5 million Asian Americans and Pacific Islanders living in the United States and the U.S.-associated Pacific Island jurisdictions.

Requests to address the Commission must be made in writing and should include the name, address, telephone number and business or professional affiliation of the interested party. Individuals or groups addressing similar issues are encouraged to combine comments and make their request to address the Commission through a single representative. The allocation of time for remarks will be adjusted to accommodate the level of expressed interest. Written requests must be mailed or faxed to The Office of the White House Initiative on AAPIs by January 14, 2005 (See **ADDRESSES**). Anyone who requires special assistance, such as sign language interpretation or other reasonable accommodations, should contact Mr. Erik Wang no later than January 7, 2005 (See **FOR FURTHER INFORMATION CONTACT**). This meeting is open to the public.

Ronald Marin,

Financial Management Officer.

[FR Doc. 05–114 Filed 1–4–05; 8:45 am]

BILLING CODE 3510–21–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

[Docket No.: 041220354–4354–01]

Small Grants Programs; Availability of Funds

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Notice.

SUMMARY: The National Institute of Standards and Technology (NIST) announces that the following programs are soliciting applications for financial assistance for FY 2005: (1) The Electronics and Electrical Engineering Laboratory Grants Program; (2) the Manufacturing Engineering Laboratory Grants Program; (3) the Chemical Science and Technology Laboratory Grants Program; (4) the Physics Laboratory Grants Program; (5) the Materials Science and Engineering Laboratory Grants Program; (6) the Building Research Grants and Cooperative Agreements Program; and (7) the Fire Research Grants Program. Each program will only consider applications that are within the scientific scope of the program as described in this notice and in the detailed program descriptions found in the Federal Funding Opportunity (FFO) announcement for these programs. Prior to preparation of a proposal, it is strongly suggested that potential applicants contact the Program Manager for the appropriate field of research, as specified in the FFO announcement found at *http://www.grants.gov*, for clarification of the program objective and to determine whether their proposal is responsive to this notice.

DATES: See below.

ADDRESSES: See below.

SUPPLEMENTARY INFORMATION: *Catalog of Federal Domestic Assistance Name and Number:* Measurement and Engineering Research and Standards—11.609

Electronics and Electrical Engineering Laboratory (EEEL) Grants Program:

Program Description: The Electronics and Electrical Engineering Laboratory (EEEL) Grants Program will provide grants and cooperative agreements for the development of fundamental electrical metrology and of metrology supporting industry and government agencies in the broad areas of semiconductors, electronic instrumentation, radio-frequency technology, optoelectronics, magnetics, video, electronic commerce as applied to electronic products and devices, the transmission and distribution of electrical power, national electrical standards (fundamental, generally quantum-based physical standards), and law enforcement standards.

DATES: All applications, paper and electronic, must be received no later than 5 p.m. eastern standard time on September 30, 2005. Proposals received between July 1, 2005 and September 30, 2005 be processed and considered for funding under this solicitation, but if selected, proposals may be funded in the next fiscal year, subject to the availability of funds.

ADDRESSES: Paper applications must be submitted to: Sheilda Bryner, Electronics and Electrical Engineering Laboratory, National Institute of Standards and Technology, 100 Bureau Drive, Stop 8100, Gaithersburg, MD 20899–8100. Electronic applications and associated proposal information should be uploaded to grants.gov.

FOR FURTHER INFORMATION CONTACT: For complete information about this program and instructions for applying by paper or electronically, read the Federal Funding Opportunity (FFO) Notice at *http://www.grants.gov*. A paper copy of the FFO may be obtained by calling (301) 975–6328. Program questions should be addressed to Sheilda Bryner, Electronics and Electrical Engineering Laboratory, National Institute of Standards and Technology, 100 Bureau Drive, Stop 8100, Gaithersburg, MD 20899–8100, Tel.: (301) 975–2220, Fax: (301) 975–4091. All grants related administration questions concerning this program should be addressed to: Joyce Brigham, NIST Grants and Agreements Management Division, (301) 975–6328; *joyce.brigham@nist.gov*. For assistance with using Grants.gov contact *support@grants.gov*.

Funding Availability: In fiscal year 2004, the EEEL Grants Program made five new awards, totaling $184,490. The amount available each year fluctuates considerably based on programmatic needs. Individual awards are expected to range between $5,000 and $150,000.

For the Electronics and Electrical Engineering Laboratory Grants Program, proposals will be considered for research projects from one to three years. When a proposal for a multi-year award is approved, funding will generally be provided for only the first year of the program. If an application is selected for funding, NIST has no obligation to provide any additional funding in connection with that award. Continuation of an award to increase funding or extend the period of performance is at the total discretion of NIST. Funding for each subsequent year of a multi-year proposal will be contingent upon satisfactory progress, continued relevance to the mission of the Electronics and Electrical Engineering Laboratory Grants Program, and the availability of funds. The multi-year awards must have scopes of work that can be easily separated into annual increments of meaningful work that represent solid accomplishments if prospective funding is not made available to the applicant, (*i.e.*, the scopes of work for each funding period must produce identifiable and meaningful results in and of themselves).

Statutory Authority: As authorized by 15 U.S.C. 272(b) and (c), the NIST Electronics and Electrical Engineering Laboratory conducts a basic and applied research program directly and through grants and cooperative agreements to eligible recipients.

Eligibility: The Electronics and Electrical Engineering Laboratory Grants Program is open to institutions of higher education; hospitals; non-profit organizations; commercial organizations; state, local, and Indian tribal governments; foreign governments; organizations under the jurisdiction of foreign governments; and international organizations.

Review and Selection Process: For the Electronics and Electrical Engineering Laboratory Grants Program, proposals will be distributed to the appropriate Division Chief or Office Director or designee based on technical area by one

or more technical professionals familiar with the programs of the Electronics and Electrical Engineering Laboratory. The proposals will be reviewed in a two-step process. First, at least three independent, objective individuals knowledgeable about the particular scientific area described in the Program Description section above that the proposal addresses will conduct a technical review of each proposal, based on the evaluation criteria described below. If non-Federal reviewers are used, the reviewers may discuss the proposals with each other, but scores will be determined on an individual basis, not as a consensus.

Reviews will be conducted on a quarterly basis, and all proposals received during the quarter will be ranked based on the reviewers' scores.

Second, the Division Chief or Office Director will make application selections. In making application selections, the Division Chief or Office Director will take into consideration the results of the reviewers' evaluations, the availability of funding, and relevance to the objectives of the Electronics and Electrical Engineering Laboratory Grants Program, as described in the Program Description section above. The final approval of selected applications and award of financial assistance will be made by the NIST Grants Officer based on compliance with application requirements as published in this notice, compliance with applicable legal and regulatory requirements, compliance with Federal policies that best further the objectives of the Department of Commerce, and whether the recommended applicants appear to be responsible. Applicants may be asked to modify objectives, work plans, or budgets and provide supplemental information required by the agency prior to award. The decision of the Grants Officer is final. Applicants should allow up to 90 days processing time.

Unsuccessful applicants will be notified in writing. The Program will retain one copy of each unsuccessful application for three years for record keeping purposes. The remaining copies will be destroyed.

Evaluation Criteria: For the Electronics and Electrical Engineering Laboratory Grants Program, the evaluation criteria and weights to be used by the technical reviewers in evaluating the proposals are as follows:

Proposal addresses specific program objectives as described in this notice (25%).

Proposal provides evidence of applicant's expertise in relevant technical area (20%).

Proposal offers innovative approach (20%).

Proposal provides realistic schedule with defined milestones (20%).

Proposal provides adequate rationale for budget (15%).

Cost Share Requirements: The Electronics and Electrical Engineering Laboratory Grants Program does not require any matching funds.

Manufacturing Engineering Laboratory (MEL) Grants Program:

Program Description: The Manufacturing Engineering Laboratory (MEL) Grants Program will provide grants and cooperative agreements in the following fields of research: Dimensional Metrology for Manufacturing, Mechanical Metrology for Manufacturing, Intelligent Systems, and Information Systems Integration for Applications in Manufacturing.

DATES: All applications, paper and electronic, must be received no later than 5 p.m. eastern standard time on September 30, 2005. Proposals received between July 1. 2005 and September 30, 2005 will be processed and considered for funding under this solicitation, but if selected, proposals may be funded in the next fiscal year, subject to the availability of funds.

ADDRESSES: Paper applications must be submitted to: Mrs. Mary Lou Norris, Manufacturing Engineering Laboratory, National Institute of Standards and Technology, 100 Bureau Drive, Stop 8200, Building 220, Room B322, Gaithersburg, Maryland 20899–8200. Electronic applications and associated proposal information should be uploaded to grants.gov.

FOR FURTHER INFORMATION CONTACT: For complete information about this program and instructions for applying by paper or electronically, read the Federal Funding Opportunity (FFO) Notice at *http://www.grants.gov*. A paper copy of the FFO may be obtained by calling (301) 975–6328. Program questions should be addressed to Mrs. Mary Lou Norris, Manufacturing Engineering Laboratory, National Institute of Standards and Technology, 100 Bureau Drive, Stop 8200, Building 220, Room B322, Gaithersburg, Maryland 20899–8200, Tel: (301) 975–3400, e-mail: *mnorris@nist.gov*. All grants related administration questions concerning this program should be addressed to: Joyce Brigham, NIST Grants and Agreements Management Division, (301) 975–6328; *joyce.brigham@nist.gov*. For assistance with using Grants.gov contact *support@grants.gov*.

Funding Availability: In fiscal year 2004, the MEL Grants Program funded 2 new awards, totaling $187,987. In fiscal year 2005 the MEL Grants Program anticipates funding of approximately $500,000, including new awards and continuing projects. Individual awards are expected to range from approximately $25,000 to $300,000.

For the MEL Grants Program, proposals will be considered for research projects from one to five years. When a proposal for a multi-year award is approved, funding will generally be provided for only the first year of the program. If an application is selected for funding, NIST has no obligation to provide any additional funding in connection with that award. Continuation of an award to increase funding or extend the period of performance is at the total discretion of NIST. Funding for each subsequent year of a multi-year proposal will be contingent upon satisfactory progress, continued relevance to the mission of the MEL program, and the availability of funds. The multi-year awards must have scopes of work that can be easily separated into annual increments of meaningful work that represent solid accomplishments if prospective funding is not made available to the applicant, (*i.e.*, the scopes of work for each funding period must produce identifiable and meaningful results in and of themselves).

Statutory Authority: As authorized under 15 U.S.C. 272(b) and (c), the MEL conducts a basic and applied research program directly and through grants and cooperative agreements to eligible recipients.

Eligibility: The MEL Grants Program is open to institutions of higher education; hospitals; non-profit organizations; commercial organizations; state, local, and Indian tribal governments; foreign governments; organizations under the jurisdiction of foreign governments; and international organizations.

Review and Selection Process: For the MEL Grants Program responsive proposals will be assigned, as received on a rolling basis, to the most appropriate area for review. At least three independent, objective individuals knowledgeable about the particular scientific area described in the Program Description section above that the proposal addresses will conduct a technical review of proposals based on the evaluation criteria. If non-Federal reviewers are used, the reviewers may discuss the proposals with each other, but scores will be determined on an individual basis, not as a consensus. The Division Chief or Laboratory Director will make application selections. In making application

selections, the Division Chief or Laboratory Director will take into consideration the results of the reviewers' evaluations, the availability of funds, and relevance to the objectives of the MEL Grants Program. These objectives are described above in the Program Description section above. The final approval of selected applications and award of financial assistance will be made by the NIST Grants Officer based on compliance with application requirements as published in this notice, compliance with applicable legal and regulatory requirements, compliance with Federal policies that best further the objectives of the Department of Commerce, and whether the recommended applicants appear to be responsible. Applicants may be asked to modify objectives, work plans, or budgets and provide supplemental information required by the agency prior to award. The decision of the Grants Officer is final.

Unsuccessful applicants will be notified in writing. The Program will retain one copy of each unsuccessful application for three years for record keeping purposes. The original application will be returned to the applicant.

Evaluation Criteria: For the MEL Grants Program, the evaluation criteria the technical reviewers will use in evaluating the proposals are as follows:

1. Rationality. Reviewers will consider the coherence of the applicant's approach and the extent to which the proposal effectively addresses scientific and technical issues.

2. Technical Merit of Contribution. Reviewers will consider the potential technical effectiveness of the proposal and the value it would contribute to the field of manufacturing engineering and metrology research.

3. Qualifications of Technical Personnel. Reviewers will consider the professional accomplishments, skills, and training of the proposed personnel to perform the work in the project.

4. Resources Availability. Reviewers will consider the extent to which the proposer has access to the necessary facilities and overall support to accomplish project objectives.

Each of these factors will be given equal weight in the evaluation process.

Cost Share Requirements: The MEL Grants Program does not require any matching funds.

Chemical Science and Technology Laboratory Grants Program:

Program Description: The Chemical Science and Technology Laboratory (CSTL) Grants Program will provide grants and cooperative agreements in the following fields of measurement science research, focused on reference methods, reference materials and reference data: Biotechnology, Process Measurements, Surface and Microanalysis Science, Physical and Chemical Properties, and Analytical Chemistry.

DATES: All applications, paper and electronic, must be received no later than 5 p.m. eastern standard time on September 30, 2005. Proposals received between July 1, 2005 and September 30, 2005 will be processed and considered for funding under this solicitation, but if selected, proposals may be funded in the next fiscal year, subject to the availability of funds.

ADDRESSES: Paper applications must be submitted to: Dr. William F. Koch, Chemical Science and Technology Laboratory, National Institute of Standards and Technology, 100 Bureau Drive, Stop 8300, Gaithersburg, MD 20899–8300. Electronic applications and associated proposal information should be uploaded to grants.gov.

FOR FURTHER INFORMATION CONTACT: For complete information about this program and instructions for applying by paper or electronically, read the Federal Funding Opportunity (FFO) Notice at *http://www.grants.gov.* A paper copy of the FFO may be obtained by calling (301) 975–6328. Program questions should be addressed to Dr. William F. Koch, Chemical Science and Technology Laboratory, National Institute of Standards and Technology, 100 Bureau Drive, Stop 8300, Gaithersburg, MD 20899–8300, Tel (301) 975–8301, e-mail: *william.koch@nist.gov.* All grants related administration questions concerning this program should be addressed to: Joyce Brigham, NIST Grants and Agreements Management Division, (301) 975–6328; *joyce.brigham@nist.gov.* For assistance with using Grants.gov contact *support@grants.gov.*

Funding Availability: No funds have been set aside specifically for support of the CSTL Grants Program. The availability of funds depends upon actual authorization of funds and other costs expected to be incurred by individual divisions within the laboratory. Where funds are identified as available for grants, those funds will be awarded to highly ranked proposals as determined by the process described in this notice.

In fiscal year 2004, the CSTL Grants Program funded 2 new awards, totaling $343,184. In fiscal year 2005, the CSTL Grants Program anticipates funding of approximately $500,000. Individual awards are expected to range from approximately $5,000 to $100,000.

For the Chemical Science and Technology Laboratory Grant Program, proposals will be considered for research projects from one to three years. When a proposal for a multi-year award is approved, funding will generally be provided for only the first year of the program. If an application is selected for funding, NIST has no obligation to provide any additional funding in connection with that award. Continuation of an award to increase funding or extend the period of performance is at the total discretion of NIST. Funding for each subsequent year of a multi-year proposal will be contingent upon satisfactory progress, continued relevance to the mission of the Chemical Science and Technology Laboratory program, and the availability of funds. The multi-year awards must have scopes of work that can be easily separated into annual increments of meaningful work that represent solid accomplishments if prospective funding is not made available to the applicant, (*i.e.* the scopes of work for each funding period must produce identifiable and meaningful results in and of themselves).

Statutory Authority: As authorized under 15 U.S.C. 272 (b) and (c), the Chemical Science and Technology Laboratory conducts a basic and applied research program directly and through grants and cooperative agreements to eligible recipients.

Eligibility: The Chemical Science and Technology Laboratory Grants Program is open to institutions of higher education; hospitals; non-profit organizations; commercial organizations; state, local, and Indian tribal governments; foreign governments; organizations under the jurisdiction of foreign governments; and international organizations.

Review and Selection Process: For the Chemical Science and Technology Laboratory Grants Program, proposals will be reviewed in a three-step process. First, the Deputy Director of CSTL, or appropriate CSTL Division Chief, will determine the compatibility of the applicant's proposal with CSTL Program Areas and the relevance to the objectives of the Chemical Science and Technology Laboratory Grants Program, described in the Program Description section above. If it is determined that the proposal is incomplete or non-responsive to the scope of the stated objectives, the proposal will not be reviewed for technical merit. If it is determined that all funds available for the CSTL Grants Program for the given year have been exhausted, the proposal

will not be reviewed for technical merit. If a proposal is determined to be incomplete or non-responsive, or if it is determined that all available funds have been exhausted. the CSTL Grants Program will retain one copy of the proposal for three years for record keeping purposes. The remaining copies will be destroyed.

Second, at least three independent, objective individuals knowledgeable about the particular measurement science area described in the section above that the proposal addresses will conduct a technical review of each proposal, based on the evaluation criteria described below. Reviews will be conducted on a quarterly basis, and all responsive, complete proposals received and reviewed since the last quarter will be ranked based on the reviewers' scores. If non-Federal reviewers are used, the reviewers may discuss the proposals with each other, but scores will be determined on an individual basis, not as a consensus.

Third, the Division Chief will make application selections, taking into consideration the results of the reviewers' evaluations, the availability of funds, and the relevance of the proposal to the program objectives described in the Program Description section above.

The final approval of selected applications and award of financial assistance will be made by the NIST Grants Officer based on compliance with application requirements as published in this notice, compliance with applicable legal and regulatory requirements, compliance with Federal policies that best further the objectives of the Department of Commerce, and whether the recommended applicants appear to be responsible. Applicants may be asked to modify objectives, work plans, or budgets and provide supplemental information required by the agency prior to award. The decisions of the Grants Officer are final.

Unsuccessful applicants will be notified in writing. The Program will retain one copy of each unsuccessful application for three years for record keeping purposes. The remaining copies will be destroyed.

Evaluation Criteria: For the Chemical Science and Technology Laboratory Grants Program, the evaluation criteria the technical reviewers will use in evaluating the proposals are as follows:

1. Rationality. Reviewers will consider the coherence of the applicant's approach and the extent to which the proposal effectively addresses scientific and technical issues.

2. Qualifications of Technical Personnel. Reviewers will consider the professional accomplishments, skills, and training of the proposed personnel to perform the work in the project.

3. Resources Availability. Reviewers will consider the extent to which the proposer has access to the necessary facilities and overall support to accomplish project objectives.

4. Technical Merit of Contribution. Reviewers will consider the potential technical effectiveness of the proposal and the value it would contribute to the field of measurement science, especially as it pertains to reference methods, reference materials and reference data in Chemical Science and Technology.

Each of these factors will be given equal weight in the evaluation process.

Cost Share Requirements: The Chemical Science and Technology Laboratory Grants Program does not require any matching funds.

Physics Laboratory Grants Program:

Program Description: The Physics Laboratory (PL) Grants Program will provide grants and cooperative agreements in the following fields of research: Electron and Optical Physics, Atomic Physics, Optical Technology, Ionizing Radiation, Time and Frequency, and Quantum Physics.

DATES: All applications, paper and electronic, must be received no later than 5 p.m. eastern standard time on September 30, 2005. Proposals received between July 1, 2005 and September 30, 2005 will be processed and considered for funding under this solicitation, but if selected, proposals may be funded in the next fiscal year, subject to the availability of funds.

ADDRESSES: Paper applications must be submitted to: Ms. Anita Sweigert, Physics Laboratory, National Institute of Standards and Technology, 100 Bureau Drive, Stop 8400, Gaithersburg, MD 20899–8400. Electronic applications and associated proposal information should be uploaded to grants.gov.

FOR FURTHER INFORMATION CONTACT: For complete information about this program and instructions for applying by paper or electronically, read the Federal Funding Opportunity (FFO) Notice at *http://www.grants.gov*. A paper copy of the FFO may be obtained by calling (301) 975–6328. Program questions should be addressed to Ms. Anita Sweigert, Physics Laboratory, National Institute of Standards and Technology, 100 Bureau Drive, Stop 8400, Gaithersburg, MD 20899–8400, Tel (301) 975–4200, e-mail: *anita.sweigert@nist.gov*. It is strongly suggested to first confirm the program objectives with the Program Manager prior to preparing a detailed proposal. All grants related administration questions concerning this program should be addressed to: Joyce Brigham, NIST Grants and Agreements Management Division, (301) 975–6328; *joyce.brigham@nist.gov*. For assistance with using Grants.gov contact *support@grants.gov*.

Funding Availability: In fiscal year 2004, the PL Grants Program funded 17 new awards, totaling $2,326,458. In fiscal year 2005, the PL Grants Program anticipates funding of approximately $1,700,000, including new awards and continuing projects. Funding availability will be apportioned by quarter. Individual awards are expected to range from approximately $5,000 to $300,000.

For the Physics Laboratory Grants Program, proposals will be considered for research projects from one to three years. When a proposal for a multi-year project is approved, funding will generally be provided for only the first year of the program. If an application is selected for funding, NIST has no obligation to provide any additional funding in connection with that award. Continuation of an award to increase funding or extend the period of performance is at the total discretion of NIST. Funding for each subsequent year of a multi-year proposal will be contingent upon satisfactory progress, continued relevance to the mission of the Physics Laboratory program, and the availability of funds. The multi-year awards must have scopes of work that can be easily separated into annual increments of meaningful work that represent solid accomplishments if prospective funding is not made available to the applicant (*i.e.*, the scopes of work for each funding period must produce identifiable and meaningful results in and of themselves).

Statutory Authority: As authorized under 15 U.S.C. 272(b) and (c), the Physics Laboratory conducts a basic and applied research program directly and through grants and cooperative agreements to eligible recipients.

Eligibility: The Physics Laboratory Grants Program is open to institutions of higher education; hospitals; non-profit organizations; commercial organizations; state, local, and Indian tribal governments; foreign governments; organizations under the jurisdiction of foreign governments; and international organizations.

Review and Selection Process: For the Physics Laboratory Grants Program, responsive proposals will be considered as follows: First, at least three independent, objective individuals knowledgeable about the particular scientific area described in the proposal

will conduct a technical review of each proposal, based on the evaluation criteria described below. Reviews will be conducted on a monthly basis within each division of the Physics Laboratory, and all proposals received during the month will be ranked based on the reviewers' scores. If non-Federal reviewers are used, reviewers may discuss the proposals with each other, but scores will be determined on an individual basis, not as a consensus.

Next, the Division Chief will make final application selections, taking into consideration the results of the reviewers' evaluations, including rank; the compilation of a slate that, when taken as a whole, is likely to best further the program interests described in the Program Description section above; and the availability of funds.

The final approval of selected applications and award of financial assistance will be made by the NIST Grants Officer based on compliance with application requirements as published in this notice, compliance with applicable legal and regulatory requirements, compliance with Federal policies that best further the objectives of the Department of Commerce, and whether the recommended applicants appear to be responsible.

Applicants may be asked to modify objectives, work plans, or budgets and provide supplemental information required by the agency prior to award.

The decisions of the Grants Officer are final.

Unsuccessful applicants will be notified in writing. The Program will retain one copy of each unsuccessful application for three years for record keeping purposes. The remaining copies will be destroyed.

Evaluation Criteria: For the Physics Laboratory Grants Program, the evaluation criteria the technical reviewers will use in evaluating the proposals are as follows:

1. Rationality. Reviewers will consider the coherence of the applicant's approach and the extent to which the proposal effectively addresses scientific and technical issues.

2. Qualifications of Technical Personnel. Reviewers will consider the professional accomplishments, skills, and training of the proposed personnel to perform the work in the project.

3. Resources Availability. Reviewers will consider the extent to which the proposer has access to the necessary facilities and overall support to accomplish project objectives.

4. Technical Merit of Contribution. Reviewers will consider the potential technical effectiveness of the proposal and the value it would contribute to the field of physics.

Each of these factors will be given equal weight in the evaluation process.

Cost Share Requirements: The Physics Laboratory Grants Program does not require any matching funds.

MSEL Grants Program:

Program Description: The Materials Science and Engineering Laboratory (MSEL) Grants Program will provide grants and cooperative agreements in the following fields of research: Ceramics; Metallurgy; Polymer Sciences; Materials Reliability; and Neutron Scattering Research and Spectroscopy.

DATES: All applications, paper and electronic, must be received no later than 5 p.m. eastern standard time on September 30, 2005. Proposals received between July 1, 2005 and September 30, 2005 will continue to be processed and considered for funding under this solicitation, but if selected, proposals may be funded in the next fiscal year, subject to the availability of funds.

ADDRESSES: Paper applications must be submitted to: Dr. Stephen W. Freiman, Materials Science and Engineering Laboratory, National Institute of Standards and Technology, 100 Bureau Drive, Stop 8500, Gaithersburg, Maryland 20899–8500. Electronic applications and associated proposal information should be uploaded to grants.gov.

FOR FURTHER INFORMATION CONTACT: For complete information about this program and instructions for applying by paper or electronically, read the Federal Funding Opportunity (FFO) Notice at *http://www.grants.gov*. A paper copy of the FFO may be obtained by calling (301) 975–6328. Program questions should be addressed to Dr. Stephen W. Freiman, Materials Science and Engineering Laboratory, National Institute of Standards and Technology, 100 Bureau Drive, Stop 8500, Gaithersburg, Maryland 20899–8500, Tel: (301) 975–5658, E-mail: *stephen.freiman@nist.gov*. All grants related administration questions concerning this program should be addressed to: Joyce Brigham, NIST Grants and Agreements Management Division, (301) 975–6328; *joyce.brigham@nist.gov*. For assistance with using Grants.gov contact *support@nist.gov*.

Funding Availability: In fiscal year 2004, the MSEL Grants Program funded 11 new awards, totaling $1,122,796. In fiscal year 2005, the MSEL Grants Program anticipates funding of approximately $4,500,000, including new awards and continuing projects. Most grants and cooperative agreements are expected to be in the $25,000 to $100,000 per year range.

For the MSEL Grants Program, proposals will be considered for research projects from one to three years. When a proposal for a multi-year award is approved, funding will generally be provided for only the first year of the program. If an application is selected for funding, NIST has no obligation to provide any additional funding in connection with that award. Continuation of an award to increase funding or extend the period of performance is at the total discretion of NIST. Funding for each subsequent year of a multi-year proposal will be contingent upon satisfactory progress, continued relevance to the mission of the MSEL program, and the availability of funds. The multi-year awards must have scopes of work that can be easily separated into annual increments of meaningful work that represent solid accomplishments if prospective funding is not made available to the applicant, (*i.e.*, the scopes of work for each funding period must produce identifiable and meaningful results in and of themselves).

Statutory Authority: As authorized under 15 U.S.C. 272 (b) and (c), the MSEL conducts a basic and applied research program directly and through grants and cooperative agreements to eligible recipients.

Eligibility: The MSEL Grants Program is open to institutions of higher education; hospitals; non-profit organizations; commercial organizations; state, local, and Indian tribal governments; foreign governments; organizations under the jurisdiction of foreign governments; and international organizations.

Review and Selection Process: For the MSEL Grants Program proposals will be reviewed in a two-step process. First, at least three independent, objective individuals knowledgeable about the particular scientific area described in the Program Description section above that the proposal addresses will conduct a technical review of proposals, as they are received on a rolling basis, based on the evaluation criteria. If non-Federal reviewers are used, the reviewers may discuss the proposals with each other, but scores will be determined on an individual basis, not as a consensus. Second, the Division Chief or Center Director or Laboratory Deputy Director will make application selections. In making application selections, the Division Chief or Center Director or Laboratory Deputy Director will take into consideration the results of the reviewers' evaluations, the availability

of funds, and relevance to the objectives of the MSEL Grants Program, described above in the Program Description section. The final approval of selected applications and award of financial assistance will be made by the NIST Grants Officer based on compliance with application requirements as published in this notice, compliance with applicable legal and regulatory requirements, compliance with Federal policies that best further the objectives of the Department of Commerce, and whether the recommended applicants appear to be responsible. Applicants may be asked to modify objectives, work plans, or budgets and provide supplemental information required by the agency prior to award. The decision of the Grants Officer is final.

Unsuccessful applicants will be notified in writing. The Program will retain one copy of each unsuccessful application for three years for record keeping purposes. The remaining copies will be destroyed.

Evaluation Criteria: For the MSEL Grants Program, the evaluation criteria the technical reviewers will use in evaluating the proposals are as follows:

1. Rationality. Reviewers will consider the coherence of the applicant's approach and the extent to which the proposal effectively addresses scientific and technical issues.

2. Qualifications of Technical Personnel. Reviewers will consider the professional accomplishments, skills, and training of the proposed personnel to perform the work in the project.

3. Resources Availability. Reviewers will consider the extent to which the proposer has access to the necessary facilities and overall support to accomplish project objectives.

4. Technical Merit of Contribution. Reviewers will consider the potential technical effectiveness of the proposal and the value it would contribute to the field of materials science and engineering and neutron research.

Each of these factors will be given equal weight in the evaluation process.

Cost Share Requirements: The MSEL Grants Program does not require any matching funds.

Building Research Grants and Cooperative Agreements Program:

Program Description: The Building Research Grants and Cooperative Agreements Program will provide grants and cooperative agreements in the following fields of research: Structures, Construction Metrology and Automation, Inorganic Materials, Polymeric Materials, HVAC & R Equipment Performance, Mechanical Systems and Controls, Heat Transfer and Alternative Energy Systems, Computer Integrated Building Processes, and Indoor Air Quality and Ventilation.

DATES: All applications, paper and electronic, must be received no later than 5 p.m. eastern standard time on September 30, 2005. Proposals received between July 1, 2005 and September 30, 2005 will be processed and considered for funding under this solicitation, but if selected, proposals may be funded in the next fiscal year, subject to the availability of funds.

ADDRESSES: Paper applications must be submitted to: Karen Perry, Building and Fire Research Laboratory, National Institute of Standards and Technology, 100 Bureau Drive, Stop 8602, Gaithersburg, MD 20899–8602. Electronic applications and associated proposal information should be uploaded to *grants.gov*.

FOR FURTHER INFORMATION CONTACT: For complete information about this program and instructions for applying by paper or electronically, read the Federal Funding Opportunity (FFO) Notice at *http://www.grants.gov*. A paper copy of the FFO may be obtained by calling (301) 975–6328. Program questions should be addressed to Karen Perry, Building and Fire Research Laboratory, National Institute of Standards and Technology, 100 Bureau Drive, Stop 8602, Gaithersburg, MD 20899–8602, Tel.: (301) 975–5910, Fax: (301) 975–4032, *http://www.bfrl.nist.gov*. All grants related administration questions concerning this program should be addressed to: Joyce Brigham, NIST Grants and Agreements Management Division, (301) 975–6328; *joyce.brigham@nist.gov*. For assistance with using Grants.gov contact *support@grants.gov*.

Funding Availability: In fiscal year 2004, the Building Research Grants and Cooperative Agreements Program funded 3 new awards, totaling $529,835. No funds have been set aside specifically for support of the Building Research Grants and Cooperative Agreements Program. The availability of funds depends upon actual authorization of funds and other costs expected to be incurred by the individual divisions. The amount available each year fluctuates considerably based on programmatic needs. Individual awards are expected to range between $5,000 and $150,000.

For the Building Research Grants and Cooperative Agreements Program, proposals will be considered for research projects from one to three years. When a proposal for a multi-year award is approved, funding will generally be provided for only the first year of the program. If an application is selected for funding, NIST has no obligation to provide any additional funding in connection with that award. Continuation of an award to increase funding or extend the period of performance is at the total discretion of NIST. Funding for each subsequent year of a multi-year proposal will be contingent upon satisfactory progress, continued relevance to the mission of the Building Research Grants and Cooperative Agreements Program, and the availability of funds. The multi-year awards must have scopes of work that can be easily separated into annual increments of meaningful work that represent solid accomplishments if prospective funding is not made available to the applicant, (*i.e.*, the scopes of work for each funding period must produce identifiable and meaningful results in and of themselves).

Statutory Authority: As authorized by 15 U.S.C. 272(b) and (c), the NIST Building and Fire Research Laboratory conducts a basic and applied research program directly and through grants and cooperative agreements to eligible recipients.

Eligibility: The Building Research Grants and Cooperative Agreements Program is open to institutions of higher education; hospitals; non-profit organizations; commercial organizations; state, local, and Indian tribal governments; foreign governments; organizations under the jurisdiction of foreign governments; and international organizations.

Review and Selection Process: All applications received in response to this announcement will be reviewed to determine whether or not they are complete and responsive. Incomplete or non-responsive applications will not be reviewed for technical merit. The Program will retain one copy of each non-responsive application for three years for recordkeeping purposes. The remaining copies will be destroyed.

Responsive proposals will be forwarded to the appropriate Division Chief, who will assign them to appropriate reviewers. At least three independent, objective individuals knowledgeable about the particular scientific area described in the Program Description section above that the proposal addresses will conduct a technical review of each proposal, based on the evaluation criteria described below. When non-Federal reviewers are used, reviewers may discuss the proposals with each other, but scores will be determined on an individual basis, not as a consensus. Reviews will be conducted no less than once per quarter, and all proposals since the last

review session will be ranked based on the reviewers' scores.

Next, the Division Chief, Laboratory Deputy Director, or Laboratory Director will make application selections. In making application selections, the Division Chief, Laboratory Deputy Director, or Laboratory Director will take into consideration the results of the evaluations, the scores of the reviewers, the availability of funds, and relevance to the objectives of the Building Research Grants and Cooperative Agreements Program, as described in the Program Description section above.

The final approval of selected applications and award of financial assistance will be made by the NIST Grants Officer based on compliance with application requirements as published in this notice, compliance with applicable legal and regulatory requirements, compliance with Federal policies that best further the objectives of the Department of Commerce, and whether the recommended applicants appear to be responsible. Applicants may be asked to modify objectives, work plans, or budgets and provide supplemental information required by the agency prior to award. The award decision of the Grants Officer is final. Applicants should allow up to 90 days processing time.

Unsuccessful applicants will be notified in writing. The Program will retain one copy of each unsuccessful application for three years for record keeping purposes. The remaining copies will be destroyed.

Evaluation Criteria: The Divisions will score proposals based on the following criteria and weights:

1. Technical quality of the research. Reviewers will assess the rationality, innovation and imagination of the proposal and the fit to NIST's in-house building research programs. (0–35 points)

2. Potential impact of the results. Reviewers will assess the potential impact and the technical application of the results to our in-house programs and the building industry. (0–25 points)

3. Staff and institution capability to do the work. Reviewers will evaluate the quality of the facilities and experience of the staff to assess the likelihood of achieving the objective of the proposal. (0–20 points)

4. Match of budget to proposed work. Reviewers will assess the budget against the proposed work to ascertain the reasonableness of the request. (0–20 points)

Cost Share Requirements: The Building Research Grants and Cooperative Agreements Program does not require any matching funds.

Fire Research Grants Program:

Program Description: The Fire Research Grants Program will provide funding for innovative ideas in the fire research area generated by the proposal writer, who chooses the topic and approach.

DATES: All applications, paper and electronic, must be received no later than 5 p.m. eastern standard time on September 30, 2005. Proposals received between May 1, 2005 and September 30, 2005 be processed and considered for funding under this solicitation, but if selected, proposals may be funded in the next fiscal year, subject to the availability of funds.

ADDRESSES: Paper applications must be submitted to: Ms. Wanda Duffin-Ricks, Building and Fire Research Laboratory (BFRL), National Institute of Standards and Technology, 100 Bureau Drive, Stop 8660, Gaithersburg, Maryland 20899–8660. Electronic applications and associated proposal information should be uploaded to *grants.gov.*

FOR FURTHER INFORMATION CONTACT: For complete information about this program and instructions for applying by paper or electronically, read the Federal Funding Opportunity (FFO) Notice at *http://www.grants.gov.* A paper copy of the FFO may be obtained by calling (301) 975–6328. Program questions should be addressed to Ms. Wanda Duffin-Ricks, Building and Fire Research Laboratory (BFRL), National Institute of Standards and Technology, 100 Bureau Drive, Stop 8660, Gaithersburg, Maryland 20899–8660, Tel: (301) 975–6863, e-mail: *wanda.duffin@nist.gov,* Web site: *http://www.bfrl.nist.gov.* All grants related administration questions concerning this program should be addressed to: Joyce Brigham, NIST Grants and Agreements Management Division, (301) 975–6328; *joyce.brigham@nist.gov.* For assistance with using Grants.gov contact *support@grants.gov.*

Funding Availability: For the Fire Research Grants Program, the annual budget is approximately $1.0 to $1.5 million. Because of commitments for the support of multi-year projects and because proposals may have been deferred from the previous year's competition, only a portion of the budget is available to fund applications received in response to this notice. Most grants and cooperative agreements are in the $25,000 to $125,000 per year range, with a maximum requested duration of three years. In fiscal year 2004, the Fire Research Grants Program funded 7 new awards, totaling $517,970.

For the Fire Research Grants Program, proposals will be considered for research projects from one to three years. When a proposal for a multi-year project is approved, funding will normally be provided for only the first year of the program. If an application is selected for funding, DoC has no obligation to provide any additional future funding in connection with that award. Funding for each subsequent year of a multi-year proposal will be contingent on satisfactory progress, continuing relevance to the mission of the NIST Fire Research Program, and the availability of funds.

Statutory Authority: As authorized by 15 U.S.C. 278f, the NIST Building and Fire Research Laboratory conducts directly and through grants and cooperative agreements, a basic and applied fire research program.

Eligibility: The Fire Research Grants Program is open to institutions of higher education; hospitals; non-profit organizations; commercial organizations; state, local, and Indian tribal governments; foreign governments; organizations under the jurisdiction of foreign governments; and international organizations.

Review and Selection Process: Prospective proposers are encouraged to contact the group leaders listed in the FFO announcement to determine the extent of interest prior to preparation of a detailed proposal. Responsive proposals will be assigned, as received on a rolling basis, to the most appropriate group. Proposals are evaluated for technical merit based on the evaluation criteria described above by at least three reviewers chosen from NIST professionals, technical experts from other interested government agencies, and experts from the fire research community at large. When non-Federal reviewers are used, reviewers may discuss the proposals with each other, but scores will be determined on an individual basis, not as a consensus. The group leaders will make funding recommendations to the Division Chief based on the technical evaluation score and the relationship of the work proposed to the objectives of the program.

In making application selections, the Division Chief will take into consideration the results of the evaluations, the scores of the reviewers, the group leader's recommendation, the availability of funds, and relevance to the objectives of the Fire Research Grants Program, as described in the Program Description section above. The final approval of selected applications and award of financial assistance will be made by the NIST Grants Officer based on compliance with application requirements as published in this

notice, compliance with applicable legal and regulatory requirements, compliance with Federal policies that best further the objectives of the Department of Commerce, and whether the recommended applicants appear to be responsible. Applicants may be asked to modify objectives, work plans, or budgets and provide supplemental information required by the agency prior to award. The award decision of the Grants Officer is final. Applicants should allow up to 90 days processing time.

Unsuccessful applicants will be notified in writing. The Program will retain one copy of each unsuccessful application for three years for record keeping purposes. The remaining copies will be destroyed.

Evaluation Criteria: For the Fire Research Grants Program, the technical evaluation criteria are as follows:

1. Technical quality of the research. Reviewers will assess the rationality, innovation and imagination of the proposal. (0–35 points).

2. Potential impact of the results. Reviewers will assess the potential impact and the technical application of the results to the fire safety community. (0–25 points)

3. Staff and institution capability to do the work. Reviewers will evaluate the quality of the facilities and experience of the staff to assess the likelihood of achieving the objective of the proposal. (0–20 points)

4. Match of budget to proposed work. Reviewers will assess the budget against the proposed work to ascertain the reasonableness of the request. (0–20 points)

Cost Share Requirements: The Fire Research Grants Program does not require any matching funds.

The following information applies to all programs announced in this notice:

The Department of Commerce Pre-Award Notification Requirements for Grants and Cooperative Agreements: The Department of Commerce Pre-Award Notification Requirements for Grants and Cooperative Agreements contained in the **Federal Register** notice of October 1, 2001 (66 FR 49917), as amended by the **Federal Register** notice published on October 30, 2002 (67 FR 66109), are applicable to this announcement. On the form SF–424, the applicant's 9-digit Dun and Bradstreet Data Universal Numbering System (DUNS) number must be entered in the Applicant Identifier block (68 FR 38402).

Collaborations with NIST Employees: All applications should include a description of any work proposed to be performed by an entity other than the applicant, and the cost of such work should ordinarily be included in the budget.

If an applicant proposes collaboration with NIST, the statement of work should include a statement of this intention, a description of the collaboration, and prominently identify the NIST employee(s) involved, if known. Any collaboration by a NIST employee must be approved by appropriate NIST management and is at the sole discretion of NIST. Prior to beginning the merit review process, NIST will verify the approval of the proposed collaboration. Any unapproved collaboration will be stricken from the proposal prior to the merit review.

Use of NIST Intellectual Property: If the applicant anticipates using any NIST-owned intellectual property to carry out the work proposed, the applicant should identify such intellectual property. This information will be used to ensure that no NIST employee involved in the development of the intellectual property will participate in the review process for that competition. In addition, if the applicant intends to use NIST-owned intellectual property, the applicant must comply with all statutes and regulations governing the licensing of Federal government patents and inventions, described at 35 U.S.C. sec. 200–212, 37 CFR part 401, 15 CFR 14.36, and in section 20 of the Department of Commerce Pre-Award Notification Requirements, 66 FR 49917 (2001), as amended by the **Federal Register** notice published on October 30, 2002 (67 FR 66109). Questions about these requirements may be directed to the Counsel for NIST, 301–975–2803.

Any use of NIST-owned intellectual property by a proposer is at the sole discretion of NIST and will be negotiated on a case-by-case basis if a project is deemed meritorious. The applicant should indicate within the statement of work whether it already has a license to use such intellectual property or whether it intends to seek one.

If any inventions made in whole or in part by a NIST employee arise in the course of an award made pursuant to this notice, the United States government may retain its ownership rights in any such invention. Licensing or other disposition of NIST's rights in such inventions will be determined solely by NIST, and include the possibility of NIST putting the intellectual property into the public domain.

Initial Screening of all Applications: All applications received in response to this announcement will be reviewed to determine whether or not they are complete and responsive to the scope of the stated objectives for each program. Incomplete or non-responsive applications will not be reviewed for technical merit. The Program will retain one copy of each non-responsive application for three years for record keeping purposes. The remaining copies will be destroyed.

Paperwork Reduction Act: The standard forms in the application kit involve a collection of information subject to the Paperwork Reduction Act. The use of Standard Forms 424, 424A, 424B, SF–LLL, and CD–346 have been approved by OMB under the respective Control Numbers 0348–0043, 0348–0044, 0348–0040, 0348–0046, and 0605–0001. Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection subject to the requirements of the Paperwork Reduction Act, unless that collection of information displays a currently valid OMB Control Number.

Research Projects Involving Human Subjects, Human Tissue, Data or Recordings Involving Human Subjects: Any proposal that includes research involving human subjects, human tissue, data or recordings involving human subjects must meet the requirements of the Common Rule for the Protection of Human Subjects, codified for the Department of Commerce at 15 CFR part 27. In addition, any proposal that includes research on these topics must be in compliance with any statutory requirements imposed upon the Department of Health and Human Services (DHHS) and other federal agencies regarding these topics, all regulatory policies and guidance adopted by DHHS, FDA, and other Federal agencies on these topics, and all Presidential statements of policy on these topics.

On December 3, 2000, the U.S. Department of Health and Human Services (DHHS) introduced a new Federal-wide Assurance of Protection of Human Subjects (FWA). The FWA covers all of an institution's Federally supported human subjects research, and eliminates the need for other types of Assurance documents. The Office for Human Research Protections (OHRP) has suspended processing of multiple project assurance (MPA) renewals. All existing MPAs will remain in force until further notice. For information about FWAs, please see the OHRP Web site at *http://ohrp.osophs.dhhs.gov/humansubjects/assurance/fwas.htm*

In accordance with the DHHS change, NIST will continue to accept the submission of human subjects protocols that have been approved by Institutional Review Boards (IRBs) possessing a current, valid MPA from DHHS. NIST also will accept the submission of human subjects protocols that have been approved by IRBs possessing a current, valid FWA from DHHS. NIST will not issue a single project assurance (SPA) for any IRB reviewing any human subjects protocol proposed to NIST.

On August 9, 2001, the President announced his decision to allow Federal funds to be used for research on existing human embryonic stem cell lines as long as prior to his announcement (1) the derivation process (which commences with the removal of the inner cell mass from the blastocyst) had already been initiated and (2) the embryo from which the stem cell line was derived no longer had the possibility of development as a human being. NIST will follow guidance issued by the National Institutes of Health at *http://ohrp.osophs.dhhs.gov/humansubjects/guidance/stemcell.pdf* for funding such research.

Research Projects Involving Vertebrate Animals: Any proposal that includes research involving vertebrate animals must be in compliance with the National Research Council's "Guide for the Care and Use of Laboratory Animals" which can be obtained from National Academy Press, 2101 Constitution Avenue, NW., Washington, DC 20055. In addition, such proposals must meet the requirements of the Animal Welfare Act (7 U.S.C. 2131 *et seq.*), 9 CFR parts 1, 2, and 3, and if appropriate, 21 CFR part 58. These regulations do not apply to proposed research using pre-existing images of animals or to research plans that do not include live animals that are being cared for, euthanized, or used by the project participants to accomplish research goals, teaching, or testing. These regulations also do not apply to obtaining animal materials from commercial processors of animal products or to animal cell lines or tissues from tissue banks.

Limitation of Liability: In no event will the Department of Commerce be responsible for proposal preparation costs if these programs fail to receive funding or are cancelled because of other agency priorities. Publication of this announcement does not oblige the agency to award any specific project or to obligate any available funds.

Executive Order 12866: This funding notice was determined to be not significant for purposes of Executive Order 12866.

Executive Order 13132 (Federalism): It has been determined that this notice does not contain policies with federalism implications as that term is defined in Executive Order 13132.

Executive Order 12372: Applications under this program are not subject to Executive Order 12372, "Intergovernmental Review of Federal Programs."

Administrative Procedure Act/ Regulatory Flexibility Act: Notice and comment are not required under the Administrative Procedure Act (5 U.S.C. 553) or any other law, for rules relating to public property, loans, grants, benefits or contracts (5 U.S.C. 553 (a)). Because notice and comment are not required under 5 U.S.C. 553, or any other law, for rules relating to public property, loans, grants, benefits or contracts (5 U.S.C. 553(a)), a Regulatory Flexibility Analysis is not required and has not been prepared for this notice, 5 U.S.C. 601 *et seq.*

Dated: December 23, 2004.

Hratch G. Semerjian,

Acting Director, NIST.

[FR Doc. 05–183 Filed 1–4–05; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Availability of Seats for the Cordell Bank National Marine Sanctuary Advisory Council

AGENCY: National Marine Sanctuary Program (NMSP), National Ocean Service (NOS), National Oceanic and Atmospheric Administration, Department of Commerce (DOC).

ACTION: Notice and request for applications.

SUMMARY: The Cordell Bank National Marine Sanctuary (CBNMS or Sanctuary) is seeking applicants for the following vacant seats on its Sanctuary Advisory Council (Council): Community At Large, Maritime Activities, Research, Education, Conservation. Applicants are chosen based upon their particular expertise and experience in relation to the seat for which they are applying; community and professional affiliations; philosophy regarding the protection and management of marine resources; and possibly the length of residence in the area affected by the Sanctuary. Applicants who are chosen as members should expect to serve 2–3 year terms, pursuant to the Council's Charter.

DATES: Applications are due by January 31, 2005.

ADDRESSES: Application kits may be obtained from Cordell Bank National Marine Sanctuary, Rowena Forest, P.O. Box 159, Olema, CA 94950. Completed applications should be sent to the same address.

FOR FURTHER INFORMATION CONTACT: Rowena Forest/CBNMS, P.O. Box 159 Olema, CA 94950, (415) 663–0314 x105, and *Rowena.forest@noaa.gov*.

SUPPLEMENTARY INFORMATION: The Advisory Council for Cordell Bank was established in 2002 to support the joint management plan review process currently underway for the CBNMS and its neighboring sanctuaries, Gulf of the Farallones and Monterey Bay National Marine Sanctuaries. The Council has members representing education, research, conservation, maritime activity, and community-at-large. The government seats are held by a representatives from the National Marine Fisheries Service, the United States Coast Guard, and the managers of the Gulf of the Farallones, Monterey Bay and Channel Islands National Marine Sanctuaries. The Council holds four regular meetings per year, and one annual retreat.

Authority: 16 U.S.C. 1431, *et seq.*

(Federal Domestic Assistance Catalog Number 11.429 Marine Sanctuary Program)

Dated: December 21, 2004.

Daniel J. Basta,

Director, National Marine Sanctuary Program, National Ocean Services, National Oceanic and Atmospheric Administration.

[FR Doc. 05–132 Filed 1–4–05; 8:45 am]

BILLING CODE 3510–NK–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Availability of Seats for the Northwestern Hawaiian Islands Coral Reef Ecosystem Reserve Advisory Council

AGENCY: National Marine Sanctuary Program (NMSP), National Ocean Service (NOS), National Oceanic and Atmospheric Administration, Department of Commerce (DOC).

ACTION: Notice and request for applications.

SUMMARY: The Northwestern Hawaiian Islands Coral Reef Ecosystem Reserve (Reserve) is seeking applicants for the following vacant seats on its Reserve Advisory Council (Council): (3) Native Hawaiian, (2) Conservation, (1) Research and (1) Commercial Fishing. Applicants are chosen based upon their particular expertise and experience in relation to

the seat for which they are applying; community and professional affiliations; philosophy regarding the protection and management of marine resources; and possibly the length of residence in the area affected by the Reserve. Applicants who are chosen as members should expect to serve 3-year terms, pursuant to the Council's Charter.

DATES: Applications are due by January 31, 2005.

ADDRESSES: Application kits may be obtained from Moani Pai, 6600 Kalaniana'ole Hwy. Suite 300, Honolulu, HI 96825, (808) 397–2660 or online at *http://hawaiireef.noaa.gov*. Completed applications should be sent to the same address.

FOR FURTHER INFORMATION CONTACT: Aulani Wilhelm, 6600 Kalaniana'ole Hwy. Suite 300, Honolulu, HI 96825, (808) 397–2660, *aulani.wilhelm@noaa.gov*.

SUPPLEMENTARY INFORMATION: The NWHI Coral Reef Ecosystem Reserve is a new marine protected area designed to conserve and protect the coral reef ecosytem and related natural and cultural resources of the area. The Reserve was established by Executive Order pursuant to the National Marine Sanctuaries Amendments Act of 2000 (Pub. L. 106–513). The NWHI Reserve was established by Executive Order 13178 (12/00), as finalized by Executive Order 13196 (1/01).

The Reserve encompasses an area of the marine waters and submerged lands of the Northwestern Hawaiian Islands, extending approximately 1200 nautical miles long and 100 nautical miles wide. The Reserve is adjacent to and seaward of the seaward boundary of Hawaii State waters and submerged lands and the Midway Atoll National Wildlife Refuge, and includes the Hawaiian Islands National Wildlife Refuge to the extent that any such refuge waters extends beyond Hawaii State waters and submerged lands. The Reserve is managed by the Secretary of Commerce pursuant to the National Marine Sanctuaries Act and the Executive Orders. The Secretary has also initiated the process to designate the Reserve as a National Marine Sanctuary. The management principles and implementation strategy and requirements for the Reserve are found in the enabling Executive Orders, which are part of the application kit and can be found on the website listed above.

In designating the Reserve, the Secretary of Commerce was directed to establish a Coral Reef Ecosystem Reserve Advisory Council, pursuant to section 315 of the National Marine Sanctuaries Act, to provide advice and recommendations on the development of the Reserve Operations Plan and the proposal to designate and manage a Northwestern Hawaiian Islands National Marine Sanctuary by the Secretary.

The National Marine Sanctuary Program (NMSP) has established the Reserve Advisory Council and is now accepting applications from interested individuals for Council Members and Alternates for each of the following citizen/constituent positions on the Council.

1. Three (3) representatives from the Native Hawaiian community with experience or knowledge regarding Native Hawaiian subsistence, cultural, religious, or other activities in the northwestern Hawaiian Islands.

2. Two (2) representatives from non-governmental wildlife/marine life, environmental, and/or conservation organizations.

3. One (1) representative from the commercial fishing industry that conducts activities in the northwestern Hawaiian Islands.

4. One representative from the non-Federal science community with experience specific to the Northwestern Hawaiian Islands and with expertise in at least one of the following areas:

(A) Marine mammal science.

(B) Coral reef ecology.

(C) Native marine flora and fauna of the Hawaiian Islands.

(D) Oceanography.

(E) Any other scientific discipline the Secretary determines to be appropriate.

The Council consists of 25 members, 14 of which are non-government voting members (the State of Hawaii representative is a voting member) and 10 of which are government non-voting members. The voting members are representatives of the following constituencies: Conservation, Citizen-At-Large, Ocean-Related Tourism, Recreational Fishing, Research, Commercial Fishing, Education, State of Hawaii and Native Hawaiian. The government non-voting seats are represented by the following agencies: Department of Defense, Department of the Interior, Department of State, Marine Mammal Commission, NOAA's Hawaiian Islands Humpback Whale National Marine Sanctuary, NOAA's National Marine Fisheries Service, National Science Foundation, U.S. Coast Guard, Western Pacific Regional Fishery Management Council, and NOAA's National Ocean Service.

Authority: 16 U.S.C. 1431, *et seq.*

(Federal Domestic Assistance Catalog Number 11.429 Marine Sanctuary Program)

Dated: December 21, 2004.

Daniel J. Basta,

Director, National Marine Sanctuary Program, National Ocean Services, National Oceanic and Atmospheric Administration.

[FR Doc. 05–131 Filed 1–4–05; 8:45 am]

BILLING CODE 3510–NK–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Environmental Statements; Notice of Intent: Washington Coastal Zone Management Program; Meetings

AGENCY: Office of Ocean and Coastal Resource Management (OCRM), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice of intent to prepare an environmental impact statement. Notice to conduct public scoping meetings in Olympia, Seattle and Mount Vernon, WA on the proposed incorporation of the revised Shoreline Master Program (SMP) Guidelines Rule (Chapter 173–26) as an amendment to the federally approved Washington Coastal Zone Management Program (WCZMP).

SUMMARY: In accordance with section 306 of the Coastal Zone Management Act of 1972, as amended (CZMA), OCRM is considering whether to approve Washington's proposed amendment to incorporate the revised WA SMP Guidelines Rule as an amendment to its federally approved WCZMP. In accordance with the National Environmental Policy Act, OCRM will conduct scoping meetings as an opportunity for federal and state agencies, local governments and their citizenry, and representatives of non-governmental organizations, American Indian tribes, or any other interest persons to identify to OCRM what impacts or issues should be addressed in the Environment Impact Statement (EIS).

DATES:

Tuesday, January 18, 2005 at 7 p.m., Washington Department of Ecology in the Auditorium, 300 Desmond Drive, Lacey, WA 98503. (Visitor parking available.)

Wednesday, January 19, 2005, at 7 p.m., Pinnacle Room—3rd Floor in The Mountaineers Building, 300 Third Avenue West, Seattle, WA 98119, (Parking lots and some street parking available with time constraints.)

Thursday, January 20, 2005, at 7 p.m. Aqua Room in Skagit County PUD,

1415 Freeway Drive, Mount Vernon, WA 98273, (Visitor parking available.)

Interested persons are welcome to submit suggestions or comments on the scope or content of the proposed EIS by attending any of the above meetings or provide written comments to the designated official below. Written comments will be accepted until February 25, 2005.

SUPPLEMENTARY INFORMATION: The WCZMP was the first in the nation to receive federal approval under the CZMA in 1976. The basis for the WCZMP participation in the federal coastal zone management program was the implementation of the Washington Shoreline Management Act of 1971 (SMA). The SMA set in motion the designation of shorelines of statewide significance, policy objectives and guidelines with respect to managing shoreline uses, a process for local governments to develop Shoreline Master Programs (SMPs) that would meet the objectives of the Act, and a management process to include the Shorelines Hearing Board that would serve as an administrative appeals body. From 1976 to the present, the WCZMP has received federal CZMA funds to supplement their state funds to implement the WCZMP.

In 1995, the Washington State Legislature directed the Department of Ecology (Ecology) to periodically review and adopt guidelines consistent with SMA policies and to integrate shorelines with the provisions of the Growth Management Act critical areas ordinances. Ecology has spent the better part of 6 years developing revised guidance for updating SMPs. The new guidelines recognize advancements in science regarding shoreline ecological processes, changes in laws, changes in the character of shoreline development and innovations in shorelines and growth management practices. More information can be found on the Washington Department of Ecology Web Site at: *http://www.ecy.wa.gov/programs/sea/SMA/index.html.*

OCRM has been requested by the State of Washington to incorporate the revised SMP Guidelines Rule into the federally approved WCZMP. OCRM has determined that this is a major federal action and will therefore develop an environmental impact statement to identify what environmental consequences may be associated with this proposed action. The State of WA adopted the revised SMP Guidelines Rule in December 2003. OCRM's consideration of Washington's proposed amendment to its already approved Federal coastal zone management program does not affect state law or regulations.

FOR FURTHER INFORMATION CONTACT: Comments and questions should be made to: Masi Okasaki, Assistant Regional Manager, Coastal Programs Division (N/ORM3), Office of Ocean and Coastal Resource Management, NOS, NOAA, 1305 East-West Highway, Silver Spring, Maryland, 20910, phone (301) 713–3155 extension 185, e-mail *wa.guidelines.noaa.gov.*

Dated: December 28, 2004.

Eldon Hout,

Director, Office of Ocean and Coastal Resource Management, National Ocean Service, National Oceanic and Atmospheric Administration.

(Federal Domestic Assistance Catalog 11.419 Coastal Zone Management Program Administration)

[FR Doc. 05–130 Filed 1–4–05; 8:45 am]

BILLING CODE 3510–08–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 122904A]

Fisheries of the Gulf of Mexico and South Atlantic Spiny Lobster Data Workshop

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of data workshop for Gulf of Mexico and South Atlantic Spiny Lobster.

SUMMARY: The State of Florida, along with the Gulf of Mexico Fishery Management Council (GMFMC) and the South Atlantic Fishery Management Council (SAFMC), will hold a data workshop, the first in a series of three workshops, to evaluate the stock status of the spiny lobster.

DATES: The data workshop will convene at 8:30 a.m. on Tuesday, January 25, 2005, and conclude no later that 5 p.m. on Thursday, January 27, 2005.

ADDRESSES: The data workshop will be held at the Florida State Regional Service Center, 2796 Overseas Highway, Suite 104, Marathon, FL.

Council address: Gulf of Mexico Fishery Management Council, 3018 U.S. Highway 301, North, Suite 1000, Tampa, FL 33619.

FOR FURTHER INFORMATION CONTACT: Stu Kennedy, Gulf of Mexico Fishery Management Council; telephone: 813-228-2815.

SUPPLEMENTARY INFORMATION: A data workshop will be held to generate an assessment data set on the Gulf of Mexico/South Atlantic Spiny Lobster. The assessment data set will include catch statistics, discard estimates, length and age composition, fishery descriptions, biological sampling intensity, fishery dependent and fishery independent monitoring results and life history characteristics. Workshop participants will draft preliminary Assessment Report sections. Participants include data collectors, database managers, stock assessment scientists, biologists, fisheries researchers, fishermen, environmentalists, Council members, international experts and staff of Councils, Commissions, and state and Federal agencies.

Although non-emergency issues not contained in this agenda may come before these groups for discussion, those issues may not be the subject of formal action during these meetings. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Dawn Aring at the Council (see **ADDRESSES**) by January 7, 2005.

Dated: December 30, 2004.

Alan D. Risenhoover,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. E4–3931 Filed 1–4–05; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 123004B]

Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The Pacific Fishery Management Council's (Council) Ad Hoc Groundfish Information Policy

Committee (GIPC) will hold a working meeting, which is open to the public.

DATES: The GIPC meeting will be held Tuesday, January 25, 2005 from 8:30 a.m. until business for the day is completed. The GIPC meeting will reconvene Wednesday, January 26, 2005, from 8:30 a.m. until noon.

ADDRESSES: The GIPC meeting will be held at the Embassy Suites Hotel Portland Airport, Cedars I and II Rooms, 7900 NE 82nd Avenue, Portland, Oregon 97220. Telephone: 503–460–3000.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 200, Portland, Oregon 97220–1384.

FOR FURTHER INFORMATION CONTACT: Mr. John DeVore, Groundfish Management Coordinator; telephone: 503–820–2280.

SUPPLEMENTARY INFORMATION: The purpose of the GIPC meeting is to formulate and recommend a groundfish information management policy to the Council. The recommended policy will categorize the types and sources of information in use for groundfish management, consider what new types of information may be available in the future, specify review requirements for new information before it can become part of the decision-making process, consider guidelines for replacing older information with new or updated information, and recommend an implementation time line that facilitates the groundfish management process while considering the magnitude of potential harm to the species of concern and disruption to the fishery that can result from untimely incorporation of new information. Specific topics that will be discussed at this meeting will be a schedule of new observer data reports, development of a policy for mid-term optimum yield adjustments during a biennial management cycle, development of a policy for inseason management adjustments, and development of a policy for considering data and models when deciding biennial specifications and management measures. No management actions will be decided by the GIPC. The GIPC's role will be development of recommendations for consideration by the Council at its March meeting in Sacramento, California.

Although nonemergency issues not contained in the meeting agenda may come before the GIPC for discussion, those issues may not be the subject of formal committee action during this meeting. Committee action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the GIPC's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Ms. Carolyn Porter at 503–820–2280 at least 5 days prior to the meeting date.

Dated: December 30, 2004.

Alan D. Risenhoover,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. E4–3930 Filed 1–4–05; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 123004A]

Pacific Fishery Management Council; Ad Hoc Allocation Committee; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The Pacific Fishery Management Council's (Council) Ad Hoc Allocation Committee (Committee) will hold a working meeting, which is open to the public. The purpose of the meeting is to develop options for allocations and other management measures for the 2005–2006 Pacific Coast groundfish fishery and to consider allocation issues associated with development of an individual quota (or dedicated access) program initiative for the Pacific Coast groundfish trawl fishery.

DATES: The meeting will be held Wednesday, January 26, 2005, from 1 p.m. until business for the day is completed. The meeting will reconvene Thursday, January 27, 2005, from 8:30 a.m. until business for the day is completed.

ADDRESSES: The meeting will be held at the Embassy Suites Hotel Portland Airport, Cedars I and II Rooms, 7900 NE 82nd Avenue, Portland, OR 97220; telephone: 503–460–3000.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 200, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: John DeVore, Groundfish Management Coordinator; telephone: 503–820–2280.

SUPPLEMENTARY INFORMATION: The purpose of the Committee meeting is to develop options for allocations and other management measures for the 2005–2006 Pacific Coast groundfish fishery and to consider allocation issues associated with development of an individual quota (or dedicated access) program initiative for the Pacific Coast groundfish trawl fishery. The Committee will discuss the types of provisions that may be necessary to prevent further overfishing, to reduce bycatch of overfished species in the various groundfish fisheries, and to reduce bycatch in nongroundfish fisheries. No management actions will be decided by the Committee. The Committee's role will be development of recommendations for consideration by the Council at its March 2005 meeting in Sacramento, CA.

Although nonemergency issues not contained in the meeting agenda may come before the Committee for discussion, those issues may not be the subject of formal Committee action during this meeting. Committee action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Committee's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Carolyn Porter at 503–820–2280 at least five days prior to the meeting date.

Dated: December 30, 2004.

Alan D. Risenhoover,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. E4–3932 Filed 1–4–05; 8:45 am]

BILLING CODE 3510–22–S

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Cancellation of Textile Visa Requirements for Laos

December 30, 2004.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner, Bureau of Customs and Border Protection canceling all previous directives concerning visa requirements for Laos.

EFFECTIVE DATE: January 1, 2005.

FOR FURTHER INFORMATION CONTACT: Philip J. Martello, Director, Trade and Data Division, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482-3400.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; Section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

Due to the expiration on December 31, 2004 of the bilateral textile agreement with Laos, the United States is cancelling visa requirements for textile products from Laos exported after that date.

In the letter below, CITA is directing the Bureau of Customs and Border Protection to cancel all textile visa requirements for goods exported from Laos on and after January 1, 2005.

D. Michael Hutchinson,

Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

December 30, 2004.

Commissioner,
Bureau of Customs and Border Protection, Washington, D.C. 20229.

Dear Commissioner: This directive cancels all previous directives issued to you by the Chairman, Committee for the Implementation of Textile Agreements concerning textile visa requirements for goods produced or manufactured in Laos. Effective for such goods exported from Laos on and after January 1, 2005, you are directed not to require a textile visa for entry into the Customs territory of the United Sates.

The Committee for the Implementation of Textile Agreement has determined that this action falls within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,
D. Michael Hutchinson,
Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 05–196 Filed 1–4–05; 8:45 am]

BILLING CODE 3510–DS–S

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Suspension of Textile Visa Requirements for Ukraine

December 30, 2004.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner, Bureau of Customs and Border Protection suspending all previous directives concerning visa requirements for Ukraine.

EFFECTIVE DATE: January 1, 2005.

FOR FURTHER INFORMATION CONTACT: Philip J. Martello, Director, Trade and Data Division, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482-3400.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; Section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

Due to the expiration on December 31, 2004 of the bilateral textile agreement with Ukraine, the United States is suspending visa requirements for textile products from Ukraine exported after that date.

Negotiations on extension of the bilateral agreement are ongoing with Ukraine. Visa requirements may be reinstated upon extension of the bilateral agreement.

In the letter below, CITA is directing the Bureau of Customs and Border Protection to temporarily suspend all textile visa requirements for goods exported from Ukraine on and after January 1, 2005.

D. Michael Hutchinson,

Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

December 30, 2004.

Commissioner,
Bureau of Customs and Border Protection, Washington, D.C. 20229.

Dear Commissioner: This directive suspends all previous directives issued to you by the Chairman, Committee for the Implementation of Textile Agreements concerning textile visa requirements for goods produced or manufactured in Ukraine, covering wool textile products subject to the quota limits under the United States - Ukraine bilateral textile agreement. Effective for such goods exported from Ukraine on and after January 1, 2005, you are directed not to require a textile visa for entry into the Customs territory of the United States.

The Committee for the Implementation of Textile Agreement has determined that this action falls within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,
D. Michael Hutchinson,
Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 05–197 Filed 1–4–05; 8:45 am]

BILLING CODE 3510–DS–S

CONSUMER PRODUCT SAFETY COMMISSION

[CPSC Docket No. 05–C0004]

New ICM L.P., Provisional Acceptance of a Settlement Agreement and Order

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: It is the policy of the Commission to publish settlements which it provisionally accepts under the Flammable Fabrics Act in the **Federal Register** in accordance with the terms of 16 CFR 1605.13. Published below is a provisionally-accepted Settlement Agreement with New ICM L.P.

DATES: Any interested person may ask the Commission not to accept this agreement or otherwise comment on its contents by filing a written request with the Office of the Secretary by January 20, 2005.

ADDRESSES: Persons wishing to comment on this Settlement Agreement should send written comments to the Comment 05–C0004, Office of the Secretary, Consumer Product Safety Commission, Washington, DC 20207.

FOR FURTHER INFORMATION CONTACT: Dennis C. Kacoyanis, Trial Attorney, Office of Compliance, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504–7587.

SUPPLEMENTARY INFORMATION: The text of the Agreement and Order appears below.

Dated: December 29, 2004.

Todd A. Stevenson,

Secretary.

Consent Order Agreement

NEW ICM L.P. ("Respondent" or "NEW ICM") a limited partnership, enters into this Consent Order Agreement ("Agreement") with the staff of the Consumer Product Safety Commission ("the staff") pursuant to the procedures set forth in section 1605.13 of the Commission's Procedures for Investigations, Inspections, and Inquiries under the Flammable Fabrics Act, 16 CFR 1605.

This Agreement and Order are for the purpose of settling allegations of the

staff that Respondent manufactured and sold purple satin pajamas made from 100% polyester and rosebud print nightgowns made from 100% polyester that failed to comply with the Standards for the Flammability of Children's Sleepwear ("Sleepwear Standards"), 16 CFR parts 1615 and 1616.

Respondent and the Staff Agree

1. The Consumer Product Safety Commission ("Commission") is an independent regulatory agency of the United States Government. The Commission has jurisdiction over this matter under the Consumer Product Safety Act (CPSA), 15 U.S.C. 2051 *et seq.*, the Flammable Fabrics Act (FFA), 15 U.S.C. 1191 *et seq.*, and the Federal Trade Commission Act (FTCA), 15 U.S.C. 41 *et seq.*

2. Respondent is a limited partnership organized and existing under the laws of the State of Texas with its principal corporate offices located at 220 Sam Bishkin Dr., El Campo, Texas 77437.

3. Respondent is now, and has been engaged in one or more of the following activities: the manufacture for sale, the sale, or the offering for sale, in commerce, or the importation into the United States, or the introduction, delivery for introduction, transportation or causing to be transported, in commerce, or the sale or delivery after sale or shipment in commerce, children's sleepwear garments that are subject to the Sleepwear Standards.

4. This Agreement is for the purpose of settling the allegations of the accompanying Complaint. This Agreement does not constitute an admission by Respondent that it violated the law. The Agreement becomes effective only upon its final acceptance by the Commission and service of the incorporated Order upon Respondent.

5. The parties agree that this Consent Order Agreement resolves the allegations of the Complaint and the Commission shall not initiate any civil or administrative action against Respondent for those alleged violations set forth in the Complaint.

6. Upon final acceptance of this Agreement by the Commission and issuance of the Final Order, Respondent knowingly, voluntarily, and completely waives any rights it may have in this matter (a) To an administrative or judicial hearing, (b) to judicial review or other challenge or contest of the validity of the Commission's actions, (c) to a determination by the Commission as to whether Respondent failed to comply with the CPSA, FFA, FTCA, and the underlying regualtions, (d) to a statement of findings of fact and conclusions of law, and (e) to any claims under the Equal Access to Justice Act.

7. Upon provisional acceptance of this Agreement by the Commission, this Agreement shall be placed on the public record and shall be published in the **Federal Register** in accordance with the procedures set forth in 16 CFR 1605.13(d). If the Commission does not receive any written objections within 15 days, the Agreement will be deemed finally accepted on the 20th day after the date it is published in the **Federal Register**.

8. In settlement of the staff's allegations of the Compliant, Respondent agrees to comply with the attached Order incorporated herein by reference.

9. Upon a violation of the attached Order by Respondent, the Commission reserves the right to take appropriate legal action against Respondent for all violations listed in the Complaint and for all violations occurring after the date of this Agreement and Respondent waives the statute of limitations.

10. For any violation occurring after the date of this Agreement, if the Commission finds that Respondent has manufactured for sale, sold, or offered for sale, in commerce, or imported into the United States, or introduced, delivered for introduction, transported or caused to be transported, in commerce, of any product, fabric, or related material which fails to comply with the Flammable Fabrics Act and the underlying regulations, Respondent will pay to the Commission upon demand a penalty in the amount of five (5) times the retail value of the product(s) in question. For purposes of this Agreement the term "product(s) in questions" shall mean product(s) that fail to comply with the FFA and the implementing regulations. This provision does not preclude the Commission from taking additional action under sections 5, 6, and 7 of the FFA, 15 U.S.C. 1194, 1195, and 1196; sections 10 and 17(b) of the FTCA, 15 U.S.C. 50 and 57(b); and any other pertinent legal provisions.

11. Respondent reserves its right to challenge the Commission's findings under paragraphs 9 and 10 of this Agreement before the Commission and to have the court review whether the Commission's decision was arbitrary and capricious.

12. The Commission may publicize the terms of this Consent Order Agreement.

13. This Agreement, and the Complaint accompanying the Agreement, may be used in interpreting the Order. Agreements, understandings, representations, or interpretations made outside this Consent Order Agreement may not be used to vary or contradict its terms.

14. Upon acceptance of the Agreement, the Commission shall issue the following Order.

15. The provisions of this Agreement shall apply to Respondent and each of its successors and assigns.

Respondent New ICM L.P.

Dated: September 22, 2004.

Daniel Zalman, President,
New ICM L.P., 220 Sam Bishkin Dr., El Campo, Texas 77437.

Dated: September 21, 2004.

J. Michael Jordan, Esquire,
Gardere Wynne Sewell LLP, Attorneys for New ICM L.P., 1000 Louisiana, Suite 3400, Houston, Texas 77002–5007.

Commissions Staff

Alan H. Schoem,
Assistant Executive Director, Office of Compliance, Consumer Product Safety Commission, Washington, DC 20207–0001.
Eric L. Stone,
Director, Legal Division, Office of Compliance.

Dated: September 29, 2004.

Dennis G. Kacoyanis,
Trial Attorney, Office of Compliance.

Complaint

Nature of Proceedings

Pursuant to the provisions of the Flammable Fabrics Act (FFA), as amended, 15 U.S.C. 1191 *et seq.;* the Federal Trade Commission Act (FTCA), as amended, 15 U.S.C. 41 *et seq.;* and the Standards for the Flammability of Children's Sleepwear (Sleepwear Standards), 16 CFR parts 1615 and 1616, the Consumer Product Safety Commission having reason to believe that NEW ICM L.P., 220 Sam Bishkin Dr., El Campo, TX 77437 has violated the provisions of said Acts; and further it appearing to the Commission that a proceeding by it in respect to those violations would be in the public interest, therefore, it hereby issues its Complaint stating its charges as follows:

1. Respondent NEW ICM, L.P. is a limited partnership organized and existing under the laws of the State of Texas, with its principal place of business located at 220 Sam Bishkin Dr., El Campo, TX 77437.

2. Respondent NEW ICM L.P. is now and has been engaged in the manufacture for sale, the sale, or the offering for sale, in commerce, or the importation into the United States, or the introduction, delivery for introduction, transportation or causing to be transported, in commerce, or the sale or delivery after a sale or shipment in commerce, as the term "commerce"

is defined in section 2(b) of the FFA, 15 U.S.C. 1191(b), "children's sleepwear" as defined in 16 CFR 1615.1 and 1616.1.

3. In 2001, Respondent NEW ICM L.P. manufactured for sale, sold, and offered for sale, in commerce, introduced, delivered for introduction, transported or caused for to be transported, in commerce, and sold or delivered after a sale or shipment in commerce 2,103 pairs of purple satin pajamas, GPU 072899, made from 100% polyester that failed to meet the flammability requirements of the Children's Sleepwear Standards, 16 CFR parts 1615 and 1615, in violation of section 3(a) of the FFA, 15 U.S.C. 1192(a).

4. In 2001, Respondent NEW ICM L.P. manufactured for sale, sold, and offered for sale, in commerce, introduced, delivered for introduction, transported or caused to be transported, in commerce, and sold or delivered after a sale or shipment in commerce 3,564 rosebud print nightgowns, GPU 072600, made from 100% polyester that failed to meet the flammability requirements of the Children's Sleepwear Standards, 16 CFR parts 1615 and 1616, in violation of section 3(a) of the FFA, 15 U.S.C. 1192(a).

5. The acts by Respondent NEW ICM L.P. set forth in paragraphs 3 and 4 of the complaint are unlawful and constitute an unfair method of competition and an unfair and deceptive practice in commerce under the FTCA, in violation of section 3(a) of the FFA, 15 U.S.C. 1192(a), for which a cease and desist order may be issued against Respondent pursuant to section 5(b) of the FFA, 15 U.S.C. 1194(b), and section 5 of the FTCA, 15 U.S.C. 45.

Relief Sought

6. The staff seeks the issuance of a cease and desist order against Respondent NEW ICM L.P. pursuant to section 5(b) of the FFA, 15 U.S.C. 1194(b), and section 5 of the FTCA, 15 U.S.C. 45.

Wherefore, the premises considered, the Commission hereby issues this Complaint on the 29th day of December, 2004.

By direction of the Commission.

Nicholas V. Marchica,
Acting Assistant Executive Director, Office of Compliance.

Order

I.

The Commission having jurisdiction over Respondent NEW ICM L.P. and over this matter under the Consumer Product Safety Act (CPSA), 15 U.S.C. 2051 *et seq.*, the Flammable Fabrics Act (FFA), 15 U.S.C. 1191 *et seq.*, and the Federal Trade Commission Act (FTCA), 15 U.S.C. 41 *et seq.*, it is hereby ordered that Respondent NEW ICM L.P. its successors, and assigns, agents, representatives, and employees, directly or through any corporation, subsidiary, division, or other business entity, or through any agency, device, or instrumentality, do forthwith cease and desist from manufacturing for sale, selling, or offering for sale, in commerce, or importing into the United States or introducing, delivering for introduction, transporting or causing to be transported, in commerce, any product, fabric, or related material that fails to comply with the Flammable Fabrics Act and the underlying regulations.

It is further ordered that following service upon Respondent NEW ICM L.P. of the Final Order in this matter, Respondent NEW ICM L.P. will notify the Commission within 30 days following the consummation of the sale of a majority of its stock or following a change in any of its corporate officers responsible for compliance with the terms of this Consent Agreement and Order.

By direction of the Commission, this Consent Agreement and Order is provisionally accepted pursuant to 16 CFR 1605.13, and shall be placed on the public record, and the Secretary is directed to publish the provisional acceptance of the Consent Order Agreement in the Commission's Public Calendar and in the **Federal Register**.

So ordered by the Commission, this 29th day of December 2004.

Todd A. Stevenson,
Secretary,
Consumer Product Safety Commission.

[FR Doc. 05–112 Filed 1–4–04; 8:45 am]
BILLING CODE 6355–01–M

DEPARTMENT OF DEFENSE

[OMB Control Number 0704–0390]

Information Collection Requirement; Defense Federal Acquisition Regulation Supplement; Taxes

AGENCY: Department of Defense (DoD).

ACTION: Notice and request for comments regarding a proposed extension of an approved information collection requirement.

SUMMARY: In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), DoD announces the proposed extension of a public information collection requirement and seeks public comment on the provisions thereof. DoD invites comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of DoD, including whether the information will have practical utility; (b) the accuracy of the estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including the use of automated collection techniques or other forms of information technology. The Office of Management and Budget (OMB) has approved this information collection requirement for use through March 31, 2005. DoD proposes that OMB extend its approval for use through March 31, 2008.

DATES: DoD will consider all comments received by March 7, 2005.

ADDRESSES: You may submit comments, identified by OMB Control Number 0704–0390, using any of the following methods:

- Defense Acquisition Regulations Web Site: *http://emissary.acq.osd.mil/dar/dfars.nsf/pubcomm*. Follow the instructions for submitting comments.
- E-mail: *dfars@osd.mil*. Include OMB Control Number 0704–0390 in the subject line of the message.
- Fax: (703) 602–0350.
- Mail: Defense Acquisition Regulations Council, Attn: Mr. Euclides Barrera, OUSD(AT&L)DPAP(DAR), IMD 3C132, 3062 Defense Pentagon, Washington, DC 20301–3062.
- Hand Delivery/Courier: Defense Acquisition Regulations Council, Crystal Square 4, Suite 200A, 241 18th Street, Arlington, VA 22202–3402.

All comments received will be posted to *http://emissary.acq.osd.mil/dar/dfars.nsf*.

FOR FURTHER INFORMATION CONTACT: Mr. Euclides Barrera, (703) 602–0296. The information collection requirements addressed in this notice are available electronically on the Internet at: *http://www.acq.osd.mil/dpap/dfars/index.htm*. Paper copies are available from Mr. Euclides Barrera, OUSD(AT&L)DPAP(DAR), IMD 3C132, 3062 Defense Pentagon, Washington, DC 20301–3062.

SUPPLEMENTARY INFORMATION:

Title and OMB Number: Defense Federal Acquisition Regulation Supplement (DFARS) Part 229, Taxes, and related clause in DFARS 252.229; OMB Control Number 0704–0390.

Needs and Uses: DoD uses this information to determine if DoD contractors in the United Kingdom have attempted to obtain relief from customs

duty on vehicle fuels in accordance with contract requirements.

Affected Public: Businesses or other for-profit institutions.

Annual Burden Hours: 92.

Number of Respondents: 23.

Responses Per Respondent: 1.

Annual Responses: 23.

Average Burden Per Response: 4 hours.

Frequency: On occasion.

Summary of Information Collection

The clause at DFARS 252.229–7010, Relief from Customs Duty on Fuel (United Kingdom), is prescribed at DFARS 229.402–70(j) for use in solicitations issued and contracts awarded in the United Kingdom that require the use of fuels (gasoline or diesel) and lubricants in taxis or vehicles other than passenger vehicles. The clause requires the contractor to provide the contracting officer with evidence that the contractor has initiated an attempt to obtain relief from customs duty on fuels and lubricants, as permitted by an agreement between the United States and the United Kingdom.

Michele P. Peterson,

Executive Editor, Defense Acquisition Regulations Council.

[FR Doc. 05–181 Filed 1–4–05; 8:45 am]

BILLING CODE 5001–08–P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

SUMMARY: The Director, Regulatory Information Management Services, Office of the Chief Information Officer, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before March 7, 2005.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Director, Regulatory Information Management Services, Office of the Chief Information Officer, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, *e.g.* new, revision, extension, existing or reinstatement; (2) title; (3) summary of the collection; (4) description of the need for, and proposed use of, the information; (5) respondents and frequency of collection; and (6) reporting and/or recordkeeping burden. OMB invites public comment.

The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: December 30, 2004.

Jeanne Van Vlandren,

Director, Regulatory Information Management Services, Office of the Chief Information Officer.

Federal Student Aid

Type of Review: Revision.

Title: Fiscal Operations Report for 2004–2005 and Application to Participate for 2006–2007 (FISAP) and Reallocation Form E40–4P.

Frequency: Annually.

Affected Public: Not-for-profit institutions; Businesses or other for-profit; State, local, or tribal gov't, SEAs or LEAs.

Reporting and Recordkeeping Hour Burden:

Responses: 5,872,

Burden Hours: 26,339.

Abstract: This application data will be used to compute the amount of funds needed by each school for the 2006–2007 award year. The Fiscal Operations Report data will be used to assess program effectiveness, account for funds expended during the 2003–2004 award year, and as part of the school funding process. The Reallocation form is part of the FISAP on the Web. Schools will use it in the summer to return unexpended funds for 2003–2004 and request supplemental Federal Work-Study (FWS) funds for 2004–2005.

Requests for copies of the proposed information collection request may be accessed from *http://edicsweb.ed.gov,* by selecting the "Browse Pending Collections" link and by clicking on link number 2658. When you access the information collection, click on "Download Attachments" to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., Potomac Center, 9th Floor, Washington, DC 20202–4700. Requests may also be electronically mailed to the Internet address *OCIO_RIMG@ed.gov* or faxed to 202–245–6621. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be directed to Joseph Schubart at his e-mail address *Joe.Schubart@ed.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. E4–3946 Filed 1–4–05; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Submission of Data by State Educational Agencies

AGENCY: National Center for Education Statistics, Institute of Education Sciences, Department of Education.

ACTION: Notice of dates of submission of State revenue and expenditure reports for fiscal year 2004 and of revisions to those reports.

SUMMARY: The Secretary of Education announces dates for the submission by State educational agencies (SEAs) of expenditure and revenue data and average daily attendance statistics on ED Form 2447 (the National Public Education Financial Survey (NPEFS)) for fiscal year (FY) 2004. The Secretary sets these dates to ensure that data are available to serve as the basis for timely distribution of Federal funds. The U.S. Bureau of the Census is the data collection agent for the National Center for Education Statistics (NCES). The data will be published by NCES and will be used by the Secretary in the calculation of allocations for FY 2006 appropriated funds.

DATES: The date on which submissions will first be accepted is March 15, 2005. The mandatory deadline for the final submission of all data, including any revisions to previously submitted data, is September 6, 2005.

ADDRESSES AND SUBMISSION INFORMATION: SEAs may mail ED Form 2447 to: Bureau of the Census, ATTENTION:

Governments Division, Washington, DC 20233–6800.

SEAs may submit data via the World Wide Web using the interactive survey form at *http://www.census.gov/govs/www/npefs.html*. If the Web form is used, it includes a digital confirmation page where a pin number may be entered. A successful entry of the pin number serves as a signature by the authorizing official. A certification form may also be printed from the Web site, and signed by the authorizing official and mailed to the Governments Division of the Bureau of the Census, at the address listed in the previous paragraph. This signed form must be mailed within five business days of Web form data submission.

Alternatively, SEAs may hand deliver submissions by 4 p.m. (eastern time) to: Governments Division, Bureau of the Census, 8905 Presidential Parkway, Washington Plaza II, room 508, Upper Marlboro, MD 20772.

If an SEA's submission is received by the Bureau of the Census after September 6, 2005, in order for the submission to be accepted, the SEA must show one of the following as proof that the submission was mailed on or before the mandatory deadline date:

1. A legibly dated U.S. Postal Service postmark.
2. A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.
3. A dated shipping label, invoice, or receipt from a commercial carrier.
4. Any other proof of mailing acceptable to the Secretary.

If the SEA mails ED Form 2447 through the U.S. Postal Service, the Secretary does not accept either of the following as proof of mailing:

1. A private metered postmark.
2. A mail receipt that is not dated by the U.S. Postal Service.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, an SEA should check with its local post office.

FOR FURTHER INFORMATION CONTACT: Ms. Sharon J. Meade, Chief, Bureau of the Census, Attention: Governments Division, Washington, DC 20233–6800. Telephone: (301) 763–7316. If you use a telecommunications device for the deaf (TDD), you may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

Individuals with disabilities may obtain this document in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) on request to: Frank Johnson, National Center for Education Statistics, Institute of Education Sciences, U.S. Department of Education, Washington, DC 20208–5651. Telephone: (202) 502–7362.

SUPPLEMENTARY INFORMATION: Under the authority of section 153(a)(1)(I) of the Education Sciences Reform Act of 2002 (Pub. L. 107–279), 20 U.S.C. 9543, which authorizes NCES to gather data on the financing of education, NCES collects data annually from SEAs through ED Form 2447. The report from SEAs includes attendance, revenue, and expenditure data from which NCES determines the average State per pupil expenditure (SPPE) for elementary and secondary education, as defined in the Elementary and Secondary Education Act of 1965, as amended (ESEA) (currently 20 U.S.C. 7801(2)).

In addition to utilizing the SPPE data as general information on the financing of elementary and secondary education, the Secretary uses these data directly in calculating allocations for certain formula grant programs, including Title I of the ESEA, Impact Aid, and Indian Education. Other programs such as the Educational Technology State Grants program (Title II of the ESEA, Part D), the Education for Homeless Children and Youth Program under Title VII of the McKinney-Vento Homeless Assistance Act, the Teacher Quality State Grants (Title II of the ESEA, Part A) Program, and the Safe and Drug-Free Schools and Communities (Title IV of the ESEA, Part A) Program make use of SPPE data indirectly because their formulas are based, in whole or in part, on State Title I allocations.

In January 2005, the Bureau of the Census, acting as the data collection agent for NCES, will mail to SEAs ED Form 2447 with instructions and request that SEAs submit data to the Bureau of the Census on March 15, 2005, or as soon as possible thereafter. SEAs are urged to submit accurate and complete data on March 15, or as soon as possible thereafter, to facilitate timely processing. Submissions by SEAs to the Bureau of the Census will be checked for accuracy and returned to each SEA for verification. All data, including any revisions, must be submitted to the Bureau of the Census by an SEA not later than September 6, 2005.

Having accurate and consistent information on time is critical to an efficient and fair allocation process and to the NCES statistical process. To ensure timely distribution of Federal education funds based on the best, most accurate data available, NCES establishes, for allocation purposes, September 6, 2005, as the final date by which the NPEFS Web form or ED Form 2447 must be submitted. If an SEA submits revised data after the final deadline that results in a lower SPPE figure, its allocations may be adjusted downward or the Department may request the SEA to return funds. SEAs should be aware that all of these data are subject to audit and that, if any inaccuracies are discovered in the audit process, the Department may seek recovery of overpayments for the applicable programs. If an SEA submits revised data after September 6, 2005, the data may also be too late to be included in the final NCES published dataset.

Electronic Access to This Document: You may view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *http://www.ed.gov/news/fedregister*.

To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC, area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.gpoaccess.gov/nara/index.html*.

Authority: 20 U.S.C. 9543.

Dated: December 30, 2004.

Grover J. Whitehurst,

Director, Institute of Education Sciences.

[FR Doc. E4–3945 Filed 1–4–05; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Agency Information Collection Extension

AGENCY: U.S. Department of Energy.

ACTION: Notice and request for comments.

SUMMARY: The Department of Energy (DOE), pursuant to the Paperwork Reduction Act of 1995, intends to extend for three years, an information collection package with the Office of Management and Budget (OMB) concerning legal collections related to invention reporting by DOE contractors, and related matters. Comments are invited on: (a) Whether the extended collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the

proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Comments regarding this proposed information collection must be received on or before March 7, 2005. If you anticipate difficulty in submitting comments within that period, contact the person listed below as soon as possible.

ADDRESSES: Written comments may be sent to: Robert J. Marchick, GC–62, U.S. Department of Energy, 1000 Independence Ave. SW., Washington, DC 20585; or by fax at 202 586–2805, or by e-mail at *robert.marchick@hq.doe.gov* and to: Sharon Evelin, Acting Director, IM–11/ Germantown Bldg., U.S. Department of Energy, 1000 Independence Ave., SW., Washington, DC 10585–1290, or by fax at 301–903–9061 or by e-mail at *sharon.evelin@hq.doe.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Robert Marchick at the address listed above.

SUPPLEMENTARY INFORMATION: This package contains: (1) OMB No. 1910–0800; (2) Package Title: Legal Collections; (3) Type of Review: Renewal; (4) Purpose: To continue to maintain DOE control and oversight of DOE and contractor invention reporting; (5) Respondents: Approx. 1894 respondents; (6) Estimated Number of Burden Hours: Approx. 14100 hours.

Statutory Authority: 42 U.S.C. 5908 (a) and (b)

Issued in Washington, DC on December 27, 2004.

Sharon Evelin,

Acting Director, Records Management Division, Office of the Chief Information Officer.

[FR Doc. 05–186 Filed 1–4–05; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Agency Information Collection Extension

AGENCY: U.S. Department of Energy.

ACTION: Notice and request for comments.

SUMMARY: The Department of Energy (DOE), pursuant to the Paperwork Reduction Act of 1995, intends to extend for three years, an information collection package with the Office of Management and Budget (OMB) concerning collection of human resource information from major DOE contractors for contract management administration, and cost control. Comments are invited on: (a) Whether the extended collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Comments regarding this proposed information collection must be received on or before March 7, 2005. If you anticipate in submitting comments within that period, contact the person listed below as soon as possible.

ADDRESSES: Written comments may be sent to: Stephanie Weakley, U.S. Department of Energy, 1000 Independence Ave., SW., Washington, DC 10585–1290, or by fax at 202/287–1656 or by e-mail at *stephanie.weakley@hq.doe.gov;* and to: Sharon Evelin, Acting Director, IM–11/ Germantown Bldg., U.S. Department of Energy, 1000 Independence Ave., SW., Washington, DC 28505–1290, or by fax at 301–903–9061 or by e-mail at *SharonEvelin@hq.doe.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Stephanie Weakley at the address listed in **ADDRESSES.**

SUPPLEMENTARY INFORMATION: This package contains: (1) *OMB No.* 1910–0100; (2) *Package Title:* Printing and Publishing Activities; (3) *Type of Review:* Renewal; (4) *Purpose:* This information is required for management oversight for DOE's Facilities Management Contractors and to ensure that the programmatic and administrative management requirements of the contract are managed efficiently and effectively; (5) *Respondents:* 307; (6) *Estimated Number of Burden Hours:* 7183.

Statutory Authority: Department of Energy Organization Act (Pub. L. 9591 of Aug. 4, 1977, 42 U.S.C. 7254).

Issued in Washington, DC on December 27, 2004.

Sharon Evelin,

Acting Director, Records Management Division, Office of the Chief Information Officer.

[FR Doc. 05–187 Filed 1–4–05; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL04–131–000]

AEP Power Marketing, Inc., AEP Service Corporation, CSW Power Marketing, Inc., CSW Energy Services, Inc., Central and South West Services, Inc.; Notice Of Initiation Of Proceeding And Refund Effective Date

December 29, 2004.

On August 9, 2004, as amended on August 10, 2004, September 16, 2004 and November 19, 2004, American Electric Power Service Corporation, on behalf of AEP Power Marketing, Inc., AEP Service Corporation, CSW Power Marketing, Inc., CSW Energy Services, Inc., and Central and South West Services, Inc. (collectively, AEP) submitted for filing generation power market screens in compliance with the Commission's orders issued April 14, 2004 and July 8, 2004.

On December 17, 2004, the Commission issued an order addressing these filings in Docket Nos. ER96–2495–020, *et al.* (Not consolidated). The Commission's order institutes a proceeding in Docket No. EL04–131–000 under section 206 of the Federal Power Act with respect to the justness and reasonableness of AEP's market-based rates.

The refund effective date in Docket No. EL04–131–000, established pursuant to section 206(b) of the Federal Power Act will be 60 days following publication of this notice in the **Federal Register.**

Magalie R. Salas,

Secretary.

[FR Doc. E4–3936 Filed 1–4–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP99–301–125]

ANR Pipeline Company; Notice of Negotiated Rate Filing

December 29, 2004.

Take notice that on December 23, 2004, ANR Pipeline Company (ANR), tendered for filing and approval amendments to two Rate Schedule ETS service agreements numbers 107873 and 109854 between ANR and Wisconsin Gas Company. ANR states that these amendments effectuate a change in primary delivery point groupings.

ANR requests that the Commission accept and approve the subject negotiated rate agreement amendments to be effective January 1, 2005.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E4–3933 Filed 1–4–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP05–136–000]

Cheyenne Plains Gas Pipeline Company, L.L.C.; Notice of Proposed Changes in FERC Gas Tariff

December 29, 2004.

Take notice that on December 23, 2004, Cheyenne Plains Gas Pipeline Company, L.L.C. (Cheyenne Plains) tendered for filing as part of its FERC Gas Tariff, Original Volume No 1, the tariff sheets listed in Appendix A to the filing, to become effective January 22, 2005.

Cheyenne states that these tariff sheets are filed to: (i) Update the list of permissible discounts, (ii) remove the First Bidder Option as a bid evaluation method for capacity release, (iii) modify the requirements for interruptible transportation service, (iv) revise the Form of Service Agreements; and (v) clarify various provisions of the Tariff.

Cheyenne Plains states that copies of its filing have been sent to all firm customers, interruptible customers, and affected state commissions.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E4–3941 Filed 1–4–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP05–135–000]

Colorado Interstate Gas Company; Notice of Proposed Changes in FERN Gas Tariff

December 29, 2004.

Take notice that on December 23, 2004, Colorado Interstate Gas Company (CIG) tendered for filing as part of its FERC Gas Tariff, First Revised Volume No. 1, the following tariff sheets to become effective January 24, 2005:

Sixth Revised Sheet No. 19,
Fourth Revised Sheet No. 273,
Original Sheet No. 273.01.

CIG states that these tariff sheets specify a timeline for the sale of available firm capacity. CIG requests that the tariff sheets become effective January 24, 2005.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention

or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E4–3940 Filed 1–4–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL05–3–000]

Kansas City Power and Light Company and Great Plains Power, Inc.; Notice of Initiation of Proceeding and Refund Effective Date

December 28, 2004.

On December 17, 2004, the Commission issued an order in Docket Nos. ER99–1005–001, 002 and 003, and ER02–725–003 and 004. The Commission's order institutes a proceeding in Docket No. EL05–3–000 under section 206 of the Federal Power Act with respect to the justness and reasonableness of Kansas City Power and Light Company's market-based rates.

The refund effective date in Docket No. EL05–3–000, established pursuant to section 206(b) of the Federal Power Act will be 60 days following publication of this notice in the **Federal Register.**

Magalie R. Salas,

Secretary.

[FR Doc. E4–3928 Filed 1–4–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL05–2–000]

Public Service Company of New Mexico; Notice of Initiation of Proceeding and Refund Effective Date

December 21, 2004.

On December 20, 2004, the Commission issued an order in the above-docketed proceeding. The Commission's order institutes a proceeding in Docket No. EL05–2–000 under section 206 of the Federal Power Act with respect to the justness and reasonableness of Public Service Company of New Mexico's market-based rates.

The refund effective date in Docket No. EL05–2–000, established pursuant to section 206(b) of the Federal Power Act will be 60 days following publication of this notice in the **Federal Register.**

Magalie R. Salas,

Secretary.

[FR Doc. E4–3929 Filed 1–4–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP05–39–000]

Questar Southern Trails Pipeline Company; Notice of Application

December 29, 2004.

Take notice that on December 22, 2004, Questar Southern Trails Pipeline Company (Questar Southern Trails), 180 East 100 South, Salt Lake City, Utah 84111, filed in Docket No. CP05–39–000 an application pursuant to section 7(b) of the Natural Gas Act for authorization to abandon, by sale, a 36-mile, 16-inch diameter portion of the West Zone of the Southern Trails pipeline, including the associated Essex delivery point to Pacific Gas & Electric Company (PG&E), located in San Bernardino County, California. Questar Southern Trails explains that the abandonment is necessary in order to provide assurance to a potential buyer that it may proceed to enter into a purchase agreement for the transfer of all West Zone assets as facilities removed from the Commission's jurisdiction. Questar Southern Trails further explains that the abandonment proposal will not affect transportation service provided through the Southern Trails pipeline to existing firm shippers since the Essex delivery point to PG&E has only been available to shippers on a day-by-day basis as a temporary, secondary delivery point, all as more fully set forth in the application which is on file with the Commission and open to public inspection. The filing may also be viewed on the Web at *http://www.ferc.gov* using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, call (202) 502–3676, or TTY, (202) 502–8659.

Any questions regarding this application should be directed to Lenard G. Wright, Director, Federal Regulation, Questar Pipeline Company, 180 East 100 South, P.O. Box 45360, Salt Lake City, Utah 84145–0360, phone: (801) 324–2459, fax: (801) 324–5485 or *lenard.wright@questar.com.*

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date, file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 14 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

Persons who wish to comment only on the environmental review of this project, or in support of or in opposition to this project, should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commentors will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review

process. Environmental commentors will not be required to serve copies of filed documents on all other parties. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the applicant. However, the non-party commentors will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission may issue a preliminary determination on non-environmental issues prior to the completion of its review of the environmental aspects of the project. This preliminary determination typically considers such issues as the need for the project and its economic effect on existing customers of the applicant, on other pipelines in the area, and on landowners and communities. For example, the Commission considers the extent to which the applicant may need to exercise eminent domain to obtain rights-of-way for the proposed project and balances that against the non-environmental benefits to be provided by the project. Therefore, if a person has comments on community and landowner impacts from this proposal, it is important either to file comments or to intervene as early in the process as possible.

The Commission strongly encourages electronic filings of comments, protests, and interventions via the Internet in lieu of paper. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site *(http://www.ferc.gov)* under the "e-Filing" link.

Comment Date: January 19, 2005.

Magalie R. Salas,

Secretary.

[FR Doc. E4–3934 Filed 1–4–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP99–163–003]

Questar Southern Trails Pipeline Company; Notice of Motion To Vacate Certificate In Part

December 29, 2004.

Take notice that on December 22, 2004, Questar Southern Trails Pipeline Company (Questar Southern Trails), 180 East 100 South, Salt Lake City, Utah 84111, filed in Docket No. CP99–163–003 a motion to vacate the certificate authority granted in 2000, to acquire, convert and construct facilities necessary to operate 209 miles of the West Zone portion of the Southern Trails pipeline project from Essex, California to its termination at Long Beach, California. Questar Southern Trails explains that it no longer intends to activate the 209-mile segment. Questar Southern Trails further explains that following receipt of abandonment authority requested in related Docket No. CP05–39–000, it intends to sell the entire West Zone of the Southern Trails pipeline from North Needles to Long Beach, California. Questar Southern Trails maintains that its decision to sell the West Zone of its pipeline will not alter the operation of or service provided through the East Zone of its pipeline from Blanco, New Mexico to North Needles, California, all as more fully set forth in the motion which is on file with the Commission and open to public inspection. The filing may also be viewed on the Web at *http://www.ferc.gov* using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, call (202) 502–3676, or TTY, (202) 502–8659.

Any questions regarding this motion should be directed to Tad M. Taylor, Senior Corporate Counsel, Questar Pipeline Company, 180 East 100 South, P.O. Box 45360, Salt Lake City, Utah 84145–0360, Phone: (801) 324–5531 *tad.taylor@questar.com.*

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date, file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 14 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

Persons who wish to comment only on the environmental review of this project, or in support of or in opposition to this project, should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commentors will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commentors will not be required to serve copies of filed documents on all other parties. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the applicant. However, the non-party commentors will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission may issue a preliminary determination on non-environmental issues prior to the completion of its review of the environmental aspects of the project. This preliminary determination typically considers such issues as the need for the project and its economic effect on existing customers of the applicant, on other pipelines in the area, and on landowners and communities. For example, the Commission considers the extent to which the applicant may need to exercise eminent domain to obtain rights-of-way for the proposed project and balances that against the non-environmental benefits to be provided by the project. Therefore, if a person has comments on community and landowner impacts from this proposal, it is important either to file comments or to intervene as early in the process as possible.

The Commission strongly encourages electronic filings of comments, protests, and interventions via the internet in lieu of paper. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site *(http://www.ferc.gov)* under the "e-Filing" link.

Comment Date: January 19, 2005.

Magalie R. Salas,

Secretary.

[FR Doc. E4–3935 Filed 1–4–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP04–14–004]

Saltville Gas Storage Company; Notice of Compliance Filing

December 29, 2004.

Take notice that on December 22, 2004, Saltville Gas Storage Company L.L.C. (Saltville) tendered for filing a compliance filing pursuant to the order issued by the Commission on November 22, 2004, in Docket Nos. CP04–13–001, CP04–14–002, and CP04–15–002.

Saltville states that copies of the filing were served on all parties on the official service list in the above captioned proceeding, as well as to all affected customers of Saltville and interested state commissions.

Any person desiring to protest this filing must file in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). Protests to this filing will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Such protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing a protest must serve a copy of that document on all the parties to the proceeding.

The Commission encourages electronic submission of protests in lieu of paper using the "eFiling" link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E4–3942 Filed 1–4–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP01–205–004]

Southern Natural Gas Company; Notice Of Negotiated Rate Tariff Filing

December 29, 2004.

Take note that on December 23, 2004, Southern Natural Gas Company (Southern) tendered for filing its Negotiated Rate Tariff Filing. Southern states that its filing requests that the Commission approve a negotiated rate arrangement between Southern and Scana Energy Marketing, Inc. (SEMI).

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E4–3939 Filed 1–4–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. OR05–4–000]

BP West Coast Products LLC and ExxonMobil Oil Corporation, Complainants v. SFPP, LP, Respondents; Notice of Complaint

December 28, 2004.

Take notice that on December 22, 2004, BP West Coast Products LLC (BP) and ExxonMobil Oil Corporation (ExxonMobil) (collectively, Complainants) tendered for filing their Fourth Original Complaint against SFPP, L.P. Complainants allege that SFPP's West Line, Watson Vapor Recovery Charge, Sepulveda Line, North Line, Oregon Line and East Line rates are unjust and unreasonable. Complainants request that the Commission review and investigate SFPP's rates; set the proceeding for an evidentiary hearing to determine just and reasonable rates for SFPP; require SFPP to pay reparations starting two years before the date of complaint for all rates; consolidate this proceeding with the complaint proceeding in Docket No. OR4–3; and award such other relief as is necessary and appropriate under the Interstate Commerce Act.

Complainants state that copies of the complaint were served on SFPP, L.P.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainants.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov*. Persons unable to file electronically

should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: January 22, 2005.

Magalie R. Salas,

Secretary.

[FR Doc. E4–3927 Filed 1–4–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL05–20–001, et al.]

Buckeye Power, Inc., et al.; Electric Rate and Corporate Filings

December 27, 2004.

The following filings have been made with the Commission. The filings are listed in ascending order within each docket classification.

1. Buckeye Power, Inc.

[Docket No. EL05–20–001]

Take notice that on December 20, 2004, Buckeye Power, Inc. (Buckeye) filed additional information regarding its November 3, 2004, filing in Docket No. EL05–20–000, in response to the Commission's November 30, 2004, deficiency letter.

Buckeye states that a copy of the filing has been served on PJM.

Comment Date: 5 p.m. Eastern Time on January 3, 2005.

2. California Independent System Operator Corporation

[Docket No. ER98–3760–011]

Take notice that on December 20, 2004, the California Independent System Operator Corporation (ISO) submitted a filing in compliance with the order issued in Docket No. ER98–3760–000 on November 19, 2004, 109 FERC ¶ 61,183.

The ISO states that this filing has been served upon all parties on the official service list for the captioned docket. In addition, the ISO further states that it has posted this filing on the ISO home page.

Comment Date: 5 p.m. Eastern Time on January 10, 2005.

3. Intercom Energy, Inc.

[Docket No. ER02–267–002]

Take notice that on December 17, 2004, Intercom Energy, Inc. submitted for filing with the Federal Energy Regulatory Commission its triennial updated market analysis in accordance with the Commission's rules and regulations.

Comment Date: 5 p.m. Eastern Time on January 7, 2005.

4. Kansas City Power & Light Company

[Docket No. ER04–982–001]

Take notice that on December 17, 2004, Kansas City Power & Light Company (KCPL) submitted a compliance filing pursuant to the Commission's Letter Order issued August 5, 2004, in Docket No. ER04–982–000.

KCPL states that copies of the filing were served upon The Empire District Electric Company as well as the Missouri Public Service Commission and the State Corporation Commission of Kansas.

Comment Date: 5 p.m. Eastern Time on January 7, 2005.

5. Illinois Power Company

[Docket No. ER05–173–000]

Take notice that on December 22, 2004, Illinois Power Company tendered for filing a Notice of Withdrawal of its November 2, 2004, filing of a "Tariff for Limited Sales of Excess Energy at Market-Based Rates" in the above referenced proceeding.

Comment Date: 5 p.m. Eastern Time on January 12, 2005.

6. PSEG Power New York Inc.

[Docket No. ER05–323–001]

Take notice that on December 17, 2004, PSEG Power New York Inc. (PSEG Power NY), filed an amendment of its December 10, 2004, filing in Docket No. ER05–323–000.

PSEG Power NY states it has served a copy of this supplemental filing on the New York Public Service Commission and the parties to the Commission's official service list for this docket.

Comment Date: 5 p.m. Eastern Time on January 7, 2005.

7. PSEG Fossil LLC, PSEG Nuclear LLC

[Docket No. ER05–324–001]

Take notice that on December 17, 2004, PSEG Fossil LLC (PSEG Fossil) and PSEG Nuclear LLC (PSEG Nuclear) (collectively, the Applicants), filed a supplement to correct their December 10, 2004 filing in Docket No. ER05–324–000.

Applicants state they have served a copy of this supplemental filing on the New Jersey Board of Public Utilities, the Pennsylvania Public Utilities Commission and the parties to the Commission's official service list for this docket.

Comment Date: 5 p.m. Eastern Time on January 7, 2005.

8. Southern California Edison Company

[Docket No. ER05–352–000]

Take notice that on December 17, 2004, Southern California Edison Company (SCE) submitted for filing a Letter Agreement which amends the Interconnection Facilities Agreement (IFA) between Eurus Energy America Corporation (Eurus Energy) and SCE, Service Agreement No. 25 under SCE's Transmission Owner Tariff FERC Electric Tariff, Second Revised Volume No. 6.

SCE states that copies of the filing were served upon the Public Utilities Commission of the State of California and Oasis Power Partners, LLC.

Comment Date: 5 p.m. Eastern Time on January 7, 2005.

9. Pacific Gas and Electric Company

[Docket No. ER05–353–000]

Take notice that on December 17, 2004, Pacific Gas and Electric Company (PG&E) tendered for filing an annual rate update, including rate schedule sheet revisions, to become effective January 1, 2005, to its Reliability Must-Run Service Agreements (RMR Agreements) with the California Independent System Operator Corporation (ISO) for Helms Power Plant (PG&E First Revised Rate Schedule FERC No. 207), San Joaquin Power Plant (PG&E First Revised Rate Schedule FERC No. 211) and Kings River Watershed (PG&E Rate Schedule FERC No. 226).

PG&E states that copies of the filing have been served upon the ISO, the California Electricity Oversight Board and the California Public Utilities Commission.

Comment Date: 5 p.m. Eastern Time on January 7, 2005.

10. San Diego Gas & Electric Company

[Docket No. ER05–354–000]

Take notice that on December 17, 2004, San Diego Gas & Electric Company (SDG&E) tendered for filing changes to its Transmission Owner Tariff Reliability Services Rates. SDG&E requests an effective date of January 1, 2005 for the proposed rate changes.

SDG&E states that copies of the filing have been served on the California Public Utilities Commission and the California Independent System Operator.

Comment Date: 5 p.m. Eastern Time on January 7, 2005.

11. Horsehead Corp.

[Docket No. ER05–355–000]

Take notice that on December 17, 2004, Horsehead Corp. filed with the Commission a Notice of Succession adopting the Rate Schedule FERC No. 1 of St. Joe Minerals Corporation as superseded, amended, and conformed to the requirements of Order No. 614, Designation of Electric Rate Schedule Sheets, 90 FERC ¶ 61,352 (2000).

Comment Date: 5 p.m. Eastern Time on January 7, 2005.

12. Entergy Services, Inc.

[Docket No. ER05–356–000]

Take notice that on December 17, 2004, Entergy Services, Inc., (Entergy Services) on behalf of Entergy Arkansas, Inc., Entergy Gulf States, Inc., Entergy Louisiana, Inc., Entergy Mississippi, Inc., and Entergy New Orleans, Inc., tendered for filing the Fifth Revised Network Integration Transmission Service Agreement between Entergy Services and East Texas Electric Cooperative, Inc., Sam Rayburn G&T Electric Cooperative, Inc., and Tex-La Electric Cooperative, Inc. Entergy Services requests an effective date of January 1, 2005.

Comment Date: 5 p.m. Eastern Time on January 7, 2005.

13. MidAmerican Energy Company

[Docket No. ER05–357–000]

Take notice that on December 17, 2004, MidAmerican Energy Company (MidAmerican), filed with the Commission an amended Network Integration Transmission Service Agreement between MidAmerican Energy Company and the City of Sergeant Bluff, Iowa (Sergeant Bluff). MidAmerican requests an effective date of January 1, 2005.

MidAmerican states that it has served a copy of the filing on Sergeant Bluff, the Iowa Utilities Board, the Illinois Commerce Commission and the South Dakota Public Utilities Commission.

Comment Date: 5 p.m. Eastern Time on January 7, 2005.

14. PacifiCorp

[Docket No. ER05–358–000]

Take notice that on December 20, 2004, PacifiCorp tendered for filing revisions to its Open Access Transmission Tariff to change PacifiCorp's mailing address applicable to all written notifications to PacifiCorp under the Open Access Transmission Tariff.

PacifiCorp states that copies of this filing were supplied to the Public Utility Commission of Oregon and the Washington Utilities and Transportation Commission. PacifiCorp's further states that the existing transmission customers were notified by e-mail.

Comment Date: 5 p.m. Eastern Time on January 10, 2005.

15. Western Systems Power Pool, Inc.

[Docket No. ER05–359–000]

Take notice that on December 20, 2004, the Western Systems Power Pool, Inc. (WSPP) requested amendment of the WSPP Agreement to include East Texas Electric Cooperative, Inc. (ETEC) as a participant. The WSPP seeks an effective date of January 1, 2005, for ETEC's membership.

WSPP states that copies of this filing will be served upon John H. Butts, Manager of ETEC, and Frederick H. Ritts of Brickfield, Burchette, Ritts & Stone, P.C., counsel to ETEC and copies will be e-mailed to WSPP members who have supplied e-mail addresses for the Contract Committee and Contacts lists.

Comment Date: 5 p.m. Eastern Time on January 10, 2005.

16. Old Dominion Electric Cooperative

[Docket No. ER05–360–000]

Take notice that on December 20, 2004, Old Dominion Electric Cooperative (Old Dominion) filed an application under section 205 of the Federal Power Act and 35.13 of the Commission's Rules and Regulations, for approval of Old Dominion's Application for Acceptance of Changes to Rate Formula That Do Not Provide for a Rate Increase, and Request for Waivers. Old Dominion requests an effective date of January 1, 2004.

Old Dominion states that a copy of the filing was served upon each of the Member Cooperatives and the public service commissions in the Commonwealth of Virginia and the states of Delaware, Maryland and West Virginia.

Comment Date: 5 p.m. Eastern Time on January 10, 2005.

17. New England Power Pool

[Docket No. ER05–361–000]

Take notice that on December 20, 2004, the New England Power Pool (NEPOOL) Participants Committee submitted an amendment to NEPOOL Market Rule 1 to provide for implementation of a test program for a seams reduction initiative involving short-notice intra-hour scheduling of energy transactions between the New England and New York control areas. NEPOOL requests an effective date of January 1, 2005.

The NEPOOL Participants Committee states that copies of these materials were sent to the NEPOOL Participants and the New England state governors and regulatory commissions.

Comment Date: 5 p.m. Eastern Time on January 10, 2005.

18. DTE Energy Marketing, Inc.

[Docket No. ER05–362–000]

Take notice that on December 20, 2004, DTE Energy Marketing, Inc. (DEM) tendered for filing a Notice of Cancellation of its Market Rate Tariff, designated as FERC Electric Rate Schedule No. 1. DEM requests an effective date of December 21, 2004.

Comment Date: 5 p.m. Eastern Time on January 10, 2005.

Standard Paragraph

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant and all parties to this proceeding.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call

(866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Linda Mitry,

Deputy Secretary.

[FR Doc. E4–3943 Filed 1–4–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER03–1079–003, et al.]

Aquila, Inc., et al.; Electric Rate and Corporate Filings

December 28, 2004.

The following filings have been made with the Commission. The filings are listed in ascending order within each docket classification.

1. Aquila, Inc.; Aquila Long Term, Inc.; Aquila Merchant Services, Inc.; Aquila Piatt County L.L.C.; MEP Clarksdale Power, LLC; MEP Flora Power, LLC; MEP Investments, LLC; MEP Pleasant Hill Operating, LLC; Pleasant Hill Marketing, LLC

[Docket Nos. ER03–1079–003, ER02–47–003, ER95–216–023, ER03–725–003, ER02–309–003, ER02–1016–001, ER99–2322–003, ER01–905–003, ER00–1851–003]

Take notice that on December 21, 2004, Aquila, Inc., Aquila Long Term, Inc., Aquila Merchant Services, Inc., Aquila Piatt County L.L.C., MEP Clarksdale Power, LLC, MEP Flora Power, LLC, MEP Investments, LLC, MEP Pleasant Hill Operating, LLC, and Pleasant Hill Marketing, LLC (collectively, Applicants) submitted for filing a joint triennial market power analysis pursuant to Acadia Power Partners LLC, *et al.*, 107 FERC ¶ 61,168 (2004). In addition, Applicants request the Commission to synchronize their future triennial market power analyses.

Comment Date: 5 p.m. Eastern Time on January 11, 2005.

2. FirstEnergy Service Corporation

[Docket No. ER03–1276–003]

Take notice that on December 21, 2004, FirstEnergy Serice Company submitted a compliance filing pursuant to the Commission's Letter Order issued October 1, 2004, in Docket No. ER03–1276–003.

Comment Date: 5 p.m. Eastern Time on January 11, 2005.

3. Wolverine Power Supply Cooperative, Inc.

[Docket Nos. ER04–132–003, EL04–38–004]

Take notice that on December 21, 2004, Wolverine Power Supply Cooperative, Inc. (Wolverine Power), submitted a compliance filing pursuant to the Commission's order issued November 22, 2004, in Docket Nos. ER04–132–000 and EL04–38–000, 109 FERC ¶ 61,191.

Wolverine Power states that a copy of this filing has been served upon each person designated on the official service list.

Comment Date: 5 p.m. Eastern Time on January 11, 2005.

4. Delmarva Power & Light Company

[Docket No. ER04–509–002, ER04–1250–001]

Take notice that on December 21, 2004, Delaware Municipal Electric Corporation, Inc. submitted a filing providing information requested by the Commission in the deficiency letter issued November 23, 2004, in Docket Nos. ER04–509–000, 001 and ER04–1250–000 regarding the September 24, 2004, filing of Delmarva Power & Light Company.

Comment Date: 5 p.m. Eastern Time on January 11, 2005.

5. Midwest Independent Transmission System Operator, Inc.

[Docket No. ER04–961–003]

Take notice that, on December 20, 2004, the Midwest Independent Transmission System Operator, Inc. (Midwest ISO) submitted Substitute Tariff Sheets to amend the compliance filing submitted on November 1, 2004 in Docket No. ER04–961–002.

The Midwest ISO states that it has electronically served a copy of this filing, with attachments, upon all Midwest ISO Members, Member representatives of Transmission Owners and Non-Transmission Owners, the Midwest ISO Advisory Committee participants, as well as all state commissions within the region. In addition, Midwest ISO states that the filing has been electronically posted on the Midwest ISO's Web site at *http://www.midwestiso.org* under the heading "Filings to FERC" for other interested parties in this matter. The Midwest ISO also states that it will provide hard copies to any interested parties upon request.

Comment Date: 5 p.m. Eastern Time on January 10, 2005.

6. Virginia Electric and Power Company

[Docket No. ER05–187–001]

Take notice that on December 21, 2004, Virginia Electric and Power Company (Dominion) tendered for filing an amendment to its November 5, 2004, filing of an amended Appendix E–2 for the service agreement under its open access transmission tariff, FERC Electric Tariff Second Revised Volume No. 5. Dominion requests that the Commission allow the amendment to become effective on November 5, 2004.

Dominion states that copies of this filing were served upon the North Carolina Electric Membership Corporation, the North Carolina Utilities Commission and the Virginia State Corporation Commission.

Comment Date: 5 p.m. Eastern Time on January 11, 2005.

7. El Segundo Power, LLC

[Docket No. ER05–363–000]

Take notice that on December 21, 2004, El Segundo Power, LLC (El Segundo) submitted for filing its Rate Schedule No. 2, a Reliability Must-Run Service Agreement (RMR Agreement) between El Segundo and the California Independent System Operator Corporation (CAISO), as well as a letter agreement dated December 20, 2004, between ESP and the CAISO setting forth additional terms and conditions that affect the RMR Agreement.

El Segundo states that copies of the filing were served upon the CAISO, Southern California Edison Company, the California Electricity Oversight Board, and the California Public Utilities Commission.

Comment Date: 5 p.m. Eastern Time on January 11, 2005.

8. Elk River Windfarm LLC

[Docket No. ER05–365–000]

Take notice that on December 21, 2004, Elk River Windfarm LLC (Elk River) filed an application for authorization to sell energy, capacity and ancillary services at market-based rates. Elk River states it is developing and will own and operate a wind energy facility in Butler County, Kansas. Elk River requests that the Commission grant waivers and blanket approvals provided to applicants that receive authority for market-based rates. El River requests an effective date of May 5, 2005.

Comment Date: 5 p.m. Eastern Time on January 11, 2005.

9. Sierra Pacific Power Company

[Docket No. ER05–366–000]

Take notice that on December 21, 2004, Sierra Pacific Power Company tendered for filing an executed Standard Large Generator Interconnection Agreement between Sierra Pacific Power Company and Barrick Goldstrike Mines Inc. Sierra Pacific Power Company requests an effective date of July 1, 2005.

Comment Date: 5 p.m. Eastern Time on January 11, 2005.

Standard Paragraph

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant and all parties to this proceeding.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Linda Mitry,

Deputy Secretary.

[FR Doc. E4–3944 Filed 1–4–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application for Amendment of License and Soliciting Comments, Motions To Intervene, and Protests

December 29, 2004.

Take notice that the following application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Amendment of license.

b. *Project No:* 785–015.

c. *Date Filed:* October 21, 2004.

d. *Applicant:* Consumers Energy Company.

e. *Name of Project:* Calkins Bridge Hydroelectric Project.

f. *Location:* The project is located on the Kalamazoo River, in Allegan County, Michigan.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a—825r.

h. *Applicant Contact:* Mr. Robert M. Neustifer, Esq., EP 11–233, Consumers Energy Company, One Energy Plaza, Jackson, MI 49201, (517) 788–2974, (517) 788–1682(Fax); and James R. Bernier, Consumers Energy Company, 330 Chesnut Street, Cadillac, MI 49601, (231) 779–5507, (231) 779–1007.

i. *FERC Contact:* Any questions on this notice should be addressed to Mrs. Anumzziatta Purchiaroni at (202) 502–6191, or e-mail address: *anumzziatta.purchiaroni@ferc.gov*.

j. *Deadline for filing comments and or motions:* January 31, 2005.

k. *Description of Request:* Consumers Energy Company, (Consumers) licensee, filed a license amendment application to remove 44.6 acres of project lands and to revise the project boundary. Consumers proposes the amendment to reflect changes in land elevation, occupancy, and use of the lands that have occurred since the development of the original license, but have not been reflected in subsequent amendments. The property proposed to be removed from the project consists of: Waste Water Treatment Plant and Rockwell Superfund Site (15.1 acres); Former Landfill Site (18.9 acres); Jaycees Park (7.4 acres); Monroe Street Flowage Channel (2.2 acres); and Perrigo Factory Site (1 acre). Consumers states in the filing that the land to be removed is not needed for project operation.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE., Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov* using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via e-mail of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or e-mail *FERCOnlineSupport@ferc.gov*, for TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, 385.211, 385.214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Responsive Documents:* Any filings must bear in all capital letters the title "COMMENTS", "RECOMMENDATIONS FOR TERMS AND CONDITIONS", "PROTEST", or "MOTION TO INTERVENE", as applicable, and the Project Number of the particular application to which the filing refers. All documents (original and eight copies) should be filed with: Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington DC 20426. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

p. *Agency Comments:* Federal, State, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

q. Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.gov* under the "e-Filing" link.

Magalie R. Salas,

Secretary.

[FR Doc. E4–3938 Filed 1–4–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. P–2082–027]

Klamath Hydroelectric Project; Notice Of Meeting

December 29, 2004.

Commission staff is scheduled to meet with representatives of the Karuk Tribe regarding the Klamath Hydroelectric Project relicensing. The meeting will be held at the location and time listed below: Karuk Community Center, 39051 Highway 96, Orleans, California 95556, January 12, 2005, 10 a.m. (P.s.t.).

Members of the public and intervenors in the referenced proceedings may attend this meeting; however, participation will be limited to tribal representatives and the Commission representatives. If the Tribe decides to disclose information about a specific location which could create a risk or harm to an archeological site or Native American cultural resource, the public will be excused for that portion of the meeting when such information is disclosed.[1] If you plan to attend this meeting, please contact John Mudre at the Federal Energy Regulatory Commission at 202–502–8902 or *john.mudre@ferc.gov*. The meeting will be transcribed by a court reporter, and public transcript will be made available by the Commission following the meeting.

Magalie R. Salas,

Secretary.

[FR Doc. E4–3937 Filed 1–4–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

National Nuclear Security Administration

Notice of Intent to Prepare a Supplemental Environmental Impact Statement to the Final Site-Wide Environmental Impact Statement for Continued Operation of the Los Alamos National Laboratory

AGENCY: U.S. Department of Energy, National Nuclear Security Administration.

ACTION: Notice of Intent.

SUMMARY: Pursuant to the National Environmental Policy Act (NEPA) of 1969, as amended (42 U.S.C. 4321 *et seq.*), the Council on Environmental Quality's (CEQ) and the U.S. Department of Energy's (DOE) regulations implementing NEPA (40 CFR parts 1500–1508 and 10 CFR part 1021, respectively), the National Nuclear Security Administration (NNSA), an agency within the DOE, announces its intent to prepare a supplemental site-wide environmental statement (S–SWEIS) to update the analyses presented in the Final Site-Wide Environmental Impact Statement for Continued Operation of the Los Alamos National Laboratory (SWEIS) (DOE/EIS–0238; January 1999). The purpose of this notice is to invite individuals, organizations, and government agencies and entities to participate in developing the scope of the S–SWEIS.

In its September 1999 Record of Decision (ROD) based on the SWEIS, DOE announced its decision to implement the Expanded Operations Alternative analyzed in the SWEIS, with modifications to weapons related production work (the Preferred Alternative), at Los Alamos National Laboratory (LANL). That decision is being implemented at LANL. Pursuant to 40 CFR 1502.20, the S–SWEIS will rely on and expand on the analysis in the original SWEIS. The No Action Alternative for the S–SWEIS is the continued implementation of the SWEIS ROD, together with other actions described and analyzed in subsequent NEPA reviews. The Proposed Action in the S–SWEIS will include changes since the SWEIS 1999 ROD.

DATES: NNSA invites comments on the scope of this S-SWEIS through February 27, 2005. NNSA will hold a public scoping meeting in Pojoaque, New Mexico, at the Pablo Roybal Elementary School on January 19, 2005, from 6 to 8 pm. Scoping comments received after February 27, 2005, will be considered to the extent practicable.

ADDRESSES: To submit comments on the scope of the S-SWEIS, questions about the document or scoping meeting, or requests to be placed on the document distribution list, please write or call: Ms. Elizabeth Withers (e-mail address: *lanl_sweis@doeal.gov;* mailing address: NNSA Los Alamos Site Office, NEPA Compliance Officer, 528 35th Street, Los Alamos, New Mexico, 87544; (toll free) telephone 1–877–491–4957 or Facsimile 505–667–9998).

FOR FURTHER INFORMATION CONTACT: For general information about the DOE NEPA process, please contact: Ms. Carol Borgstrom, Director, Office of NEPA Policy and Compliance (EH–42), U.S. Department of Energy, 1000 Independence Avenue, SW, Washington, DC 20585, 202–586–4600, or leave a message at 1–800–472–2756.

SUPPLEMENTARY INFORMATION: LANL is located in north-central New Mexico, 60 miles north-northeast of Albuquerque, 25 miles northwest of Santa Fe, and 20 miles southwest of Española in Los Alamos and Santa Fe Counties. It is located between the Jemez Mountains to the west and the Sangre de Cristo Mountains and Rio Grande to the east. LANL occupies about 40 square miles (104 square kilometers) and is operated for NNSA under contract, by the University of California. (The contract for LANL's management and operation is undergoing a competitive bid process; however, the selection of the LANL management and operations contractor in the future will not affect the nature of the NNSA and DOE work performed at LANL.)

LANL is a multidisciplinary, multipurpose institution primarily engaged in theoretical and experimental research and development. LANL has been assigned science, research and development, and production mission support activities that are critical to the accomplishment of the national security objectives (as reflected in the ROD for the September 1996 Final Programmatic Environmental Impact Statement for Stockpile Stewardship and Management (DOE/EIS–0236)). Specific LANL assignments will continue for the foreseeable future include production of War-Reserve products, assessment and certification of the stockpile, surveillance of the War-Reserve components and weapon systems, ensuring safe and secure storage of strategic materials, and management of excess plutonium inventories. LANL's main role in the fulfillment of DOE mission objectives includes a wide range of scientific and technological capabilities that support nuclear materials handling, processing and fabrication; stockpile management; materials and manufacturing technologies; nonproliferation programs; and waste management activities.

The Final LANL SWEIS, issued in January 1999, considered the operation of LANL at various levels for about a 10-year period of time. Alternatives considered in that document were: No Action Alternative, the Expanded Operations Alternative, the Reduced Operations Alternative, and the Greener Alternative. In addition to providing an overview of the LANL site and its activities and operations, the SWEIS identified 15 LANL "Key Facilities" for the purposes of NEPA analysis. "Key

[1] Protection from public disclosure involving this kind of specific information is based upon 18 CFR 4.32(b)(3)(ii) of the Commission's regulations implementing the Federal Power Act.

Facilities" are those facilities that house operations with the potential to cause significant environmental impacts; are of most interest or concern to the public based on scoping comments; or are facilities that would be the most subject to change due to potential programmatic decisions. The operations of these "Key Facilities" were described in the SWEIS and, together with other non-key facility functions, formed the basis of the description of LANL facilities and operations analyzed for their potential impacts. The Preferred Alternative was the Expanded Operations Alternative with certain reductions in weapons-related manufacturing capabilities. This alternative was chosen for implementation in the ROD issued in September 1999.

In mid-2004, NNSA undertook the preparation of a Supplement Analysis for the SWEIS pursuant to DOE's regulatory requirement to evaluate site-wide NEPA documents at least every 5 years (10 CFR 1021.330) and determine whether the existing EIS remains adequate, to prepare a new site-wide EIS, or prepare a supplement to the existing EIS. During the development of this Supplement Analysis, NNSA decided to proceed immediately with a supplement to the existing SWIES in order to expedite the NEPA process and to save time and money. DOE NEPA regulations (10 CFR 1021.314) require the preparation of a Supplemental EIS if there are substantial changes to a proposal or significant new circumstances or information relevant to environmental concerns. Substantial changes to the level of LANL operations may result from proposed, modified or enhanced activities and operations within LANL facilities (discussed later in subsequent paragraphs of this Notice), and new circumstances and information with regard to effects from the Cerro Grande Fire (which burned a part of LANL), a reduction in the size of the LANL reservation due to recent land conveyance and transfers, and contaminant migration have come to light over the past five years that could be deemed significant under 10 CFR 1021.314.

Since the issuance of the Final SWEIS in 1999, DOE and NNSA have finalized several environmental impact statements, environmental assessments (EA), and a special environmental analysis dealing with LANL operations and actions taken immediately after the 2000 Cerro Grande Fire. The activities analyzed in these NEPA documents and developing changes to the LANL environmental setting led NNSA to conclude it would be prudent and efficient to begin updating the SWEIS now by preparing a supplemental SWEIS. NNSA will use the S–SWEIS to consider the potential impacts of proposed modifications to LANL activities, as well as the cumulative impacts associated with on-going activities at LANL, on the changed LANL environment.

The S–SWEIS will provide a review of the impacts resulting from implementing the SWEIS ROD over the past 5 years at LANL and compare these impacts to the impacts projected in the SWEIS analyses for that alternative to provide an understanding of the SWEIS's ability to identify potential impacts. The S–SWEIS analyses will focus primarily on aspects of the existing environment that could be impacted by newly proposed changes to LANL operations at certain facilities and by environmental cleanup actions that could occur over the next 5 to 6 years in response to a consent order from the State of New Mexico. The S–SWEIS Proposed Action will analyze projected impacts anticipated from operating LANL at the 1999 ROD level for at least the next 5 years, with some modified work now being proposed at certain facilities. NNSA is considering proposed operational changes within at least two new "Key Facilities" at LANL:

- The Nicholas C. Metropolis Center for Modeling and Simulation (formerly called the Strategic Computing Complex), and
- The Nonproliferation and International Security Center (NISC).

The construction and operation of the Nicholas C. Metropolis Center for Modeling and Simulation were analyzed in a December 1998 EA and a finding of no significant impact (FONSI) for that proposed action was issued based on the impact analyses for operating the computational facility up to a 50–TeraOp platform (a TeraOp is a trillion floating point operations per second). The Center has been constructed and is currently operating below the operations level analyzed in the 1998 EA; however, NNSA proposes to increase the facility's operational capacity up to 100 TeraOps before 2009 with corresponding increases to the facility's consumption of water and electrical power resources. This proposed increase in the operating platform from 50 TeraOps up to 100 TeraOps will be analyzed in the S–SWEIS.

The NISC's construction and operation were analyzed in a July 1999 EA and a FONSI was issued for that proposed action based on the impact analyses for consolidating activities and operating the facility as it was envisioned at that time. The facility is currently operating as evaluated in the 1999 EA; however, NNSA is now proposing to move certain operations from the Technical Area 18 (TA–18) Pajarito Site (another of LANL's "Key Facilities," which is also discussed in the following paragraph) into the NISC. This would change the amount of nuclear material stored in the facility, with corresponding potential increases to worker exposures in the case of a site accident. The proposed changes to operations and material stored in NISC will be analyzed in the S–SWEIS.

NNSA will also eliminate one former LANL "Key Facility" identified in the 1999 SWEIS—the TA–18 Pajarito Site. In its 2002 EIS (the TA–18 Relocation Final EIS (DOE/EIS–319)) and ROD, the NNSA decided to relocate TA–18 security category I and II operations and associated nuclear material to the Nevada Test Site. Implementation of the relocation decision began in 2004 and will continue over the next 5 years. After relocation of operations and materials, this facility will no longer be a LANL "Key Facility" within the meaning of the SWEIS, and therefore will not be listed as such a facility. There are certain proposals related to the relocation of the TA–18 security category III and IV operations and the disposition of the TA–18 facilities that were not analyzed in the 2002 EIS; these proposed actions and their projected impacts will be evaluated in the S–SWEIS impact analyses.

Certain aspects of operational changes, construction and activities that have occurred or are being proposed for LANL over the next 5 years that were not analyzed in the 1999 SWEIS will also be considered and analyzed in the S–SWEIS. Changes that have been made to existing LANL operations that will also be considered further in the S–SWEIS include some permanent modifications to on-going operations that have recently been made as a result of decreases in specific work and projects performed at some LANL facilities, and changes to the locations of various types of materials at risk (MAR) at LANL facilities or off-site locations. Examples of newly proposed actions at LANL include the remediation of 10 major material disposal areas (MDAs) at LANL; the operation of a Biosafety Level-3 (BSL–3) Facility (this facility will become part of an existing "Key Facility" at LANL, the former Health Research Laboratory (HRL) now known as the Bioscience Facilities); the construction and operation of a new solid waste transfer station, an office and light laboratory complex, a consolidated warehouse and truck inspection station, and a new

radiography facility; and recently proposed increases in the types and quantities of sealed sources accepted for waste management at LANL. Some of these newly proposed actions may be analyzed explicitly in the S–SWEIS in project specific analyses, while others may be analyzed in separate EAs to be prepared over the next several months, such as the new BSL–3 Facility EA. The potential impacts of the BSL–3 Facility will be included in the S–SWEIS evaluation of cumulative impacts, as will the impacts of all of the newly proposed actions. A comparison of the newly projected operational impacts will also be made to the projected impacts identified in the SWEIS.

The NEPA compliance process for the BSL–3 Facility at LANL has spanned several years. In early 2002, the NNSA issued an EA and FONSI for the construction and operation of the facility at LANL. Due to the need to consider new circumstances and information relevant to the actual construction of the BSL–3 Facility and its future operation, the NNSA withdrew the 2002 FONSI for operating this facility and determined that a new EA should be prepared that re-evaluates the proposed operations of the facility as it has been constructed. The new EA is currently being prepared and a draft EA will be issued for public review and comment in early 2005. The EA will be used by NNSA in making a decision about whether to issue a FONSI for operation of the BSL–3 Facility. If a FONSI cannot be issued, the analyses for the operation of the BSL–3 Facility will be included in the S–SWEIS Proposed Action.

In accordance with applicable DOE and CEQ NEPA regulations, the No Action Alternative will also be analyzed in the S–SWEIS. In this case, the No Action Alternative will be the continued implementation of the 1999 ROD at LANL over the next 5 years as this alternative was originally analyzed in the SWEIS, and will also include the implementation of other actions selected in DOE and NNSA RODs supported by separate NEPA reviews (specifically, actions analyzed since the issuance of the final SWEIS in the Final Environmental Impact Statement for the Conveyance and Transfer of Certain Land Tracts Administered by the U.S. Department of Energy and Located at Los Alamos National Laboratory, Los Alamos and Santa Fe Counties, New Mexico (DOE/EIS–293), the Final Environmental Impact Statement for the Proposed Relocation of Technical Area 18 Capabilities and Materials at Los Alamos National Laboratory (DOE/EIS–319), the Final Environmental Impact Statement for the Chemistry and Metallurgy Research Building Replacement Project at Los Alamos National Laboratory, Los Alamos, New Mexico (DOE/EIS–0350), and in about 20 various EAs and their associated FONSIs, as well as actions categorically excluded from the need for preparation of either an EA or an EIS). The Los Alamos Site Office has posted a list of EAs and their associated FONSIs that pertain to LANL operations dating from the completion of the 1999 SWEIS on their Web site at: *http://www.doeal.gov/LASO/nepa*. The full text of most of these EAs is also available through links provided at that Web site; copies of all of the documents may be obtained by contacting Ms. Withers at any of the addresses provided previously in this Notice.

Changes or new information have also surfaced regarding the environmental setting at LANL over the past 5 years that may affect future LANL operations, such as changes to LANL watersheds as the result of the Cerro Grande Fire, new information and changes resulting from thinning the forests around LANL, and the long-term effects from the regional drought. Additionally, there have been changes to both the number of LANL workers and to the surrounding population that have occurred or are being projected that are different from those on which the SWEIS socioeconomic and other impact analyses were based. To the extent that changes to or new information about the existing LANL environment may significantly affect natural and cultural resource areas originally considered in the 1999 SWEIS, projected impacts associated with implementing the Proposed Action over the next 5 years at LANL will be analyzed in the S–SWEIS.

Direct, indirect, and unavoidable impacts to the various natural and cultural resources present at LANL, together with irreversible and irretrievable commitments and mitigations, will also be analyzed in the S–SWEIS. Further, operational and site differences require a re-evaluation of LANL operational accident analyses and a new assessment and understanding of cumulative impacts of LANL operations will also be addressed.

Public Scoping Process: The scoping process is an opportunity for the public to assist the NNSA in determining the issues for impact analysis, and at least one public scoping meeting is held. The purpose of the scoping meeting is to provide attendees an opportunity to present oral and written comments, ask questions, and discuss concerns regarding the S–SWEIS with NNSA officials. Comments and recommendations can also be mailed to Elizabeth Withers at any of the identified addresses noted in the previous paragraphs of this Notice. The S–SWEIS meeting will use a format to facilitate dialogue between NNSA and the public and will be an opportunity for individuals to provide written or oral statements. NNSA welcomes specific comments or suggestions on the content of the document that could be considered. The potential scope of the S–SWEIS discussed in the previous portions of this Notice is tentative and is intended to facilitate public comment on the scope of this S–SWEIS. It is not intended to be all-inclusive, nor does it imply any predetermination of potential impacts. The S–SWEIS will describe the potential environmental impacts of the alternatives by using available data where possible and obtaining additional data where necessary. Copies of written comments and transcripts of oral comments provided to NNSA during the scoping period will be available at the following locations: Los Alamos Outreach Center, 1350 Central Avenue, Suite 101, Los Alamos, New Mexico, 87544; and the Zimmerman Library, University of New Mexico, Albuquerque, New Mexico 87131.

S–SWEIS Preparation Process: The S–SWEIS preparation process begins with the publication of this Notice of Intent in the **Federal Register**. After the close of the public scoping period, NNSA will begin developing the draft S–SWEIS. NNSA expects to issue the Draft S–SWEIS for public review in the fall of 2005. Public comments on the Draft S–SWEIS will be received during a comment period of at least 45 days following publication of the Notice of Availability. The Notice of Availability, also published in the **Federal Register**, along with notices placed in local newspapers, will provide dates and locations for public hearings on the Draft S–SWEIS and the deadline for comments on the draft document. Issuance of the Final S–SWEIS is scheduled for early 2006.

Issued in Washington, DC, this 29th day of December, 2004.

Everet H. Beckner,

Deputy Administrator for Defense Programs, National Nuclear Security Administration.

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ENVIRONMENTAL PROTECTION AGENCY

[FRL–7857–5]

State Program Requirements; Approval of Revisions to the National Pollutant Discharge Elimination System (NPDES) Program; Louisiana

AGENCY: Environmental Protection Agency (EPA).

ACTION: Approval of revisions to the Louisiana Pollutant Discharge Elimination System program.

SUMMARY: Pursuant to a request by the Environmental Protection Agency (EPA) and as required by 40 CFR 123.62, the State of Louisiana submitted a request for approval of revisions to the Louisiana Pollutant Discharge Elimination System (LPDES) program, which was originally approved on August 27, 1996. Through the submission of the revised program authorization documents, including a complete program description, a Memorandum of Agreement (MOA) with EPA Region 6, and an Attorney General's Statement, the Louisiana Department of Environmental Quality (LDEQ) seeks approval of the proposed revisions to the LPDES program. Today, EPA Region 6 is publishing notice of its approval of the revised LPDES program and is responding to comments received during the 30-day public notice period on the proposed revisions. EPA is approving the State's request based upon the requirements of 40 CFR part 123 after considering all comments received.

Pursuant to an October 9, 2001, petition from numerous environmental groups in Louisiana requesting EPA withdraw LDEQ's authorization to administer the LPDES program along with EPA program reviews of the water permitting and enforcement programs, EPA delineated seven performance measures for LDEQ in a letter dated February 14, 2003, from Tracy Mehan, former EPA Assistant Administrator for Water, and John Peter Suarez, former EPA Assistant Administrator for Enforcement and Compliance Assurance, to former Governor M. J. Foster. Former Governor Foster replied in a letter dated March 27, 2003, with the commitment of LDEQ and the State of Louisiana to complete the seven performance measures. With the submission of the revision to the LPDES program, LDEQ completed the last of the seven performance measures. Regional Administrator Richard Greene notified Governor Kathleen Blanco of the completion of the performance measures in a letter dated May 13, 2004. After evaluation of the comments and other information related to this **Federal Register** notice regarding the revision to the LPDES program authorization, EPA is denying the petition for EPA to withdraw LDEQ's authorization to administer the LPDES program.

Section 402 of the Clean Water Act (CWA) created the National Pollutant Discharge Elimination System (NPDES) program under which EPA may issue permits for the point source discharge of pollutants to waters of the United States under conditions required by the Act. Section 402(b) requires EPA to authorize a state to administer an equivalent state program, upon the Governor's request, provided the state has appropriate legal authority and a program sufficient to meet the Act's requirements. The regulatory requirements for state program approval are set forth in 40 CFR part 123. Today, EPA is announcing its final approval action on the revisions to the LPDES program, the Regional Administrator has notified the State, has signed the revised MOA, and is publishing notice of the action in the **Federal Register** along with responses to comments received.

Comments, Discussion, and EPA Responses

EPA received 12 comments on the revision to the LPDES program authorization documents. The comments received were from the Tulane Environmental Law Clinic representing the Louisiana Environmental Action Network, the Louisiana Audubon Council, the Gulf Restoration Network, the Association of Community Organizations for Reform Now, the Lake Pontchartrain Basin Foundation, CFACT, the Lake Maurepas Society, and the Concerned Citizens of Livingston Parish; American Electric Power; and The Dow Chemical Company. The comments and responses, in their entirety are listed below.

Comment 1: LDEQ has no right to judicial review of Administrative Law Judge (ALJ) decisions and thus ALJs can force LDEQ to issue permits the agency believes are illegal.

Discussion by Commenter: Louisiana law provides that in an adjudication by the Division of Administrative Law (DAL), the decision of the ALJ is final and "the agency shall have no authority to override such a decision or order." In addition, La. R.S. 49:992(B)(3) states that "no agency or official thereof, or other person acting on behalf of an agency or official thereof, shall be entitled to judicial review of a decision made pursuant to this chapter". This provision impairs LDEQ's ability to carry out the LPDES program properly because it cannot appeal an adverse decision. Consequently, LDEQ may be required to issue a permit that violates the CWA. In short, this regulation limits the authority of LDEQ, as the agency primarily responsible for administering the federal CWA within the state, to ensure that all permits it issues comply with the law, and instead places that burden on the public, who must intervene to object to a wrongfully issued permit.

Commenters assert that EPA's response is that La. R.S. 49:992(D)(2) allows LDEQ to be exempt from the DAL provisions "if required by a federal mandate". Accordingly, if EPA requires LDEQ to conduct or to render a final order in an adjudication proceeding as a condition of federal funding, LDEQ can conduct its adjudicatory hearings 'in house' rather than under the DAL. The Program Description further states that "assuming [LDEQ] was to conduct adjudicatory hearings 'in house', it maintains the authority to do so." In that case, the decision of the hearing officer would become final unless the Secretary grants administrative review, in which case he would make the final decision.

Commenters believe that EPA's response does not clearly address the problem. To the best of our knowledge, EPA has not yet required "as a condition of federal funding" that LDEQ conduct in house adjudication proceedings. Until and unless EPA does so, La. R.S. 49:992(D)(2) will be inapplicable and thus irrelevant. Accordingly, to ensure that LDEQ has adequate authority to administer the NPDES program in Louisiana, EPA's approval must specifically provide that LDEQ conduct all adjudicatory hearings "in house" rather than under the DAL as a condition of federal funding.

EPA Response: The commenters are correct in stating that La. R.S. 49:992(B) precludes LDEQ from appealing an adverse decision in an adjudication by the DAL. However, EPA does not believe this restriction on the agency's power requires withdrawal of the State's authority to run the NPDES program. This issue arises only if a request for hearing is filed by the permit applicant within 30 days after he receives notice of LDEQ's issuance of the NPDES permit. If the hearing request is granted by the Secretary of LDEQ, an adjudicative hearing is held by an ALJ with DAL, an agency independent of LDEQ. The ALJ's decision concerning the permit appeal is final, and under State law, LDEQ cannot unilaterally revise an adverse decision or appeal it to State Court. Therefore, an ALJ could

order LDEQ to make revisions to a permit that LDEQ does not believe comport with the CWA.

Although EPA does not believe this situation to be ideal, there are additional safeguards in place to insure final issuance of an NPDES permit that meets all the requirements of the CWA. First of all, pursuant to La. R.S. 30:2050.21, any "aggrieved person" may appeal a final permit action to State District Court. "Aggrieved person" is defined by La. R.S. 30:2004(17) as any "natural or juridical person who has a real and actual interest that is or may be adversely affected by a final action under this Subtitle." Thus, even though LDEQ cannot appeal an adverse NPDES permit decision by an ALJ, members of the general public, so long as they meet the broad definition of "aggrieved person," may. The public's right to appeal is bolstered by the fact that any decision by an ALJ under these circumstances, that results in a major modification to an NPDES permit, requires LDEQ to prepare a new draft permit and notice it to the public for public comment. See Louisiana Administrative Code (LAC) 33:2903. Under LAC 33:3123, after the close of the public comment period, LDEQ must notify each person who has submitted written comments or requested notice of the final permit decision, and such notice must include reference to the procedures for appealing the decision.

Another safeguard to LDEQ's permit issuance process is EPA's oversight role. Under the MOA signed by LDEQ and EPA upon authorization of the LPDES program, if the terms of any permit, including any permit over which EPA has waived review, are affected in any way by administrative action, LDEQ must forward to EPA a copy of the administrative decision, along with a copy of the permit affected with any changes identified. EPA has the right to object to such a modified permit under Section 402(d)(2) of the CWA and 40 CFR 123.44. If EPA objects to such a permit and LDEQ fails to revise the permit to comply with EPA's objections, exclusive authority to issue the permit reverts to EPA pursuant to 40 CFR 123.44(h)(3).

As a result of the additional safeguards in place, EPA believes LDEQ's inability to appeal an adverse permitting decision of an ALJ does not undercut LDEQ's ability to implement an adequate LPDES program. However, EPA is aware of the fact that Acts 739 and 1332 of the 1999 Regular Session of the Louisiana legislature, which created the DAL and which precluded any agency of the State from seeking judicial review of a decision of a DAL ALJ, have been ruled unconstitutional by the 19th Judicial District Court in Louisiana. (See, Judge Janice C. Clark's judgment in *J. Robert Wooley, in his capacity as Commissioner of Insurance, State of Louisiana* v. *State Farm Fire and Casualty Insurance Company,* et al., Suit No. 502,311 (19th J.D.C. 3/15/04). The District Court's ruling is currently on appeal to the Louisiana Supreme Court, which heard oral argument on September 7, 2004, and has taken the matter under advisement. Should the Supreme Court's ruling on this matter indicate the need to revisit this issue, EPA will do so at that time.

Comment 2: The public receives no notice of hearings and thus has no opportunity to intervene.

Discussion by Commenter: An "aggrieved person" can request an adjudicatory hearing on a disputed issue of fact or law, which the Secretary may grant "when equity and justice require". An aggrieved person also has the right to intervene as a party in an adjudicatory hearing when the intervention "is unlikely to unduly broaden the issues or to unduly impede the resolution of the matter under consideration." However, these provisions offer the public little protection because state law does not provide the public with any right to notification of a request for an adjudicatory hearing by permit applicants. Nor does state law provide the public with a right to notification of the results of such a hearing. Without notice, the public effectively never has an opportunity to intervene. Accordingly, to ensure adequate public participation in adjudicatory hearings, EPA's approval must be conditioned on LDEQ's agreement to provide a minimum of 30 days notice of adjudicatory hearings and settlements, including at a minimum, notice published in the public notices section of LDEQ's Web page (currently *http://www.deq.state.la.us/news/PubNotice*) and public notice list-serve.

EPA Response: CWA Section 402(b) and 40 CFR part 123 establish the minimum requirements for public participation in approved State NPDES programs. In regard to permit issuance, States seeking NPDES authorization must have authority sufficient "to insure that the public, and any other State the waters of which may be affected, receive notice of each application for a permit and to provide an opportunity for public hearing before a ruling on each such application." In regard to enforcement, 40 CFR 123.27(d) requires States to provide for public participation in the State enforcement process in one of two ways: (A) The State must allow intervention as of right in any civil or administrative action to obtain enforcement remedies by any citizen with an interest that is or may be adversely affected; or (B) The State must investigate and provide written responses to all citizen complaints, not oppose intervention by any citizen when permissive intervention may be authorized by statute, rule, or regulation, and publish notice of and provide at least 30 days for public comment on any proposed settlement of a State enforcement action. EPA believes LDEQ is in compliance with the federal requirements for public participation in both permitting and enforcement.

Pursuant to LAC 33:IX.3113, LDEQ provides public notice of every draft permit prepared by the agency and of every notice of intent to deny a permit application. As required by both federal and State regulations, notice is provided by mailing a copy of the notice to persons on a mailing list that includes any person who requests in writing to be on the list and by publication of the notice in a daily or weekly newspaper within the area affected by the facility or activity. LDEQ also publishes notices of draft NPDES permits on its public Web site. The public notice on draft permits provides for a public comment period of at least 30 days, during which any interested person may submit written comments and/or request a public hearing. A public hearing is held anytime LDEQ finds, on the basis of requests, a significant degree of public interest in a draft permit, or at the agency's discretion whenever, for instance, a hearing might clarify one or more issues involved in the permit decision. LAC 33:IX.3115 & 3117.

LDEQ chose to provide for public participation in enforcement matters in accordance with the second method allowed by 40 CFR 123.27(d). The State investigates and provides written responses to citizen complaints, and does not oppose intervention by any citizen in adjudicatory hearings held at the request of the respondent regarding any disputed issue of material fact or law arising from a compliance order or penalty assessment. Such adjudicatory hearings are held by an ALJ with the DAL. LDEQ also publishes notice of each proposed settlement of a State enforcement action on its public Web site at least 45 days prior to final action on the proposed settlement, and, as a condition to settlement, requires respondents to publish notice of the proposed settlement in a newspaper of general circulation in the parish in which the violations occurred at least 45 days prior to final action.

Although LDEQ does not provide specific notice to the public of the request for an adjudicatory hearing by the applicant in regard to permit issuance or by the respondent in regard to an enforcement action, neither the CWA nor implementing federal regulations require it to do so. However, it is easy enough for persons interested in a particular permit or enforcement matter (the existence of which is widely publicized by LDEQ) to find out if a hearing has been requested, granted or scheduled by contacting the Legal Affairs Division at LDEQ or the DAL.

Comment 3: Timely permit issuance requires consistent additional funding.

Discussion by Commenter: Allowing facilities to operate without a valid discharge permit is a violation of the CWA Section 301(a). Even so, Louisiana regulations currently authorize a facility that submits an application at least 180 days before the permit expires to continue operating until LDEQ can reissue the permit. The 2002 Audit revealed that "these continuations may result in DEQ not reissuing permits for several years." As of January 2001, 54% of major water permits and 10% of minor water permits were expired.

The Revised MOA requires that LDEQ reissue all expiring permits "as close as possible to their expiration dates," and that LDEQ may not modify any continued permit. However, the problem remains that many facilities are illegally discharging into the waters of Louisiana without a permit. These facilities may be subject to an enforcement action for these violations. Thus, both the regulated community and the public have an interest in ensuring that LDEQ issue permits before they expire.

LDEQ revised its LPDES Permit Issuance Strategy ("Permit Issuance Strategy") on April 30, 2003. It provided $1.49 million in federal grant money for the 2003 fiscal year to pay for EPA contract support to assist with permit issuance. According to the report, as of May 1, 2003, 244 major facilities exist in Louisiana, and 95 of those permits are backlogged. The plan reports LDEQ will have no major permit backlog by the end of 2005. Of the 1637 minor facilities in Louisiana, 869 are operating under a current permit—332 are expired but continued, and 446 have unknown status. LDEQ projects it will have a minor permit backlog of 9.5% by the end of 2005. EPA considers a level of less than 10% expired permits to be indicative of a well-maintained program. Further, in a July 30, 2003, letter to Region 6, LDEQ reported that it had met or exceeded performance measures for permit issuance from January 1 through July 30 of 2003. This is excellent progress. However, LDEQ must reach a point where it can handle its permitting workload without relying on federal grants. Without a long-term budgetary solution, LDEQ will once again have a backlog.

EPA's approval must therefore be conditioned on assurance of adequate funding of LPDES, for example, (1) a program of permit fees adequate to cover the program's administration or (2) the Governor's adherence to a specific and signed commitment to seek a specific minimum level of funding for LPDES that EPA concludes, based on analysis in the record, is adequate for a well-maintained program.

EPA Response: LDEQ's LPDES program receives the bulk of it's funding (83%) from the States' Environmental Trust Fund. The Environmental Trust Fund receives it funding from permit fees and administrative penalties. Thirteen percent of funds that support the LPDES program are from the Federal 106 Grant Program. The commentor notes that LDEQ has made excellent progress for permit issuance from January 1 through July 30 of 2003, and further states that LDEQ must reach a point where it can handle its permitting workload without relying on federal grants. In the first quarter of calendar year 2003, EPA and LDEQ agreed that in order to document that the State had the capabilities to administer the LPDES program, that LDEQ would issue 35 major and provide coverage for 300 minor individual permits for calendar year 2003. All work on the permits was to be completed by LDEQ staff. Contractor drafted permits were not included in the count. For calendar year 2003, LDEQ drafted and issued 36 major permits and provided coverage for 382 individual minor facilities. Coverage for 236 of the minor permits were provided by individual permits and the remaining permits (186) were provided coverage under general permits. All of this was completed without contractor support.

In calendar year 2004, LDEQ continues to make excellent progress in its permit issuance. As of August 2004, LDEQ has a major individual permit universe of 254 permits of which 84% are current and a minor permit universe of 6042 (individual and non-storm water general permits) of which 92% are current. LDEQ's overall backlog rate for individual majors, minors, and non-storm water general permits for August is 8%. Only one state in Region 6 has a better overall permit issuance rate. LDEQ has committed to issuing 60 individual major and 300 individual minor permits for calendar year 2004. Of the 28 major permits and 303 minor permits issued so far in calendar year 2004, six major permits and 39 minor permits were written by a contractor.

Comment 4: EPA must ensure that LDEQ regularly inspects permitted facilities.

Discussion by Commenter: La. R.S. 30:2012 provides that "[e]very permit shall as a matter of law be conditioned upon the right of the secretary or his representative to make an annual monitoring inspection and, when appropriate, an exigent inspection of the facility operating thereunder." However, the 2002 Audit found that LDEQ failed to inspect 4 percent of permitted major facilities in fiscal year 2000 and 2001, as well as 31% of minor permitted facilities.

Section 5.3 of the Program Description requires regional Surveillance Division personnel to conduct routine inspections of permitted major and minor discharges via unannounced visits in accordance with the NPDES Compliance Inspections Manual and LDEQ Standard Operating Procedure (SOP) #1108. It also lists six factors that determine the frequency of inspections. These factors are (a) facility compliance history; (b) facility location; (c) potential environmental impact; (d) operational practices being steady or seasonal; (e) grant or funding commitments made by LDEQ; and (f) any other relevant environmental, health, or enforcement factors. In addition, the Revised MOA requires the Louisiana Compliance Monitoring Strategy be submitted to EPA annually, and it will list major and minor permittees to be subject of state compliance inspections. This is a good improvement. However, inspections are essential to proper enforcement of the CWA, and thus EPA oversight is crucial to ensuring that LDEQ is conducting inspections properly and in a timely manner.

EPA Response: EPA does not believe that the regulations define, with no flexibility, a precise number or type of inspections that must occur. Rather, the regulations in 40 CFR 123.26(e)(5) require States to show that they have "procedures and ability" to inspect all major dischargers and all Class I sludge management facilities, where applicable. Thus, the regulations require a showing of capacity and a commitment to a level-of-effort for inspections, reserving discretion to the two sovereign governments to decide what number of inspections to undertake, and the identity of the facilities to be inspected. These judgments are matters of enforcement discretion, and under this discretion, EPA and LDEQ have agreed, and

included commitments in the Annual Performance Partnership Grant Agreement, that LDEQ will inspect 90% of the Major, 92–500 Minor, and Significant Minor facilities annually. It was also agreed that the significant minor definition would be determined and agreed upon, by EPA and LDEQ, prior to the beginning of each inspection year. For the current inspection year, beginning 7/1/04, the significant minor universe has been determined to represent the Total Environmental Solutions, Incorporated (TESI) facilities included in the Consent Decree (approximately 172 facilities).

There is not a specific targeting strategy utilized in selecting the facilities to be included in the 90%, because the number represents the majority of the facilities in the universe, and because LDEQ considers the 90% to be a hedge on perfection, due to the fact that the intent is to inspect 100%. Based on evaluation of data for the last inspection year, beginning 7/1/03 and ending 6/30/04, EPA determined that LDEQ conducted inspections at 98% of the Major and 92–500 Minor facilities. In the future, because of national priorities, the percentage may be reduced, and at that time, factors for selection will be considered, such as environmental harm, location, and compliance history. In addition to meeting and exceeding the commitments agreed in the Annual Performance Partnership Grant Agreement, LDEQ has also conducted inspections at nearly 3,000 facilities, covered by Minor or General Permits, during each of the last three inspection years. LDEQ plans to inspect all of the general permit sewage treatment plants every 3 years. Currently, there are more than 4000 of these facilities. LDEQ has also implemented a Regional Circuit Rider Approach, which results in the issuance of a Notice of Deficiency (NOD) accompanied by an Expedited Penalty Agreement of up to $3,000 for minor violations. Noncompliance with the NOD will result in a referral to Enforcement for further action.

Although EPA believes that LDEQ is currently conducting inspections properly and in a timely manner, EPA, as part of its oversight role, will continue to monitor the state's inspection program through oversight audits and review of information submitted by LDEQ.

Comment 5: Neither Region 6 nor LDEQ has established a timeframe for completing enforcement actions.

Discussion by Commenter: The LPDES Program Description provides that the Surveillance Division is responsible for referring inspections or investigations that result in findings of areas of concern to the enforcement division within 30 working days. However, LDEQ has not established a mandated timeframe for completing enforcement actions, or for obtaining the information it needs to bring an enforcement action. This process alone can take weeks, months or years. Although every enforcement action presents its own facts and circumstances, LDEQ should establish a definitive timeframe for bringing enforcement actions. In the past, as many as 80% of water enforcement actions were entered over 150 days after the violation occurred.

EPA's approval must therefore be conditioned on LDEQ's adherence to a written schedule (and reporting obligation) that will show by 2008 that at least 80% of LDEQ's water enforcement actions are brought within (1) 60 days of an inspection uncovering violations and (2) 150 days of a violation.

EPA Response: Section I.C. of the MOA indicates that the state has primary responsibility for implementing the LPDES program in accordance with the MOA, specified sections of the CWA, applicable state legal authority, applicable requirements of 40 CFR, applicable federal regulations, the Multi-Media/Multi-year Enforcement Memorandum of Understanding and the annual Performance Partnership Grant. LDEQ has the primary responsibility to establish LPDES program priorities with consideration of EPA Region 6 and national NPDES goals, and objectives. The Enforcement Response Guide (ERG), included in the referenced Enforcement Actions SOP #1215, is consistent with the EPA ERG and provides a guide to be used for selecting the most appropriate response or set of responses to instances of noncompliance.

The annual Performance Partnership Grant referenced in the MOA establishes timeframes for responses to specific activities/commitments. This agreement requires that the state identify and initiate enforcement action for majors, 92–500 minors and significant minors with inspection deficiencies within 90 days of the date which enforcement receives the inspection report. It also specifies that LDEQ identify and initiate enforcement actions for identified violations for the same classes of facilities within 90 days of receipt of the Discharge Monitoring Report (DMR). Based on the facility reviews conducted during the most recent EPA site visit, and review of information received at EPA during the year, it has been determined that in the majority of the instances, where the inspection noted areas of concern, actions were issued within an average of 20 days. It was also noted that in many of the instances where a warning letter was issued as the initial action, there was a follow-up enforcement order issued within 60 days, escalating that initial action. Instances of significant non-compliance are addressed within the timeframes established in the oversight guidance. Isolated instances of non-compliance may not merit a formal enforcement action when the violation occurs. However, when these isolated instances are combined with inspection violations or other instances of non-compliance, action may be warranted in accordance with the ERG. For example, an isolated violation, which occurs in January, may not merit a Formal Enforcement Action until detection of a subsequent violation and/or inspection deficiency, which perhaps occurs in May.

Comment 6: LDEQ must collect the penalties it assesses.

Discussion by Commenter: The 2002 audit revealed that LDEQ had not collected nearly $4.5 million, equaling 75% of the monetary penalties assessed in 1999, 2000, and 2001 fiscal years. SOP #1215 provides that an enforcement action may be made executory "if violations continue after issuance of a final enforcement action, or if a final penalty action is not paid." It further provides that "the Legal Division has a goal that all enforcement cases should be brought to final resolution within 12 months of the Legal Division's acceptance of the case." However, neither the Revised MOA, the Program Documents, nor SOP #1215 provide assurances that LDEQ will pursue the penalties they have assessed, much less recover them. Proper inspection, timely enforcement and aggressive penalty collection motivate industry to comply with the CWA. If any of these elements are lacking, the deterrent effect of penalty assessment is lost.

EPA's approval must therefore be conditioned on LDEQ's adherence to a written schedule (and reporting obligation) that will show by 2008 that at least 80% of LDEQ's water penalty assessments are collected within 60 days of becoming final and collectable.

EPA Response: LDEQ maintains that the data presented in the 2002 legislative audit is not an accurate representation of the actual figures. The audit's figures include several categories of monies not actually owed to LDEQ. For instance, the difference between the cash component in finalized settlement agreements and the appealed penalty assessments, which are associated with

the settlements, are not owed to LDEQ. Penalty assessments under appeal are not considered final enforcement actions and thus are not owed to LDEQ, until the appeal process has been completed. LDEQ maintains that removing monies not actually owed to LDEQ from the "uncollected penalties" calculation would significantly lower the uncollected amount for all media.

Regardless of what the actual figures are, LDEQ has committed to aggressively pursue collection of all penalty dollars, including, if necessary, going to court to obtain judgment for those penalties that remain unpaid after a reasonable period of time. As a result, EPA does not believe it is necessary to require LDEQ's adherence to the written schedule suggested by the commenter. However, as a part of its statutorily mandated oversight of the LPDES program, EPA will continue to monitor LDEQ's enforcement program, including its assessment and collection of penalties, for consistency with the CWA and other applicable federal regulations, guidance and policies.

Comment 7: LDEQ must provide accurate and accessible information on compliance status.

Discussion by Commenter: For several years, LDEQ has failed to keep sufficient records as to self-monitoring reports, has maintained inaccurate compliance status information, and has lost or misfiled important documents. In addition, in its 2003 mid-year review of LDEQ, the EPA noted that "the Electronic Document Management System (EDMS) remains problematic for public retrieval and review of LPDES permits and supporting materials. The database contains voluminous amounts of information and the poor indexing of materials and files containing misfiled information makes the system difficult for the public to use." During the review, EPA noted that "the EDMS was too cumbersome to complete the file review because documents were not correctly indexed."

Revised MOA IV.B.1 requires LDEQ to conduct "timely and substantive reviews and keep complete records of all written materials relating to the compliance status of LPDES permittees." Required records include Compliance Schedule Reports, DMRs, Compliance Inspection Reports, and any other report required by the permit. Revised MOA IV.B.1.a further requires LDEQ to operate a system to determine if the self-monitoring reports are submitted, submitted reports are timely, complete and accurate, and that permit conditions are met.

In order to meet these requirements, LDEQ has prepared SOP #1453 governing the Permit Compliance System (PCS), which is a national database of NPDES information. The goals of this system are to ensure the accuracy, timeliness and completeness of all submissions. Improved accuracy, timeliness and completeness of submissions are vitally important. However, LDEQ must also ensure that the public is able to access this information. Importantly, LDEQ has committed to enter data which it deems appropriate, and that the decision will be made without public input. Therefore, citizens may be deprived of important data regarding the compliance of industrial and municipal facilities.

To improve public access, LDEQ should promptly allow online access to information. EPA's approval must therefore be conditioned on (1) LDEQ's immediate inclusion of full copies of current and future DMRs and other records of compliance in its electronic, searchable (currently "EDMS") records management system, (2) LDEQ's inclusion of WENDB data elements; (3) LDEQ's adherence to a schedule for providing online public access to CWA compliance records by August 2005.

EPA Response: During the most recent Enforcement Program Review which was conducted June 2004, EPA staff noted significant improvements in the process for utilizing the EDMS at LDEQ. It appears that the continuous analysis and revisions being made to the system have been beneficial. LDEQ has enhanced the indexing system which provides more descriptive information for the documents in the system. While attempting to locate documents in the system, it was noted that documents included an additional description, which was helpful in the identification process. The percent of documents located during this review was found to have improved by 46% for minor facilities and 38% for major facilities from the March 2003 review. There were no documents found to be imaged under the incorrect identification number for the files included in the search. Because of the fact that DMRs are produced on a type of paper that does not scan well, those documents are maintained as paper records in files onsite. These documents were readily available and were found to be filed under the correct record numbers. The program documents require only that the state maintain adequate public files for each permittee at the central office and must be accessible to EPA and the public. Instructions for the various request options for access to public records are available on the LDEQ Web page (*publicrecords@la.gov*).

Under the Program MOA, LDEQ is committed to enter all permit related and enforcement WENDB data into the National PCS for all Major, 92–500 Minor and Significant Minor facilities. Significant Minors are identified as those minor facilities mutually agreed upon by both EPA and LDEQ and identified in the Annual State Program Performance Partnership Grant.

Comment 8: LDEQ must provide public notice for all permit applications it receives.

Discussion by Commenter: LDEQ should issue public notices for *all* permit applications it receives, not just for major facilities and general permits. This enables citizens to be informed of all the sources of pollution in their area and gives them an opportunity to provide input during the permitting process.

EPA Response: LDEQ meets or exceeds EPA's public participation requirements in its permitting program. LDEQ must demonstrate to EPA that it can carry out the NPDES program and that state requirements are at least as stringent as the federal requirements. LAC 33:IX.2415.C.2 was patterned after the federal regulations. Federal regulations require that draft major permits undergo public noticing in a newspaper and go through a comment period. Louisiana regulations are further interpreted to extend this requirement to include minor permits, making Louisiana regulations more stringent than the federal requirements. In addition, the Program Description and LDEQ SOPs include requirements for issuing public notice in a newspaper for both major and minor individual draft permits.

Comment 9: EPA must take prompt action if LDEQ fails to abide by the Revised MOA or the Program Description.

Discussion by Commenter: We acknowledge that LDEQ has made significant improvements in its administration of the LPDES. We also believe that LDEQ's current Secretary and Deputy Secretary have demonstrated a sincere desire to run a professional, well-maintained program. Nonetheless, each of the problems discussed above has existed since 1996, when EPA first authorized Louisiana to administer the LPDES program. The citizens of Louisiana are therefore being asked to wait for LDEQ to catch up, while facilities continue to operate with expired permits, to violate their effluent limits, and to illegally impair the waters of the State of Louisiana. Given the pervasive nature of these problems and the significant efforts required to remedy them, the EPA should exercise

strong oversight over LPDES until LDEQ has demonstrated that it has the regulatory and legal structure and funding necessary to administer the program in full compliance with the CWA and has established a track record of running a well-maintained program.

EPA Response: It is the intent of EPA to take prompt action if LDEQ does not meet its commitments in the MOA. EPA will continue its oversight and review of the LDEQ water permitting and enforcement programs at the mid-year and end-of-year reviews of the Performance Partnership Grant program. Twice each year, EPA reviews the commitments made by LDEQ and the progress on those commitments in the water permitting and enforcement programs. If EPA determines that adequate progress is not being made in the water program, in line with the LDEQ program commitments and the MOA, EPA will work with LDEQ on appropriate actions to correct noted deficiencies.

Comment 10: III.D. Permit Reissuance: This section contains language that reads "in no event will permits that have been administratively continued beyond their expiration date be modified." American Electric Power (AEP) requests that EPA clarify that this language is only applicable to "major modifications", and is not applicable to "minor modifications" as defined in 40 CFR 124.5 and 122.63 (specifically applicable to NPDES permits).

Discussion by Commenter: AEP contends that in some cases the state may not process a permit application within the prescribed processing period (minimum of 180 days prior to the expiration date of the permit). AEP believes the permittee (applicant) should be allowed to have minor modifications accommodated by the permitting authority without having to re-apply and/or re-initiate the public participation process via re-noticing of the application. As such, AEP recommends that the draft language be modified to "in no event will permits that have been administratively continued beyond their expiration date be allowed to incorporate major modifications without formal modification of the application and re-initiation of the public participation process. Upon consent of the permittee, the Director may allow minor modifications to these permits."

EPA Response: 40 CFR 122.46 and LAC 33:IX. 2365 state that the effective term of a permit shall not exceed five years and shall not be extended by modification beyond the five year period. LAC 33:IX. 2321, and 40 CFR 122.6 list two causes to administratively extend a permit beyond its expiration date, (1) the permittee has submitted a timely and complete application prior to the expiration date of the permit and (2) through no fault of the permittee the permitting authority has not reissued the permit. Permits continued in this manner remain fully effective and enforceable. To modify a permit that has been administratively continued would, in affect, be extending the permit beyond the specified period.

Comment 11: It should be made clear that information appropriately declared "proprietary" by the permittee cannot be released to the public.

Discussion by Commenter: Section II.A.5 reads as follows: LDEQ will remain in compliance with federal right to know statutes and Louisiana public records law, while protecting sensitive information. Material containing security procedures, criminal intelligence information pertaining to terrorist-related activity, or threat or vulnerability assessments created, collected, or obtained in the prevention of terrorist-related activity, including but not limited to physical security information, proprietary information, operational plans, and the analysis of such information, or internal security information is not required to be disclosed under an exemption in the Louisiana Public Records Law (La. R.S. 44:3.1)

Although the exempted material is not regarded as public record, there is no prohibition from releasing the material. LDEQ will consider the merits of each request on a case-by-case basis while striving to achieve balance between the public's right to know, security issues, and applicable federal and state statutes.

The next to the last paragraph of this section as referenced above, describes several types of information that might be collected by the agency but are not *required* to be disclosed. The listing of information includes "proprietary information". The next paragraph states that though the above mentioned material is not regarded as public record, it can be released at the discretion of the LDEQ.

EPA Response: The commenter is correct that information properly claimed as proprietary by the permittee will not be released to the public, provided the Secretary of LDEQ makes the determination that confidentiality is necessary to "[p]rotect trade secrets, proprietary secrets and information, and commercial or financial information." La. R.S. 30:2030. However, La. R.S. 30:2074(D)(7) and LAC 33:IX.2323 specify that no claim of confidentiality will be accepted for certain categories of information associated with LPDES permit applicants or permittees, including all information required by the permit application, the permit itself, and any effluent or discharge data.

Comment 12: There should be no reason, other than those currently in the regulations, to limit the ability to modify a permit that is legally active. This restriction on the permitting agency (LDEQ) is beyond the authority given the EPA in either statute or promulgated regulations. It can only result in hardship on the permit holder with no environmental benefit.

Discussion by Commenter: Section III.D. reads as follows: All expiring permits shall be reissued as close as possible to their expiration dates. In no event will permits which have been administratively continued beyond an expiration date be modified. The LDEQ may use the flexibility allowed in EPA's Permitting for Environmental Results Initiative (August 15, 2003) to account for and to prioritize these facilities that remain in the backlog. LDEQ plans to utilize the approved Permit Issuance Strategy as its guide for permit issuance, and will update/revise the strategy yearly to reflect ongoing permit issuance goals.

This section prohibits modification of a permit that has been administratively continued beyond its expiration date. It has been our experience that permits may be administratively extended for some time. Awaiting the often lengthy time necessary for a complete re-issuance of an expired permit but continued permit when a modification is needed could result in substantial conflict with business timing or our ability to continue compliant operations under changing conditions. The relevant section of Louisiana Title 33 Section 309 reads: C. If the applicant submits a timely and complete application pursuant to LAC 33:IX.309.A, and the department, through no fault of the applicant, fails to act on the application on or before the expiration date of the existing permit, the permittee shall continue to operate the facility under the terms and conditions of the expired permit which shall remain in effect until final action on the application is taken by the department. If the application is denied or the terms of the new permit contested, the expired permit shall remain in effect until the appeal process has been completed and a final decision rendered unless the secretary finds that an emergency exists which requires that immediate action be taken and in such case any appeal or request for review shall not suspend the implementation of the action ordered.

Permits continued under this Section remain fully effective and enforceable.

EPA Response: 40 CFR 122.46 and LAC 33:IX. 2365 state that the effective term of a permit shall not exceed five years and shall not be extended by modification beyond the five year period. LAC 33:IX. 2321, and 40 CFR 122.6 list two causes to administratively extend a permit beyond its expiration date, (1) the permittee has submitted a timely and complete application prior to the expiration date of the permit and (2) through no fault of the permittee the permitting authority has not reissued the permit. Permits continued in this manner remain fully effective and enforceable. To modify a permit that has been administratively continued would, in affect, be extending the permit beyond the specified period.

Petition To Withdraw LPDES Program

On October 9, 2001, a petition for withdrawal of the CWA NPDES program authorization for the State of Louisiana was filed by the Tulane Environmental Law Clinic on behalf of the Louisiana Environmental Action Network, Louisiana Audubon Council, Gulf Coast Restoration Network, Association of Community Organizations for Reform Now, Lake Pontchartrain Basin Foundation, CFACT, Lake Maurepas Society, Concerned Citizens of Livingston Parish, St. John Citizens for Environmental Justice, Louisiana Communities United and Concerned Citizens of Iberville Parish. Supplements to the October 9, 2001, petition were filed on December 19, 2001, February 22, 2002, and September 17, 2002.

The petition, as supplemented ("the Petition"), alleges that the State of Louisiana is not administering the LPDES program in accordance with the CWA, 40 CFR part 123 or the MOA signed by EPA and LDEQ upon program authorization. Specifically, the Petition alleges:

(1) Deficiencies in the States's permitting program, including insufficient statutes and regulations to ensure meaningful public participation, lax procedures for identifying point sources and a large backlog of expired permits;

(2) Deficiencies in the State's compliance monitoring system, including insufficient record keeping regarding self-monitoring reports, inaccurate and inaccessible information on compliance status, inadequate compliance inspections and inadequate guidance to the regulated community;

(3) Deficiencies in the State's enforcement program, including failure to timely identify NPDES violations, failure to bring enforcement actions sufficient to deter future violations, failure to issue timely enforcement actions, failure to assess and collect penalties, improper use of beneficial environmental projects (BEPs) and failure to comply with the requirements for public participation in the enforcement process;

(4) Deficiencies in the State's records management; and

(5) Deficiencies in the State's legal authority, including an inability to appeal permits altered by the administrative review process and a failure to promulgate new authorities necessary to comply with the requirements of NPDES authorization.

Based on these allegations, the Petition requests that EPA initiate formal proceedings to withdraw the LPDES program under Section 402(c)(3) of the CWA and 40 CFR 123.64(b), including a public hearing as provided for under those sections.

In response to the Petition and in accordance with 40 CFR 123.64(b), EPA staff conducted an informal investigation of the allegations in the Petition to determine whether cause exists to commence withdrawal proceedings. EPA's informal investigation included on-site reviews of LPDES files, interviews with LDEQ management and staff, and an evaluation by EPA staff of information and data concerning program implementation provided in writing to EPA by LDEQ. The data collected as a result of the informal investigation supplemented the large body of information already in EPA's possession as a result of EPA's ongoing statutory oversight responsibilities with respect to the LPDES program. Simultaneous with EPA's informal investigation under 40 CFR 123.64(b), former Governor M.J. Foster, Jr. convened a special Governor's Task Force to review the administration of the LPDES program, also in response to citizens' concerns.

Both the multi-stakeholder Task Force created by Governor Foster, and EPA, through performance of its general oversight duties and through its informal investigation, found weaknesses in LDEQ's operation of the LPDES program. The Governor's Task Force shared its findings in recommendations to the Governor for improvements in the State program. EPA worked directly with LDEQ in the development of a list of seven performance measures aimed at addressing both EPA's and the citizens' concerns. These seven performance measures, which were forwarded to Governor Foster in a February 14, 2003, letter from EPA Assistant Administrators for the Office of Water and the Office of Enforcement and Compliance Assurance, identified specific actions to be performed by LDEQ within specified time frames in the areas of NPDES permitting and enforcement. The actions included drafting and issuing a specified number of permits, improving public access to LDEQ files, clarifying certain requirements under LDEQ's Penalty rule and its BEP rule, clarifying and implementing procedures in regard to LDEQ's unilateral enforcement actions, revising all LPDES program authorization documents and providing a legal opinion from LDEQ counsel and the Louisiana Attorney General's Office regarding the State's ability to enforce penalties against municipalities. Further discussion of the Performance Measures and the various changes made to the LPDES program can be found in EPA's **Federal Register** notice of the revised LPDES program authorization documents, 69 FR 50199, August 13, 2004.

By letter dated May 12, 2004, EPA Regional Administrator Richard Greene informed the Governor of Louisiana that LDEQ had successfully completed all seven performance measures. EPA is greatly encouraged by the timely completion of these performance measures and by the State of Louisiana's renewed commitment to making its NPDES program as strong and effective as any in the Country. In June, 2004, EPA staff performed a follow-up review of LDEQ's administration of the LPDES program in order to assess LDEQ's implementation of the processes and procedures outlined in the revised LPDES program authorization documents. As a result of that review, EPA staff determined that LDEQ was implementing the changes agreed to as a result of the performance measures and that the agency's administration of the LPDES program showed marked improvement.

EPA has concluded our informal investigation of the allegations in the Petition and determined that cause does not exist to initiate program withdrawal proceedings. The criteria for responding to citizens' petitions for withdrawal of state NPDES programs are set out in 40 CFR 123.63. These criteria relate generally to the State's legal authorities, program administration and enforcement activities (see 40 CFR 123.63(a)(1)–(3)), as well as other components. Those criteria are general in nature and vest EPA with discretion in deciding whether cause exists to commence proceedings to withdraw a state's NPDES authority. For example, 40 CFR 123.63(a)(3) states that the

Administrator may withdraw program approval when the state's enforcement program fails to comply with the requirements of 40 CFR part 123, including (i) failure to act on permit or other program violations, (ii) failure to seek and collect adequate penalties, and (iii) failure to inspect and monitor regulated facilities. However, Federal regulations do not specify with any precision the number of times a state must, for instance, fail to act on permit or other program violations before NPDES authority should be withdrawn. Rather, the CWA and the regulations vest EPA with substantial discretion to determine whether a State is failing to meet minimum federal requirements. The structure of the CWA provides for primary NPDES authority to rest with the states, and Congress intended for EPA to exercise its oversight capacity in furtherance of appropriate State regulations of point source discharges under Section 402(b). With no bright line separating an insufficient program from a sufficient one, EPA must use its discretion to determine if the particular actions or inactions of an NPDES authorized state fall within a range of what EPA considers acceptable under the CWA and 40 CFR part 123.

In certain areas identified in the Petition, EPA concluded that improvements were warranted in the State's administration of the program. These areas related primarily to recordkeeping, data management and compliance and enforcement. The State has made substantial improvements in these areas. EPA is continuing to work with Louisiana, as EPA works with all State NPDES permitting authorities, to achieve ever greater levels of environmental protection. However, as the program now stands, EPA has concluded that the LPDES program is within the range of NPDES program practices required under the CWA and 40 CFR part 123, so that withdrawal proceedings are not an appropriate response.[1]

Thus, EPA has determined that cause does not exist to commence formal withdrawal proceedings under 40 CFR 123.64(b). EPA will continue to monitor the State's program, both through routine oversight procedures, as well as through special national initiatives such as the Permitting for Environmental Results (PER) program. If any additional concerns are noted in the State's LPDES program as a result of this oversight, they will be addressed at that time.

[1] EPA's record for this decision contains a "Crosswalk" between the specific allegations in the Petition and EPA's findings in regard to each allegation. To receive a copy of this Crosswalk, please contact Cathy Gilmore at (214) 665–6766 or Renea Ryland at (214) 665–2130.

FOR FURTHER INFORMATION CONTACT: Ms. Diane Smith, EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202, Telephone: (214) 665–7191, or via e-mail to the following address: *smith.diane@epa.gov.*

Conclusion

After evaluation of the comments and other information related to this **Federal Register** notice regarding the revision to the LPDES program authorization, I hereby provide public notice of the approval for the State of Louisiana to administer, in accordance with 40 CFR part 123, the LPDES program and denial of the petition for EPA to withdraw LDEQ's authorization to administer the LPDES program.

Dated: December 28, 2004.

Richard E. Greene,

Regional Administrator, EPA Region 6.

[FR Doc. 05–178 Filed 1–4–05; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission for Extension Under Delegated Authority

December 22, 2004.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act (PRA) of 1995, Public Law No. 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before March 7, 2005. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all Paperwork Reduction Act (PRA) comments to Cathy Williams, Federal Communications Commission, Room 1–C823, 445 12th Street, SW., Washington, DC 20554 or via the Internet to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection(s), contact Cathy Williams at (202) 418–2918 or via the Internet at *Cathy.Williams@fcc.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–1072.

Title: Digital Channel Election Form: Third Round Election, FCC Form 386.

Form Number: FCC Form 386.

Type of Review: Extension of a currently approved collection

Respondents: Business or other for-profit entities; Not-for-profit institutions.

Number of Respondents: 85.

Estimated Time per Response: 2–5 hours.

Frequency of Response: One-time reporting requirement.

Total Annual Burden: 173 hours.

Total Annual Cost: $86,000.

Privacy Impact Assessment: No impact(s).

Needs and Uses: On September 7, 2004, the FCC released the Report and Order, In the Matter of Second Periodic Review of the Commission's Rules and Policies Affecting the Conversion to Digital Television, MB Docket No. 03–15, FCC 04–192, which implements several steps necessary for the continued progress of the conversion of the nation's television system from analog to digital (DTV) technology. The Order established the timing and procedures necessary to determine the post-transition core channels on which digital stations will operate, to be specified in a new Table of Allotments to be issued by the Commission. The Order implements a multi-step channel election process which starts with licensees/permittees filing certain pre-election certifications on FCC Form 381. Television broadcast licensees and permittees that have not received a tentative channel designation by the third round in the channel election process will use FCC Form 386 to make

a channel election. Licensees that have received a tentative channel designation for a low VHF channel or a channel subject to international coordination issues may use this form to seek an alternate tentative channel designation.

OMB Control Number: 3060–1073.

Title: Digital Channel Election Form: Second Round Election, FCC Form 385.

Form Number: FCC Form 385.

Type of Review: Extension of a currently approved collection

Respondents: Business or other for-profit entities; Not-for-profit institutions.

Number of Respondents: 25.

Estimated Time per Response: 5 hours.

Frequency of Response: One-time reporting requirement.

Total Annual Burden: 125 hours.

Total Annual Cost: $43,000.

Privacy Impact Assessment: No impact(s).

Needs and Uses: On September 7, 2004, the FCC released the Report and Order, In the Matter of Second Periodic Review of the Commission's Rules and Policies Affecting the Conversion to Digital Television, MB Docket No. 03–15, FCC 04–192, which implements several steps necessary for the continued progress of the conversion of the nation's television system from analog to digital (DTV) technology. The Order established the timing and procedures necessary to determine the post-transition core channels on which digital stations will operate, to be specified in a new Table of Allotments to be issued by the Commission. The Order implements a multi-step channel election process that starts with licensees/permittees filing certain pre-election certifications on FCC Form 381. Licensees/Permittees with only "out-of-core channels", as well as licensees./ permittees electing to be treated like them, will file channel elections in the second round. This Second Round Conflict Decision Form 385 will be used by licensees and permittees that were notified after the Second Round of channel elections that their channel election results in an interference conflict. These licensees and permittees will indicate on FCC Form 385 the decision they make regarding the conflict.

OMB Control Number: 3060–1074.

Title: Digital Channel Election Form: Second Round Election, FCC Form 384.

Form Number: FCC Form 384.

Type of Review: Extension of a currently approved collection

Respondents: Business or other for-profit entities; Not-for-profit institutions.

Number of Respondents: 100.

Estimated Time per Response: 2–5 hours.

Frequency of Response: One-time reporting requirement.

Total Annual Burden: 203 hours.

Total Annual Cost: $101,000.

Privacy Impact Assessment: No impact(s).

Needs and Uses: On September 7, 2004, the FCC released the Report and Order, In the Matter of Second Periodic Review of the Commission's Rules and Policies Affecting the Conversion to Digital Television, MB Docket No. 03–15, FCC 04–192, which implements several steps necessary for the continued progress of the conversion of the nation's television system from analog to digital (DTV) technology. The Order established the timing and procedures necessary to determine the post-transition core channels on which digital stations will operate, to be specified in a new Table of Allotments to be issued by the Commission. The Order implements a multi-step channel election process to be used to determine post-transition DTV channels. FCC Form 384 will be used by full power television broadcast licensees and permittees without currently assigned in-core channel(s), as well as those licensees/permittees that released their only assigned in-core channel(s) in Round One of elections, to make a channel election in Round Two for their final DTV operation.

OMB Control Number: 3060–1075.

Title: Digital Channel Election Form: First Round Election, FCC Form 383.

Form Number: FCC Form 383.

Type of Review: Extension of a currently approved collection

Respondents: Business or other for-profit entities; Not-for-profit institutions.

Number of Respondents: 413.

Estimated Time per Response: 5 hours.

Frequency of Response: One-time reporting requirement.

Total Annual Burden: 2,065 hours.

Total Annual Cost: $702,000.

Privacy Impact Assessment: No impact(s).

Needs and Uses: On September 7, 2004, the FCC released the Report and Order, In the Matter of Second Periodic Review of the Commission's Rules and Policies Affecting the Conversion to Digital Television, MB Docket No. 03–15, FCC 04–192, which implements several steps necessary for the continued progress of the conversion of the nation's television system from analog to digital (DTV) technology. The Order established the timing and procedures necessary to determine the post-transition core channels on which digital stations will operate, to be specified in a new Table of Allotments to be issued by the Commission. The Order implements a multi-step channel election process for selecting post-transition DTV channels. FCC Form 383, First Round Conflict Decision Form, will be used to make a decision concerning interference conflicts by licensees and permittees that were notified after the First Round of channel elections that their channel election results in an interference conflict.

OMB Control Number: 3060–1076.

Title: Digital Channel Election Form: First Round Election, FCC Form 382.

Form Number: FCC Form 382.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities; Not-for-profit institutions.

Number of Respondents: 1,666.

Estimated Time per Response: 2–5 hours.

Frequency of Response: One-time reporting requirement.

Total Annual Burden: 3,383 hours.

Total Annual Cost: $1,686,000.

Privacy Impact Assessment: No impact(s).

Needs and Uses: On September 7, 2004, the FCC released the Report and Order, In the Matter of Second Periodic Review of the Commission's Rules and Policies Affecting the Conversion to Digital Television, MB Docket No. 03–15, FCC 04–192, which implements several steps necessary for the continued progress of the conversion of the nation's television system from analog to digital (DTV) technology. The Order established the timing and procedures necessary to determine the post-transition core channels on which digital stations will operate, to be specified in a new Table of Allotments to be issued by the Commission. The Order implements a multi-step channel election process to be used to select post-transition DTV channels. FCC Form 382 is used by television broadcast licensees and permittees currently assigned at least one in-core channel (*i.e.*, channels 2–51) to make a channel election in Round One of the DTV channel election process for their final DTV operation.

Federal Communications Commission.

William F. Caton,

Deputy Secretary.

[FR Doc. 05–118 Filed 1–4–05; 8:45 am]

BILLING CODE 6712–10–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission, Comments Requested

December 23, 2004.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act (PRA) of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before March 7, 2005. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all Paperwork Reduction Act (PRA) comments to Judith B. Herman, Federal Communications Commission, Room 1–C804, 445 12th Street, SW., Washington, DC 20554 or via the Internet to *Judith-B.Herman@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection(s), contact Judith B. Herman at (202) 418–0214 or via the Internet at *Judith-B.Herman@fcc.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060–0298.

Title: Tariff (Other than the Tariff Review Plan)—Part 61.

Form No.: Not Applicable.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit.

Number of Respondents: 580.

Estimated Time Per Response: 114 hours.

Frequency of Response: On occasion, annual and biennial reporting requirements and third party disclosure requirement.

Total Annual Burden: 66,120 hours.

Total Annual Cost: $835,000.

Privacy Act Impact Assessment: Not Applicable.

Needs and Uses: Part 61 is designed to ensure that all tariffs filed by common carriers are formally sound, well organized, and provide the Commission and the public with sufficient information to determine the justness and reasonableness as required by the Act, of the rates, terms and conditions in those tariffs. In the Seventh Report and Order in CC Docket No. 96–262 released on April 27, 2001, the Commission had limited the application of its' tariff rules to interstate access services provided by nondominant local exchange carriers. The Commission is requesting an extension (no change) to this information collection in order to obtain the full three year clearance from the OMB. The Commission is reducing the number of burden hours and costs to the respondents for this information collection due to less carriers filing this information with the Commission.

OMB Control No.: 3060–0391.

Title: Program to Monitor the Impacts of the Universal Service Support Mechanism, CC Docket Nos. 98–202 and 96–45.

Form No.: Not Applicable.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit.

Number of Respondents: 210 respondents; 1,456 responses.

Estimated Time Per Response: .666 hours (40 minutes).

Frequency of Response: Annual reporting requirement and third party disclosure requirement.

Total Annual Burden: 971 hours.

Total Annual Cost: Not Applicable.

Privacy Act Impact Assessment: Not Applicable.

Needs and Uses: The Commission has a program to monitor the impacts of the universal service support mechanisms. The program requires periodic reporting by telephone companies and the universal service administrator. The information is used by the Commission, Federal-State Joint Boards, Congress and the general public to assess the impacts of the decisions of the Commission and the Joint Boards. Prior to 2002, the Commission required the following data to be collected: local, intrastate toll, and interstate dial equipment minutes, interstate dial equipment minute factors, and interstate access minutes. After the necessary 60 day public comment period, the Commission plans to submit this revised collection to OMB, because the dial equipment minutes reporting categories were eliminated due to separations reforms (*see* FCC 01–162). Thus, only the interstate access minutes remain to be reported.

OMB Control No.: 3060–0823.

Title: Pay Telephone Reclassification Memorandum Opinion and Order, CC Docket No. 96–128.

Form No.: Not Applicable.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit.

Number of Respondents: 400.

Estimated Time Per Response: 112 hours.

Frequency of Response: On occasion reporting requirement, recordkeeping requirement and third party disclosure requirement.

Total Annual Burden: 44,700 hours.

Total Annual Cost: $480,000.

Privacy Act Impact Assessment: Not Applicable.

Needs and Uses: In the Memorandum Opinion and Order issued in CC Docket No. 96–128, the Wireline Competition Bureau of the Federal Communications Commission clarified requirements established in the Payphone Orders for the provision of payphone-specific coding digits by Local Exchange Carriers and Payphone Service Providers (PSPs), to Interexchange Carriers (IXCs), beginning on October 7, 1977. Specifically, the Order clarified that only Flexible Automatic Numbering Identification (FLEX ANI) complies with the requirements; requires that LECs file tariffs to reflect FLEX ANI as a non-chargeable option to IXCs; requires that LECs file tariffs to recover costs associated with implementing FLEX ANI; and grants permission and certain waivers. The Commission is seeking extension (no change) to this information collection and the respondents, burden hours and burden costs remain unchanged.

Federal Communications Commission.

William F. Caton,

Deputy Secretary.

[FR Doc. 05–119 Filed 1–4–05; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at *www.ffiec.gov/nic/*.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than January 31, 2005.

A. Federal Reserve Bank of Atlanta (Sue Costello, Vice President) 1000 Peachtree Street, N.E., Atlanta, Georgia 30303:

1. Crescent Banking Company, Jasper, Georgia; to acquire 100 percent of the voting shares of Futurus Financial Services, Inc., and thereby indirectly acquire Futurus Bank, N.A., both of Alpharetta, Georgia.

B. Federal Reserve Bank of St. Louis (Glenda Wilson, Community Affairs Officer) 411 Locust Street, St. Louis, Missouri 63166-2034:

1. FSB Bancorp, Inc., Houston, Texas; to become a bank holding company by acquiring 100 percent of the voting shares of Evergreen Bancshares, Inc., and thereby indirectly acquire First State Bank, both of Crossett, Arkansas.

C. Federal Reserve Bank of San Francisco (Tracy Basinger, Director, Regional and Community Bank Group) 101 Market Street, San Francisco, California 94105-1579:

1. Frontier Financial Corporation, Everett, Washington; to acquire up to 20 percent of the voting shares of Skagit State Bank, Burlington, Washington.

Board of Governors of the Federal Reserve System, December 30, 2004.

Margaret McCloskey Shanks,

Assistant Secretary of the Board.

[FR Doc. 05–209 Filed 1–4–05; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Proposed Collection; Comment Request; Extension

AGENCY: Federal Trade Commission ("FTC").

ACTION: Notice.

SUMMARY: The information collection requirements described below have been submitted to the Office of Management and Budget ("OMB") for review, as required by the Paperwork Reduction Act ("PRA"). The FTC is seeking public comments on its proposal to extend through December 31, 2006, the current PRA clearance for information collection requirements for its Mortgage Disclosure Study. That clearance was scheduled to expire on November 30, 2004. On November 22, 2004, the OMB granted the FTC's request for a short-term extension to December 31, 2004, to allow for this second opportunity to comment.

DATES: Comments must be submitted on or before February 4, 2005.

ADDRESSES: Interested parties are invited to submit written comments. Comments should refer to "Mortgage Disclosure Study—FTC File No. P025505," to facilitate the organization of comments. A comment filed in paper form should include this reference both in the text and on the envelope, and should be mailed or delivered to the following address: Federal Trade Commission/Office of the Secretary, Room H–159 (Annex X), 600 Pennsylvania Avenue, NW., Washington, DC 20580. The FTC is requesting that any comment filed in paper form be sent by courier or overnight service, if possible, because U.S. postal mail in the Washington area and at the Commission is subject to delay due to heightened security precautions. Alternatively, comments may be filed in electronic form (in ASCII format, WordPerfect, or Microsoft Word) as part of or as an attachment to e-mail messages directed to the following e-mail box: *MortgageDS@ftc.gov*. If the comment contains any material for which confidential treatment is requested, it must be filed in paper form, and the first page of the document must be clearly labeled "Confidential." [1]

All comments should additionally be submitted to: Office of Management and Budget, Attention: Desk Officer for the Federal Trade Commission. Comments should be submitted via facsimile to (202) 395–6974 because U.S. Postal Mail is subject to lengthy delays due to heightened security precautions.

The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. All timely and responsive public comments will be considered by the Commission, and will be available to the public on the FTC Web site, to the extent practicable, at *http://www.ftc.gov*. As a matter of discretion, the FTC makes every effort to remove home contact information for individuals from the public comments it receives before placing those comments on the FTC Web site. More information, including routine uses permitted by the Privacy Act, may be found in the FTC's privacy policy, at *http://www.ftc.gov/ftc/privacy.htm*.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be addressed to James M. Lacko, Economist, Bureau of Economics, Federal Trade Commission, 600 Pennsylvania Avenue, NW., Washington, DC 20580. Telephone: (202) 326–3387; e-mail *MortgageDS@ftc.gov*.

SUPPLEMENTARY INFORMATION: On September 28, 2004, the FTC sought comment on the information collection requirements associated with the Mortgage Disclosure Study (OMB Control Number 3084–0126). See 69 FR 57932. No comments were received. Pursuant to the OMB regulations that implement the PRA (5 CFR Part 1320), the FTC is providing this second opportunity for public comment while seeking OMB approval to extend the

[1] Commission Rule 4.2(d), 16 CFR 4.2(d). The comment must be accompanied by an explicit request for confidential treatment, including the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. The request will be granted or denied by the Commission's General Counsel, consistent with applicable law and the public interest. *See* Commission Rule 4.9(c), 16 CFR 4.9(c).

existing paperwork clearance for the rule.[2]

Deceptive lending cases at the FTC and elsewhere suggest that consumers who do not understand the terms of their mortgages can be subject to deception, that deception can occur even when consumers receive the disclosures required by the Truth-in-Lending Act, 15 U.S.C. 1601 *et seq.* (TILA), and that deception about mortgage terms can result in substantial consumer injury.

Despite a long history of mortgage disclosure requirements and many legislative and regulatory proposals regarding disclosures, little empirical evidence exists to document the effect of current disclosures on consumer understanding of mortgage terms, consumer mortgage shopping behavior, or consumer mortgage choice.

The Mortgage Disclosure Study will examine: (1) How consumers search for and choose mortgages; (2) how consumers use and understand information about mortgages, including required disclosures; and (3) whether improved disclosures might improve consumer understanding, consumer mortgage shopping, and consumers' ability to avoid deception. The research also may assist the targeting of the FTC's enforcement actions by identifying areas most prone to consumer misunderstanding and lender deception and may help refine disclosure remedies imposed on deceptive lenders.

1. Description of the Collection of Information and Proposed Use

The FTC is conducting this study in two phases: (1) A qualitative research phase; and (2) a quantitative research phase. The qualitative research phase includes two focus groups and 36 in-depth interviews. The quantitative research will include copy tests of current and alternative disclosures. Results from the first phase will be used to refine the design of the second phase.

The two focus groups and 25 of the in-depth interviews have been completed under the current PRA clearance and are not part of this extension request.[3] Eleven of the in-depth interviews have not yet been conducted. Accordingly, this extension request covers information collection for the 11 in-depth interviews that remain for the qualitative phase and the copy tests for the quantitative phase.

The remaining in-depth interviews will be conducted with 11 consumers who have recently completed a mortgage transaction. Respondents will be asked to bring their loan documents to the interview. Some of the interviews will be with consumers who obtained their mortgage from a prime lender and some will be with consumers who obtained their mortgage from a subprime lender. The purpose of the interviews is to gain in-depth knowledge of the extent to which consumers use, search for, and understand mortgage information—including information about their own recent loans.

The quantitative research phase will consist of copy test interviews of 800 consumers who entered into a mortgage transaction within the previous two years. If possible, approximately half of the respondents will be consumers who obtained their mortgage from a prime lender and half will be consumers who obtained their mortgage from a subprime lender. The purpose of the copy tests will be to examine whether alternative disclosures can improve consumer understanding of mortgage terms and help to reduce potential deception about mortgage offers. The findings from the focus groups and in-depth interviews will be used to refine the alternative disclosures used in the copy tests.

All information will be collected on a voluntary basis. The FTC has contracted with two consumer research firms (one each for the qualitative and quantitative phases) to recruit respondents, conduct the interviews, and write a brief methodological report. The results will assist the FTC in determining how required disclosures and other information affect consumers' ability to understand the cost and features of mortgages. This understanding will further the FTC's mission of protecting consumers and competition in this important market.

2. Estimated Hours Burden

Qualitative Research

The qualitative phase is complete except for 11 in-depth interviews. If all respondents for those interviews are single decision makers, this would amount to an 11 hour burden. However, some of the interviews may include couples. Assuming that about half of the interviews include couples, the hours burden for the in-depth interviews would increase to 17 hours ((6 × 2 hours) + (5 × 1 hour)).

Quantitative Research

Approximately 800 consumers who engaged in a mortgage transaction during the previous two years will participate in the quantitative phase of the research. Each copy test interview will take roughly 20–30 minutes. The estimated hours burden for the quantitative phase ranges from 267 hours (800 respondents × ⅓ hour per respondent) to 400 hours (800 respondents × ½ hour per respondent).

Total

The total estimated hours burden for both phases of the study ranges from 278 hours (11 hours + 267 hours) to 417 hours (17 hours + 400 hours).

William E. Kovacic,

General Counsel.

[FR Doc. 05–176 Filed 1–4–05; 8:45 am]

BILLING CODE 6750–01–P

[2] In its September 28, 2004 Federal Register Notice, the FTC indicated it was seeking to extend the current PRA clearance through December 31, 2005. The FTC staff expect the consumer research for the Mortgage Disclosure Survey to be completed by that date, but is now seeking to extend the current PRA clearance through December 31, 2006, to allow for any unanticipated delays.

[3] The September 28, 2004 Federal Register Notice included all of the in-depth interviews in the extension request; 25 of those interviews were subsequently completed under the current clearance and are not a part of this extension request.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0437]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Third-Party Review Under the Food and Drug Administration Modernization Act, Third-Party Premarket Submission Review, and Quality System Inspections Under the United States/European Community Mutual Recognition Agreement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by February 4, 2005.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and

Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Devices; Third-Party Review Under FDAMA, Third-Party Premarket Submission Review, and Quality System Inspections Under U.S./E.C. Mutual Recognition Agreement (OMB Control Number 0910–0378)—Extension

Section 210 of the Food and Drug Administration Modernization Act (FDAMA) established section 523 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360m), directing FDA to accredit persons in the private sector to review certain premarket applications and notifications. Participation in this third-party review program by accredited persons is entirely voluntary. A third party wishing to participate will submit a request for accreditation to FDA. Accredited third-party reviewers have the ability to review a manufacturer's submission under section 510(k) of the act (21 U.S.C. 360(k)) for selected devices. After reviewing a submission, the reviewer will forward a copy of the 510(k) submission, along with the reviewer's documented review and recommendation to FDA. Third-party reviews should maintain records of their 510(k) reviews and a copy of the 510(k) for a reasonable period of time, usually a period of 3 years. This information collection will allow FDA to continue to implement the accredited person review program established by FDAMA and improve the efficiency of 510(k) review for low-to-moderate risk devices.

The third-party program under the U.S/European Community (E.C.) Mutual Recognition Agreement (MRA) is intended to implement that part of the U.S./E.C. MRA that covers the exchange of quality system evaluation reports for all medical devices and premarket evaluation reports for selected low-to-moderate risk devices. Under the MRA, firms may apply to become designated as a U.S. conformity assessment body (CAB). Firms who are designated will be qualified to conduct quality system evaluations for all classes of devices and product type evaluations and verifications for selected devices based on European Union (EU) requirements under the voluntary third-party program authorized by MRA. Firms designated as EU CABs could conduct quality system evaluations for all classes of devices and premarket 510(k) evaluations for selected devices based on FDA's requirements. Under the voluntary third-party program, reports of these evaluations would be submitted by the EU CABs to FDA. The EU CABs would also be required to maintain copies of their evaluation reports for a period of no less than 3 years.

In the **Federal Register** of October 14, 2004 (69 FR 61021), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

Respondents to this information collection are businesses or other for-profit organizations.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Item	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Requests for accreditation	15	1	15	24	360
510(k) reviews conducted by accredited third parties	15	14	210	40	8,400
Premarket reports by EU CABs	9	5	45	40	1,800
Quality system reports by EU CABs	9	4	36	32	1,152
Total					11,712

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.–ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

Item	No. of Record-keepers	Annual Frequency per Recordkeeper	Total Annual Records	Hours per Record-keeper	Total Hours
510(k) reviews	15	14	210	10	2,100
Premarket reports by EU CABs	9	5	45	10	450
Quality system reports by EU CABs	9	4	36	10	360
Total					2,910

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The burdens are explained as follows:

I. Reporting

A. Requests for Accreditation

Under the agency's third-party review pilot program, the agency received 37 applications for recognition as third-party reviewers, of which the agency recognized 7. In the past 3 years, however, the agency has averaged receipt of 15 applications for recognition of third-party review accredited persons, and 9 EU CABS. The agency has accredited 15 of the applicants to conduct third-party reviews, and 9 EU CABs.

B. 510(k) Reviews Conducted by Accredited Third Parties

In the 18 months under the third-party review pilot program, FDA received only 22 total 510(k)s that requested and were eligible for review by third parties. Because the third-party review program is not as limited in time as the pilot program, and is expanded in scope, the agency anticipates that the number of 510(k)s submitted for third-party review will remain the same as they were during the last OMB approval in 2001. The agency has experienced that the number of 510(k)s submitted by accredited persons for third-party review since the last OMB approval in 2001 has been approximately 210 annually, which is 14 annual reviews per each of the estimated 15 accredited reviewers.

1. Premarket Reports

Under this program, EU CABs will be able to perform third-party evaluations for certain products produced in Europe for export to the United States. EU CABs would be required to submit to FDA reports of their evaluations. Based upon information gathered since this collection was last reviewed in 2001, the agency has experienced that nine European manufacturers have not received any third-party requests for review annually. The agency estimates, based on dialog with EU officials and actual experience, nine firms will be designated to act as EU CABs.

2. Quality System Reports

Under this program, EU CABs will be able to perform third-party evaluations of the quality systems established by manufacturers of European products produced for export to the United States. EU CABs would be required to submit to FDA reports of their evaluations. Based upon information gathered during the negotiation of the U.S./E.C. MRA and actual experience since the collection was last approved by OMB in 2001, the agency anticipates that European manufacturers will request third-party audits for approximately 36 medical device products annually. The agency estimates that nine EU CABs will perform these evaluations.

II. Recordkeeping

Third-party reviewers are required to keep records of their review of each submission. The agency anticipates approximately 210 annual submissions of 510(k)s for third-party review.

As stated previously, firms designated as EU CABs will be able to perform third-party evaluations of quality systems and premarket submissions for certain products produced for export to the United States. Such review will be conducted consistent with FDA's regulatory requirements, and FDA will require the reviewers to keep, in their records, a copy of the report that they submit to FDA for each review. The agency anticipates that 45 premarket reports and 36 quality system reports will be generated and required to be maintained by EU CABs annually. The agency further estimates that each reviewer will require no more than 10 hours (2 hours per recordkeeping per report) for each to maintain such records annually.

Dated: December 28, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–109 Filed 1–4–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2004D–0377 and 2004D–0378]

International Conference on Harmonisation; Draft Guidances on E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs and S7B Nonclinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals; Availability; Reopening of Comment Periods

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment periods.

SUMMARY: The Food and Drug Administration (FDA) is reopening until February 18, 2005, the comment periods for the draft guidances entitled "E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs" and "S7B Nonclinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals." The draft guidances were prepared under the auspices of the International Conference on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use. FDA published notices of availability of the draft guidances in the **Federal Register** of September 13, 2004 (69 FR 55163 and 69 FR 55164, respectively). FDA is taking this action in response to requests to extend the comment periods for both draft guidances.

DATES: Submit written or electronic comments on the draft guidances by February 18, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written comments on the draft guidances to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* Submit written requests for single copies of the draft guidances to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send two self-addressed adhesive labels to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidances.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance entitled "E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs": Douglas C. Throckmorton, Center for Drug Evaluation and Research (HFD–1), Food and Drug Administration, 5600 Fishers Lane,Rockville MD, 20857, 301–594–5400.

Regarding the guidance entitled "S7B Nonclinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals": John Koerner, Center for Drug Evaluation and Research (HFD–110), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5338.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 13, 2004, FDA announced the availability of the following two draft guidances prepared under the auspices of the ICH:

• "E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs" (69 FR 55163; Docket No. 2004D–0377) provides recommendations to sponsors concerning clinical studies to assess the potential of a new drug to cause cardiac arrhythmias, focusing on the assessment of changes in the QT/QTc interval on the electrocardiogram as a predictor of risk.

• "S7B Nonclinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals" (69 FR 55164; Docket No. 2004D–0378) describes a nonclinical testing strategy for assessing the potential of a test substance to delay ventricular repolarization and includes information concerning nonclinical assays and an integrated risk assessment.

Interested persons were given until December 13, 2004, to submit comments on the draft guidances.

On December 13, 2004, FDA received letters from Wyeth Pharmaceuticals requesting that the agency extend the comment periods for the draft guidances.

In response to these requests, FDA has decided to reopen the comment period on the draft guidances until February 18, 2005, to allow the public more time to review and comment on the contents.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidances on or before February 18, 2005. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Identify comments with the corresponding docket number of the draft guidance as follows: Docket No. 2004D–0377 "E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs" and Docket No. 2004D–0378 "S7B Nonclinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals." The draft guidances and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m. Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance documents at *http://www.fda.gov/ohrms/dockets/default.htm*, *http://www.fda.gov/cder/guidance/index.htm*, or *http://www.fda.gov/cber/publications.htm*.

Dated: December 28, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 05–110 Filed 1–4–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1998N–0046]

Annual Comprehensive List of Guidance Documents at the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing its annual comprehensive list of all guidance documents currently in use at the agency. This list is being published under FDA's good guidance practices (GGPs) regulations. It is intended to inform the public of the existence and availability of all of our current guidance documents. It also provides information on guidance documents that have been added or withdrawn in the past year.

DATES: We welcome general comments on this list and on agency guidance documents at any time.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. We have provided information in the tables in the **SUPPLEMENTARY INFORMATION** section of this document on where to obtain a single copy of any of the guidance documents listed.

FOR FURTHER INFORMATION CONTACT: *Regarding GGPs*: Lisa Helmanis, Office of Policy (HF–26), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3480.

SUPPLEMENTARY INFORMATION:

I. Background

FDA's GGPs were published in the **Federal Register** of September 19, 2000 (65 FR 56468), and became effective October 19, 2000. GGPs are intended to ensure involvement of the public in the development of guidance documents, and to enhance understanding of the availability, nature, and legal effect of such guidance (§ 10.115 (21 CFR 10.115)). In § 10.115(n)(2), FDA stated that it intended to publish an annual comprehensive list of guidance documents. The list in this document updates a comprehensive list that published October 24, 2001 (66 FR 53836).

The following comprehensive list identifies all guidances that have been issued and are in use, and all draft guidances that have been distributed for comment and not for implementation. Any guidances that have been withdrawn since the last publication of this comprehensive list are also identified. These withdrawn guidances include some final and draft guidances that had been withdrawn prior to the date of publication of this list, and some that are being withdrawn as of this date. In accordance with the agency's general policy on guidances, you may comment on this list and on any FDA guidance document at any time. Please note that although we have stated that the "Guidance for Industry on Qualified Health Claims in Labeling of Conventional Foods and Dietary Supplements" (December 2002) has been "replaced" by subsequent guidance, the agency has not abandoned the position in the 2002 guidance regarding reasonable consumer standard.

We have organized the documents by the issuing center or office within FDA, and have identified the pertinent intended users or regulatory activities. The dates in the list refer to the date we issued the guidances or, where applicable, the last date we revised a document. Because each issuing center or office maintains its own database, there are slight variations in the way in which they provide information in the tables in this document.

The following most frequently used Internet sites for agency guidances are provided for future reference:

• Center for Biologics Evaluation and Research (CBER): *http://www.fda.gov/cber/guidelines.htm*

• Center for Drug Evaluation and Research (CDER): *http://www.fda.gov/cder/guidance/index.htm*

• Center for Devices and Radiological Health (CDRH): *http://www.fda.gov/cdrh/guidance.html*

• Center for Food Safety and Applied Nutrition (CFSAN): *http://www.cfsan.fda.gov/dms/guidance.html*

• Center for Veterinary Medicine (CVM): *http://www.fda.gov/cvm/guidance/published.htm*

• Office of Regulatory Affairs (ORA) and Office of the Commissioner: *http:/*

/www.fda.gov/opacom/morechoices/industry/guidance.htm

GUIDANCE DOCUMENTS ISSUED BY CBER

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
			Mailing Address	Internet Address
Guidelines for Immunization of Source Plasma (Human) Donors With Blood Substances	June 1980	FDA regulated industry	Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 1–800–835–4709 or 301–827–1800	*http://www.fda.gov/cber/guidelines.htm*
Collection of Human Leukocytes for Further Manufacturing (Source Leukocytes)	January 28, 1981	Ditto (Do)	Do.	*http://www.fda.gov/cber/memo.htm*
Interferon Test Procedures: Draft Points to Consider (PTC) in the Production and Testing of Interferon Intended for Investigational Use in Humans	July 28, 1983	Do.	Do.	*http://www.fda.gov/cber/guidelines.htm*
Deferral of Blood Donors Who Have Received the Drug Accutane (isotretinoin/Roche; 13-cis-retinoic acid)	February 28, 1984	Do.	Do.	*http://www.fda.gov/cber/memo.htm*
Equivalent Methods for Compatibility Testing	December 14, 1984	Do.	Do.	Do.
Plasma Derived From Therapeutic Plasma Exchange	December 14, 1984	Do.	Do.	Do.
Draft PTC in the Production and Testing of New Drugs and Biologicals Produced by Recombinant DNA Technology	April 10, 1985	Do.	Do.	*http://www.fda.gov/cber/guidelines.htm*
Reduction of the Maximum Platelet Storage Period to 5 Days in an Approved Container	June 2, 1986	Do.	Do.	*http://www.fda.gov/cber/memo.htm*
To In Vitro Diagnostic Reagent Manufacturers: Guidance on the Labeling of Human Blood Derived In Vitro Diagnostic Devices in Regard to Labeling for HTLV–III/LAV Antibody Testing	December 6, 1986	Do.	Do.	Do.
Guideline on General Principles of Process Validation	May 1987	Do.	Do.	*http://www.fda.gov/cber/guidelines/htm*
Deferral of Donors Who Have Received Human Pituitary-Derived Growth Hormone	November 25, 1987	Do.	Do.	*http://www.fda.gov/cber/memo.htm*
Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices	December 1987	Do.	Do.	*http://www.fda.gov/cber/guidelines.htm*
Recommendations for the Management of Donors and Units That Are Initially Reactive for Hepatitis B Surface Antigen (HbsAg)	December 2, 1987	Do.	Do.	*http://www.fda.gov/cber/memo.htm*
Extension of Dating Period for Storage of Red Blood Cells, Frozen	December 4, 1987	Do.	Do.	Do.
To Licensed In Vitro Diagnostic Manufacturers: Handling of Human Blood Source Materials	December 23, 1987	Do.	Do.	Do.
Recommendations for Implementation of Computerization in Blood Establishments	April 6, 1988	Do.	Do.	Do.
Control of Unsuitable Blood and Blood Components	April 6, 1988	Do.	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CBER—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
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Discontinuance of Prelicensing Inspection for Immunization Using Licensed Tetanus Toxoid and Hepatitis B and Rabies Vaccines	July 7, 1988	Do.	Do.	Do.
Physician Substitutes	August 15, 1988	Do.	Do.	Do.
To Licensed Manufacturers of Blood Grouping Reagents: Criteria for Exemption of Lot Release	August 26, 1988	Do.	Do.	Do.
Revised Guideline for the Collection of Platelets, Pheresis	October 7, 1988	Do.	Do.	Do.
To Manufacturers of HTLV–I Antibody Test Kits: Antibody to Human T-Cell Lymphotropic Virus, Type I (HTLV–I) Release Panel I	October 18, 1988	Do.	Do.	Do.
HTLV–1 Antibody Testing	November 29, 1988	Do.	Do.	Do.
Use of Recombigen HIV–1 LA Test	February 1, 1989	Do.	Do.	Do.
Guidance for Autologous Blood and Blood Components	March 15, 1989	Do.	Do.	Do.
Use of Recombigen HIV–1 Latex Agglutination (LA) Test	August 1, 1989	Do.	Do.	Do.
Draft PTC in the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Antibodies to the Human Immunodeficiency Virus, Type 1	August 8, 1989	Do.	Do.	*http://www.fda.gov/cber/guidelines.htm*
PTC in the Collection, Processing, and Testing of Ex Vivo Activated Mononuclear Leukocytes for Administration to Humans	August 22, 1989	Do.	Do.	Do.
Requirements for Computerization of Blood Establishments	September 8, 1989	Do.	Do.	*http://www.fda.gov/cber/memo.htm*
Abbott Laboratories' HIVAG–1 Test for HIV–1 Antigen(s) Not Recommended for Use as a Donor Screen	October 4, 1989	Do.	Do.	Do.
Guideline for Collection of Blood or Blood Products From Donors With Positive Tests for Infectious Disease Markers ("High Risk" Donors)	October 26, 1989	Do.	Do.	Do.
Guideline for the Determination of Residual Moisture in Dried Biological Products	January 1990	Do.	Do.	*http://www.fda.gov/cber/guidelines.htm*
Autologous Blood Collection and Processing Procedures	February 12, 1990	Do.	Do.	*http://www.fda.gov/cber/memo.htm*
Use of Genetic Systems HIV–2 EIA	June 21, 1990	Do.	Do.	Do.
FDA Request for Information on Blood Storage Patterns and Red Cell Contamination by *Yersinia Enterocolitica*	March 15, 1991	Do.	Do.	Do.
Revision to October 26, 1989, Guideline for Collection of Blood or Blood Products From Donors With Positive Tests for Infectious Disease Markers ("High Risk" Donors)	April 17, 1991	Do.	Do.	Do.
Deficiencies Relating to the Manufacture of Blood and Blood Components	March 20, 1991	Do.	Do.	Do.
Responsibilities of Blood Establishments Related to Errors and Accidents in the Manufacture of Blood and Blood Components	March 20, 1991	Do.	Do.	Do.
FDA Recommendations Concerning Testing for Antibody to Hepatitis B Core Antigen (Anti-HBc)	September 10, 1991	Do.	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CBER—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
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Disposition of Blood Products Intended for Autologous Use That Test Repeatedly Reactive for Anti-HCV	September 11, 1991	Do.	Do.	Do.
Clarification of FDA Recommendations for Donor Deferral and Product Distribution Based on the Results of Syphilis Testing	December 12, 1991	Do.	Do.	Do.
Supplement to the PTC in the Production and Testing of New Drugs and Biologics Produced by Recombinant DNA Technology: Nucleic Acid Characterization and Genetic Stability	April 6, 1992	Do.	Do.	*http://www.fda.gov/cber/guidelines.htm*
Revised Recommendations for the Prevention of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products	April 23, 1992	Do.	Do.	*http://www.fda.gov/cber/memo.htm*
Use of Fluorognost HIV–1 Immunofluorescent Assay (IFA)	April 23, 1992	Do.	Do.	Do.
Revised Recommendations for Testing Whole Blood, Blood Components, Source Plasma, and Source Leukocytes for Antibody to Hepatitis C Virus Encoded Antigen (Anti-HCV)	April 23, 1992	Do.	Do.	Do.
Exemptions to Permit Persons With a History of Viral Hepatitis Before the Age of Eleven Years to Serve as Donors of Whole Blood and Plasma: Alternative Procedures, 21 CFR 640.120	April 23, 1992	Do.	Do.	Do.
Changes in Equipment for Processing Blood Donor Samples	July 21, 1992	Do.	Do.	Do.
Nomenclature for Monoclonal Blood Grouping Reagents	September 28, 1992	Do.	Do.	Do.
Volume Limits for Automated Collection of Source Plasma	November 4, 1992	Do.	Do.	Do.
FDA's Policy Statement Concerning Cooperative Manufacturing Arrangements for Licensed Biologics	November 25, 1992	Do.	Do.	*http://www.fda.gov/cber/guidelines.htm*
Revision of October 7, 1988, Memo Concerning Red Blood Cell Immunization Programs	December 16, 1992	Do.	Do.	*http://www.fda.gov/cber/memo.htm*
Draft PTC in the Characterization of Cell Lines Used to Produce Biologicals	July 12, 1993	Do.	Do.	*http://www.fda.gov/cber/guidelines.htm*
Guidance on Alternatives to Lot Release for Licensed Biological Products	July 20, 1993	Do.	Do.	Do.
Recommendations Regarding License Amendments and Procedures for Gamma Irradiation of Blood Products	July 22, 1993	Do.	Do.	*http://www.fda.gov/cber/memo.htm*
Deferral of Blood and Plasma Donors Based on Medications	July 28, 1993	Do.	Do.	Do.
Revised Recommendations for Testing Whole Blood, Blood Components, Source Plasma, and Source Leukocytes for Antibody to Hepatitis C Virus Encoded Antigen (Anti-HCV)	August 5, 1993	Do.	Do.	Do.
Clarification of the Use of Unlicensed Anti-HCV Supplemental Test Results in Regard to Donor Notification	August 19, 1993	Do.	Do.	Do.
Draft Guideline for the Validation of Blood Establishment Computer Systems	September 28, 1993	Do.	Do.	*http://www.fda.gov/cber/guidelines.htm*
Guidance Regarding Post Donation Information Reports	December 10, 1993	Do.	Do.	*http://www.fda.gov/cber/memo.htm*

GUIDANCE DOCUMENTS ISSUED BY CBER—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
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Donor Suitability Related to Laboratory Testing for Viral Hepatitis and a History of Viral Hepatitis	December 22, 1993	Do.	Do.	Do.
Recommendations for the Invalidation of Test Results When Using Licensed Viral Marker Assays to Screen Donors	January 3, 1994	Do.	Do.	Do.
Recommendations for Deferral of Donors for Malaria Risk	July 26, 1994	Do.	Do.	Do.
Office of Establishment Licensing and Product Surveillance (OELPS), Advertising and Promotional Labeling Staff, Procedural Guidance Document (Draft)	August 1994	Do.	Do.	*http://www.fda.gov/cber/guidelines.htm*
Guidance for Industry for the Submission of Chemistry, Manufacturing, and Controls Information for Synthetic Peptide Substances	November 1994	Do.	Do.	Do.
Recommendations to Users of Medical Devices That Test for Infectious Disease Markers by Enzyme Immunoassay (EIA) Test Systems	December 20, 1994	Do.	Do.	*http://www.fda.gov/cber/memo.htm*
Timeframe for Licensing Irradiated Blood Products	February 3, 1995	Do.	Do.	Do.
Revision of August 27, 1982, FDA Memo: Requirements for Infrequent Plasmapheresis Donors	March 10, 1995	Do.	Do.	Do.
To All Licensed Establishments Performing Red Blood Cell Immunizations: Revised Recommendations for Red Blood Cell Immunization Programs for Source Plasma Donors	March 14, 1995	Do.	Do.	Do.
Recommendations for the Deferral of Current and Recent Inmates of Correctional Institutions as Donors of Whole Blood, Blood Components, Source Leukocytes, and Source Plasma	June 8, 1995	Do.	Do.	Do.
Guideline for Quality Assurance in Blood Establishments	July 11, 1995	Do.	Do.	*http://www.fda.gov/cber/guidelines.htm*
FDA Guidance Document Concerning Use of Pilot Manufacturing Facilities for the Development and Manufacture of Biological Products	July 11, 1995	Do.	Do.	Do.
Recommendations for Labeling and Use of Units of Whole Blood, Blood Components, Source Plasma, Recovered Plasma, or Source Leukocytes Obtained From Donors With Elevated Levels of Alanine Aminotransferase (ALT)	August 8, 1995	Do.	Do.	*http://www.fda.gov/cber/memo.htm*
Recommendations for Donor Screening With a Licensed Test for HIV–1 Antigen	August 8, 1995	Do.	Do.	Do.
PTC in the Manufacture and Testing of Therapeutic Products for Human Use Derived From Transgenic Animals	1995	Do.	Do.	*http://www.fda.gov/cber/guidelines.htm*
Draft Reviewers' Guide: Informed Consent for Plasmapheresis/Immunization	October 1, 1995	FDA personnel	Do.	Do.
Draft Reviewers' Guide: Disease Associated Antibody Collection Program	October 1, 1995	Do.	Do.	Do.
Draft Document Concerning the Regulation of Placental/Umbilical Cord Blood Stem Cell Products Intended for Transplantation or Further Manufacturing Into Injectable Products	December 1995	Do.	Do.	*http://www.fda.gov/cber/memo.htm*

GUIDANCE DOCUMENTS ISSUED BY CBER—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
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Donor Deferral Due to Red Blood Cell Loss During Collection of Source Plasma by Automated Plasmapheresis	December 4, 1995	FDA regulated industry	Do.	Do.
Draft Document Concerning the Regulation of Peripheral Blood Hematopoietic Stem Cell Products Intended for Transplantation or Further Manufacturing Into Injectable Products	February 1996	Do.	Do.	Do.
International Conference on Harmonisation (ICH) Final Guideline on Quality of Biotechnological Products: Analysis of the Expression Construct in Cells Used for Production of r-DNA Derived Protein Products	February 23, 1996	Do.	Do.	*http://www.fda.gov/cber/guidelines.htm*
ICH Final Guideline on the Need for Long-Term Rodent Carcinogenicity Studies of Pharmaceuticals	March 1, 1996	Do.	Do.	Do.
Additional Recommendations for Donor Screening With a Licensed Test for HIV–1 Antigen	March 14, 1996	Do.	Do.	*http://www.fda.gov/cber/memo.htm*
FDA Guidance Concerning Demonstration of Comparability of Human Biological Products, Including Therapeutic Biotechnology-Derived Products	April 1996	Do.	Do.	*http://www.fda.gov/cber/guidelines.htm*
Additional Recommendations for Testing Whole Blood, Blood Components, Source Plasma, and Source Leukocytes for Antibody to Hepatitis C Virus Encoded Antigen (Anti-HCV)	May 16, 1996	Do.	Do.	*http://www.fda.gov/cber/memo.htm*
Guidance for Industry—The Content and Format for Pediatric Use Supplements	May 1996	Do.	Do.	*http://www.fda.gov/cber/guidelines.htm*
Guidance on Applications for Products Comprised of Living Autologous Cells Manipulated Ex Vivo and Intended for Structural Repair or Reconstruction	May 1996	Do.	Do.	Do.
Recommendations and Licensure Requirements for Leukocyte-Reduced Blood Products	May 29, 1996	Do.	Do.	*http://www.fda.gov/cber/memo.htm*
ICH Final Guidelines on Stablity Testing of Biotechnological/Biological Products	July 10, 1996	Do.	Do.	*http://www.fda.gov/cber/guidelines.htm*
Recommendations for the Quarantine and Disposition of Units From Prior Collections From Donors With Repeatedly Reactive Screening Tests for Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and Human T-Lymphotropic Virus Type I (HTLV–I)	July 19, 1996	Do.	Do.	*http://www.fda.gov/cber/memo.htm*
Guidance for Industry for the Submission of Chemistry, Manufacturing, and Controls Information for a Therapeutic Recombinant DNA-Derived Product or a Monoclonal Antibody Product for In Vivo Use	August 1996	Do.	Do.	*http://www.fda.gov/cber/guidelines.htm*
Interim Recommendations for Deferral of Donors at Increased Risk for HIV–1 Group O Infection	December 11, 1996	Do.	Do.	*http://www.fda.gov/cber/memo.htm*
PTC on Plasmid DNA Vaccines for Preventive Infectious Disease Indications	December 1996	Do.	Do.	*http://www.fda.gov/cber/guidelines.htm*
Guidance for the Submission of Chemistry, Manufacturing, and Controls Information and Establishment Description for Autologous Somatic Cell Therapy Products	January 1997	Do.	Do.	Do.
Reviewer Guidance for a Premarket Notification Submission for Blood Establishment Computer Software	January 13, 1997	FDA personnel	Do.	Do.

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
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PTC in the Manufacture and Testing of Monoclonal Antibody Products for Human Use	February 28, 1997	FDA regulated industry	Do.	Do.
Proposed Approach to Regulation of Cellular and Tissue-Based Products	February 28, 1997	Do.	Do.	Do.
Guidance for Industry for the Evaluation of Combination Vaccines for Preventable Diseases: Production, Testing, and Clinical Studies	April 1997	Do.	Do.	Do.
ICH Guidelines for the Photostability Testing of New Drug Substances and Products	May 16, 1997	Do.	Do.	Do.
Guidance for Industry: Changes to an Approved Application: Biological Products	July 1997	Do.	Do.	Do.
Guidance for Industry: Changes to an Approved Application for Specified Biotechnology and Specified Synthetic Biological Products	July 1997	Do.	Do.	Do.
Guidance for Industry: Screening and Testing of Donors of Human Tissue Intended for Transplantation	July 1997	Do.	Do.	Do.
Guidance for Industry: Donor Screening for Antibodies to HTLV–II	August 1997	Do.	Do.	Do.
Guidance for Industry: Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products: Clarification of What to Report	August 1997	Do.	Do.	Do.
Guidance for Industry: The Sourcing and Processing of Gelatin to Reduce the Potential Risk Posed by Bovine Spongiform Encephalopathy (BSE) in FDA-Regulated Products for Human Use	September 1997	Do.	Do.	Do.
Guidance for FDA and Industry: Direct Final Rule Procedures	November 21, 1997	FDA personnel and regulated industry	Do.	Do.
Draft Guidance for Industry: Promoting Medical Products in a Changing Healthcare Environment; I. Medical Product Promotion by Healthcare Organizations or Pharmacy Benefits Management Companies (PBMs)	December 1997	FDA regulated industry	Do.	Do.
Guidance for Industry: Industry-Supported Scientific and Educational Activities	November 1997	Do.	Do.	Do.
Guidance for Industry: Year 2000 Date Change for Computer Systems and Software Applications Used in the Manufacture of Blood Products	January 1998	Do.	Do.	Do.
Draft Guidance for Industry: Container and Closure Integrity Testing In Lieu of Sterility Testing as a Component of the Stability Protocol for Sterile Products	January 28, 1998	Do.	Do.	Do.
Draft Guidance for Industry: Manufacturing, Processing, or Holding Active Pharmaceutical Ingredients.	March 1998	Do.	Do.	Do.
Guidance for Industry: Guidance for Human Somatic Cell Therapy and Gene Therapy	March 1998	Do.	Do.	Do.
Draft Guidance for Industry: Instructions for Submitting Electronic Lot Release Protocols to CBER	May 1998	Do.	Do.	Do.

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
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Guidance for Industry: Classifying Resubmissions in Response to Action Letters	May 14, 1998	Do.	Do.	Do.
Guidance for Industry: Pharmacokinetics in Patients With Impaired Renal Function—Study Design, Data Analysis, and Impact on Dosing and Labeling	May 1998	Do.	Do.	Do.
Guidance for Industry: Standards for the Prompt Review of Efficacy Supplements, Including Priority Efficacy Supplements	May 15, 1998	Do.	Do.	Do.
Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drugs and Biological Products	May 1998	Do.	Do.	Do.
Draft Guidance for Industry: Stability Testing of Drug Substances and Drug Products	June 1998	Do.	Do.	Do.
Guidance for Industry: Errors and Accidents Regarding Saline Dilution of Samples Used for Viral Marker Testing	June 1998	Do.	Do.	Do.
ICH Guidance on Ethnic Factors in the Acceptability of Foreign Clinical Data	June 10, 1998	Do.	Do.	Do.
Draft Guidance for Industry: Exports and Imports Under the FDA Export Reform and Enhancement Act of 1996	June 12, 1998	Do.	Do.	Do.
Guidance for Industry: Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997—Elimination of Certain Labeling Requirements	July 1998	Do.	Do.	Do.
Guidance for Industry: Environmental Assessment of Human Drug and Biologics Applications	July 1998	Do.	Do.	Do.
Draft Guidance for Industry: Submitting Debarment Certification Statements	September 1998	Do.	Do.	Do.
Guidance for Industry: How to Complete the Vaccine Adverse Event Reporting System Form (VAERS–1)	September 1998	Do.	Do.	Do.
Guidance for Industry: Fast Track Drug Development Programs—Designation, Development, and Application Review	July 2004	Do.	Do.	Do.
ICH Guidance on Statistical Principles for Clinical Trials	September 16, 1998	Do.	Do.	Do.
ICH Guidance on Quality of Biotechnological/Biological Products: Derivation and Characterization of Cell Substrates Used for Production of Biotechnological/Biological Products	September 21, 1998	Do.	Do.	Do.
ICH Guidance on Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Origin	September 24, 1998	Do.	Do.	Do.
Draft Guidance for Industry: General Considerations for Pediatric Pharmacokinetic Studies for Drugs and Biological Products	November 1998	Do.	Do.	Do.
Guidance for Industry: FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products	December 1998	Do.	Do.	Do.
Draft Guidance for Industry: Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling	January 1999	Do.	Do.	Do.

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			Mailing Address	Internet Address
Guidance for Industry: Content and Format of Chemistry, Manufacturing, and Controls Information and Establishment Description Information for a Vaccine or Related Product	January 1999	Do.	Do.	Do.
Guidance on Amended Procedures for Advisory Panel Meetings	January 26, 1999	Do.	Do.	Do.
Draft Guidance for Industry; Providing Regulatory Submissions in Electronic Format—General Considerations	October 2003	Do.	Do.	*http://www.fda.gov/cber/esub/esubguid.htm*
Guidance for Industry: Population Pharmacokinetics	February 1999	Do.	Do.	*http://www.fda.gov/cber/guidelines.htm*
Guidance for Industry: Clinical Development Programs for Drugs, Devices, and Biological Products for the Treatment of Rheumatoid Arthritis (RA)	February 1999	Do.	Do.	Do.
Guidance for Industry: For the Submission of Chemistry, Manufacturing, and Controls and Establishment Description Information for Human Plasma-Derived Biological Products, Animal Plasma, or Serum-Derived Products	February 1999	Do.	Do.	Do.
Draft Guidance for Industry: Accelerated Approval Products—Submission of Promotional Materials	March 1999	Do.	Do.	Do.
Guidance for Industry: Content and Format of Chemistry, Manufacturing, and Controls Information and Establishment Description Information for a Biological In Vitro Diagnostic Product	March 1999	Do.	Do.	Do.
Guidance for Industry: Public Health Issues Posed by the Use of Nonhuman Primate Xenografts in Humans	April 1999	Do.	Do.	Do.
Guidance for Industry on the Content and Format of Chemistry, Manufacturing, and Controls Information and Establishment Description Information for an Allergenic Extract or Allergen Patch Test	April 1999	Do.	Do.	Do.
Guidance for Industry for the Submission of Chemistry, Manufacturing, and Controls and Establishment Description Information for Human Blood and Blood Components Intended for Transfusion or for Further Manufacture and for the Completion of the Form FDA 356h "Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use"	May 1999	Do.	Do.	Do.
Draft Guidance for Industry for Platelet Testing and Evaluation of Platelet Substitute Products	May 1999	Do.	Do.	Do.
Guidance for Industry: Efficacy Studies to Support Marketing of Fibrin Sealant Products Manufactured for Commercial Use	May 1999	Do.	Do.	Do.
Draft Reviewer Guidance: Evaluation of Human Pregnancy Outcome Data	June 1999	FDA personnel	Do.	Do.
Draft Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Prior Collections From Donors With Repeatedly Reactive Screening Tests for Hepatitis C Virus (HCV); (2) Supplemental Testing, and the Notification of Consignees and Transfusion Recipients of Donor Test Results for Antibody to HCV (Anti-HCV)	June 1999	FDA regulated industry	Do.	Do.

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
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ICH Guidance on the Duration of Chronic Toxicity Testing in Animals (Rodent and Nonrodent Toxicity Testing)	June 25, 1999	Do.	Do.	Do.
Draft Guidance for Industry: Clinical Development Programs for Drugs, Devices, and Biological Products Intended for the Treatment of Osteoarthritis (OA)	July 1999	Do.	Do.	Do.
Draft Guidance for Industry: Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations	July 1999	Do.	Do.	Do.
Draft Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics	August 1999	Do.	Do.	Do.
Guidance for Industry: Consumer-Directed Broadcast Advertisements	August 1999	Do.	Do.	Do.
Guidance for Industry: Possible Dioxin/PCB Contamination of Drug and Biological Products	August 1999	Do.	Do.	Do.
Guidance for Industry: Submission of Abbreviated Reports and Synopses in Support of Marketing Applications	August 1999	Do.	Do.	Do.
ICH Guidance on Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products	August 18, 1999	Do.	Do.	Do.
Guidance for Industry: Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act	September 1999	Do.	Do.	Do.
Guidance for Industry: Providing Regulatory Submissions to CBER in Electronic Format—Biologics Marketing Applications (Biologics License Application (BLA), Product License Application (PLA)/Establishment License Application (ELA), and New Drug Application (NDA)); revised	November 1999	Do.	Do.	Do.
Guidance for Industry: In Vivo Drug Metabolism/Drug Interaction Studies—Study Design, Data Analysis, and Recommendations for Dosing and Labeling	November 1999	Do.	Do.	Do.
ICH of Technical Requirements for Registration of Pharmaceuticals for Human Use; M4: Common Technical Document	November 8, 1999	Do.	Do.	Do.
Guidance for Industry: In the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Nucleic Acid Sequences of Human Immunodeficiency Viruses Types 1 and 2	December 1999	Do.	Do.	Do.
Guidance for Reviewers: Potency Limits for Standardized Dust Mite and Grass Allergen Vaccines: A Revised Protocol	November 2000	FDA personnel	Do.	Do.
Guidance for Industry: Formal Meetings With Sponsors and Applicants for PDUFA Products	February 2000	FDA regulated industry	Do.	Do.
Guidance for Industry: Formal Dispute Resolution: Appeals Above the Division Level	February 2000	Do.	Do.	Do.
Guidance for Industry: Gamma Irradiation of Blood and Blood Components: A Pilot Program for Licensing	February 2000	Do.	Do.	Do.

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
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Draft Guidance for Industry: Content and Format of the Adverse Reactions Section of Labeling for Human Prescription Drugs and Biologics	May 2000	Do.	Do.	Do.
Guidance for Industry: Recognition and Use of a Standard for the Uniform Labeling of Blood and Blood Components	June 2000	Do.	Do.	Do.
Draft Guidance for Industry: Recommendations for Donor Questioning Regarding Possible Exposure to Malaria	June 2000	Do.	Do.	Do.
Draft Guidance for Industry: Pediatric Oncology Studies in Response to a Written Request	June 2000	Do.	Do.	Do.
Guidance for Industry: Availability of Licensed Donor Screening Tests Labeled for Use With Cadaveric Blood Specimens	June 2000	Do.	Do.	Do.
Draft Guidance for Industry: Chronic Cutaneous Ulcer and Burn Wounds—Developing Products for Treatment	June 2000	Do.	Do.	Do.
Draft Guidance for Industry: Analytical Procedures and Methods Validation—Chemistry, Manufacturing, and Controls Documentation	August 2000	Do.	Do.	Do.
Draft Guidance for Industry: Considerations for Reproductive Toxicity Studies for Preventive Vaccines for Infectious Disease Indications	August 2000	Do.	Do.	Do.
Guidance for Industry: Q & A Content and Format of INDs for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-Derived Products	October 2000	Do.	Do.	Do.
Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Followup of Patients in Clinical Trials Using Retroviral Vectors	October 2000	Do.	Do.	Do.
Guidance for Industry: Submitting and Reviewing Complete Responses to Clinical Holds	October 2000	Do.	Do.	Do.
Guidance for Industry: Testing Limits in Stability Protocols for Standardized Grass Pollen Extracts	November 2000	Do.	Do.	Do.
Guidance for Industry: Use of Sterile Connecting Devices in Blood Bank Practices	November 2000	Do.	Do.	Do.
Draft Guidance for Industry: Recommendations for Complying With the Pediatric Rule (21 CFR 314.55(a) and 601.27(a))	November 2000	Do.	Do.	Do.
ICH Guidance for Industry: E11 Clinical Investigation of Medicinal Products in the Pediatric Population	December 2000	Do.	Do.	Do.
Guidance for Industry: Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees	December 2000	Do.	Do.	Do.
ICH Guidance on Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances	December 29, 2000	Do.	Do.	Do.
PHS Guideline on Infectious Disease Issues in Xenotransplantation	January 19, 2001	Do.	Do.	Do.

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
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Draft Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion	January 2001	Do.	Do.	Do.
Guidance for Industry: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods	January 2001	Do.	Do.	Do.
Draft Guidance for Industry: Providing Regulatory Submissions in Electronic Format—Prescription Drug Advertising and Promotional Labeling	January 2001	Do.	Do.	Do.
Guidance for Industry: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods—Technical Correction	February 2001	Do.	Do.	Do.
Draft Guidance for Industry: Disclosing Information Provided to Advisory Committees in Connection With Open Advisory Committee Meetings Related to the Testing or Approval of Biologic Products and Convened by the Center for Biologics Evaluation and Research	February 2001	Do.	Do.	Do.
Draft Guidance for Industry: Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines	March 2001	Do.	Do.	Do.
Guidance for Industry: Acceptance of Foreign Clinical Studies	March 2001	Do.	Do.	Do.
Guidance for Industry: Financial Disclosure by Clinical Investigators	March 2001	Do.	Do.	Do.
Guidance for Industry: Monoclonal Antibodies Used as Reagents in Drug Manufacturing	March 2001	Do.	Do.	Do.
Draft Guidance for Industry: Reports on the Status of Postmarketing Studies—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997	April 2001	Do.	Do.	Do.
Draft Guidance for Industry: Providing Regulatory Submissions in Electronic Format—Postmarketing Expedited Safety Reports	May 2001	Do.	Do.	Do.
Guidance for Industry: E10 Choice of Control Group and Related Issues in Clinical Trials	May 2001	Do.	Do.	Do.
Draft Guidance for Industry: IND Meetings for Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Information	May 2001	Do.	Do.	Do.
Draft Guidance for Industry: Clinical Studies Section of Labeling for Prescription Drugs and Biologics—Content and Format	July 2001	Do.	Do.	Do.
Guidance for Industry: CBER Pilot Licensing Program for Immunization of Source Plasma Donors Using Immunogen Red Blood Cells Obtained From an Outside Supplier	July 2001	Do.	Do.	Do.
Guidance for Industry: Revised Recommendations Regarding Invalidation of Test Results of Licensed and 510(k) Cleared Bloodborne Pathogen Assays Used to Test Donors	July 2001	Do.	Do.	Do.
ICH Guidance for Industry: S7A Safety Pharmacology Studies for Human Pharmaceuticals	July 2001	Do.	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CBER—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
			Mailing Address	Internet Address
Guidance for FDA Reviewers: Premarket Notification Submissions for Empty Containers for the Collection and Processing of Blood and Blood Components	July 2001	Do.	Do.	Do.
Guidance for FDA Reviewers: Premarket Notification Submissions for Transfer Sets (Excluding Sterile Connecting Devices)	July 2001	Do.	Do.	Do.
Guidance for FDA Reviewers: Premarket Notification Submissions for Blood and Plasma Warmers	July 2001	Do.	Do.	Do.
Guidance for Industry: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture	July 2001	Do.	Do.	Do.
Draft Guidance for FDA Reviewers: Premarket Notification Submissions for Automated Testing Instruments Used in Blood Establishments	August 2001	Do.	Do.	Do.
Draft Guidance for Industry: Biological Product Deviation Reporting for Licensed Manufacturers of Biological Products Other Than Blood and Blood Components	August 2001	Do.	Do.	Do.
Draft Guidance for Industry: Biological Product Deviation Reporting for Blood and Plasma Establishments	August 2001	Do.	Do.	Do.
Guidance for Industry: Variances for Blood Collection From Individuals With Hereditary Hemochromatosis	August 2001	Do.	Do.	Do.
Draft Guidance for Industry: Submitting Type V Drug Master Files to the CBER	August 2001	Do.	Do.	Do.
Draft Guidance for Industry: Premarket Notifications (510(k)s) for In Vitro HIV Drug Resistance Genotype Assays: Special Controls	August 2001	Do.	Do.	Do.
Draft Guidance for Industry: Submitting Marketing Applications According to the ICH-CTD Format—General Considerations	August 2001	Do.	Do.	Do.
ICH Guidance: Q7A Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients	August 2001	Do.	Do.	Do.
ICH Guidance on M4 Common Technical Document	August 2001	Do.	Do.	Do.
Guidance for Industry: Cancer Drug and Biological Products—Clinical Data in Marketing Applications	October 2001	Do.	Do.	Do.
Guidance for Industry: Content and Format of Geriatric Labeling	October 2001	Do.	Do.	Do.
Guidance for Industry: Recommendations for Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Possible Exposure to Anthrax	October 2001	Do.	Do.	Do.
Draft Guidance for Clinical Trial Sponsors on the Establishment and Operation of Clinical Trial Data Monitoring Committees	November 2001	Do.	Do.	Do.
Guidance for Industry: Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act	November 2001	Do.	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CBER—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
			Mailing Address	Internet Address
Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products	January 2002	Do.	Do.	Do.
Guidance for Industry: General Principles of Software Validation; Final Guidance for Industry and FDA Staff	January 2002	Do.	Do.	Do.
Draft Guidance for Industry: Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products From Xenotransplantation Product Recipients and Their Intimate Contacts	February 2002	Do.	Do.	Do.
Guidance for Industry: Validation of Procedures for Processing of Human Tissues Intended for Transplantation	March 2002	Do.	Do.	Do.
Guidance for Industry; Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions	March 2002	Do.	Do.	*http://www.fda.gov/cber/gdlns/clintrial031802.pdf*
Guidance for Industry: Providing Regulatory Submissions to CBER in Electronic Format—Investigational New Drug Applications (INDs)	March 2002	Do.	Do.	*http://www.fda.gov/cber/guidelines.htm*
Guidance for Industry: E2BM Data Elements for Transmission of Individual Case Safety Reports	April 2002	Do.	Do.	Do.
Draft Guidance for Industry; A Modified Lot-Release Specification for Hepatitis B Surface Antigen (HBsAg) Assays Used to Test Blood, Blood Components, and Source Plasma Donations	April 2002	Do.	Do.	Do.
Guidance for Industry: Container Closure Systems for Packaging Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Documentation	May 1999	Do.	Do.	Do.
Guidance for Industry: Container Closure Systems for Packaging Human Drugs and Biologics; Questions and Answers	May 2002	Do.	Do.	Do.
Draft Guidelines for Ensuring the Quality of Information Disseminated to the Public (HHS Guideline)	May 2002	Do.	Do.	Do.
Guidance for Industry: Special Protocol Assessment	May 2002	Do.	Do.	Do.
Draft Guidance for Industry: Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)	June 2002	Do.	Do.	Do.
Draft Guidance for Industry: 21 CFR Part 11; Electronic Records; Electronic Signatures, Electronic Copies of Electronic Records	August 2002	Do.	Do.	Do.
Guidance for Industry: Establishing Pregnancy Exposure Registries	August 2002	Do.	Do.	Do.
Draft Guidance for Industry: Drugs, Biologics, and Medical Devices Derived From Bioengineered Plants for Use in Humans and Animals	September 2002	Do.	Do.	Do.
Draft Guidance for Industry: Nonclinical Studies for Development of Pharmaceutical Excipients	September 2002	Do.	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CBER—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
			Mailing Address	Internet Address
The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles; Final Guidance for FDA and Industry	October 2002	Do.	Do.	Do.
Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Human Dura Mater	December 18, 2003	Do.	Do.	*http://www.fda.gov/cber/gdlns/humduramat.pdf*
Guidance for Industry: Recommendations for Deferral of Donors and Quarantine and Retrieval of Blood and Blood Products in Recent Recipients of Smallpox Vaccine (Vaccinia Virus) and Certain Contacts of Smallpox Vaccine Recipients	December 2002	Do.	Do.	*http://www.fda.gov/cber/guidelines.htm*
Draft Guidance for Industry and Reviewers on Estimating the Safe Starting Dose in Clinical Trials for Therapeutics in Adult Healthy Volunteers	December 2002	Do.	Do.	Do.
ICH Guidance for Industry; Q1D Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products	January 2003	Do.	Do.	Do.
Draft Guidance for Industry: Collection of Race and Ethnicity Data in Clinical Trials	January 2003	Do.	Do.	Do.
Draft Guidance for Industry: Drug Product: Chemistry, Manufacturing, and Controls Information	January 2003	Do.	Do.	Do.
ICH Guidance for Industry: M4 CTD—Safety: Questions and Answers	February 2003	Do.	Do.	Do.
Guidance for Industry and FDA Staff: Quality System Information for Certain Premarket Application Reviews	February 2003	Do.	Do.	Do.
ICH Guidance for Industry: Q3A Impurities in New Drug Substances	February 2003	Do.	Do.	Do.
Draft Guidance for Industry; Comparability Protocols—Chemistry, Manufacturing, and Controls Information	February 2003	Do.	Do.	Do.
Assessing User Fees: PMA Supplement Definitions, Modular PMA Fees, BLA and Efficacy Supplement Definitions, Bundling Multiple Devices in a Single Application, and Fees for Combination Products; Guidance for Industry and FDA	February 25, 2003	Do.	Do.	*http://www.fda.gov/cber/dap/devpubs.htm*
Guidance for Industry and FDA: FY 2003 MDUFMA Small Business Qualification Worksheet and Certification	March 2003	Do.	Do.	*http://www.fda.gov/cber/guidelines.htm*
ICH Guidance for Industry: M2 eCTD: Electronic Common Technical Document Specification	April 2003	Do.	Do.	Do.
Guidance for Industry: Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans	April 2003	Do.	Do.	Do.
Guidance for Industry: Recommendations for the Assessment of Donor Suitability and Blood Product Safety in Cases of Suspected Severe Acute Respiratory Syndrome (SARS) or Exposure to SARS	April 2003	Do.	Do.	Do.
Guidance for Industry, FDA Staff, and Third Parties; Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria	October 4, 2004	Do.	Do.	*http://www.fda.gov/cber/dap/devpubs.htm*

GUIDANCE DOCUMENTS ISSUED BY CBER—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
			Mailing Address	Internet Address
Guidance for Industry: Exposure-Response Relationships—Study Design, Data Analysis, and Regulatory Applications	April 2003	Do.	Do.	*http://www.fda.gov/cber/guidelines.htm*
Guidance for Industry: Revised Recommendations for the Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection	May 2003	Do.	Do.	Do.
Guidance for Industry: Pharmacokinetics in Patients With Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling	May 2003	Do.	Do.	Do.
Draft Guidance for Industry and FDA Staff: Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002—Identification of Manufacturer of Medical Devices	June 2003	Do.	Do.	Do.
Guidance for FDA Staff: The Leveraging Handbook, An Agency Resource for Effective Collaborations	June 2003	Dc.	Do.	Do.
Draft Guidance for Industry: Providing Regulatory Submissions in Electronic Format—Postmarketing Periodic Adverse Drug Experience Reports	June 2003	Do.	Do.	Do.
Draft Guidance for Industry: Revised Recommendations for Donor and Product Management Based on Screening Tests for Syphilis	June 2003	Do.	Do.	Do.
Guidance for Industry and FDA Staff: Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices	July 2003	Do.	Do.	Do.
Guidance for Industry: Streamlining the Donor Interview Process: Recommendations for Self-Administered Questionnaires	July 2003	Do.	Do.	Do.
Draft Guidance for Industry and FDA Staff: Premarket Assessment of Pediatric Medical Devices	July 2003	Do.	Do.	Do.
Draft Guidance for Review Staff and Industry: Good Review Management Principles for PDUFA Products	July 2003	Do.	Do.	Do.
Compliance Program Guidance Manual (drugs and biologics)	Dates vary—Individual issue dates	Do.	Do.	*http://www.fda.gov/cber/cpg/cpg.htm*
ICH Guidance for Industry: Q3C—Tables and List	November 2003	Do.	Do.	*http://www.fda.gov/cber/guidelines.htm*
ICH Guidance for Industry: Q3B(R) Impurities in New Drug Products	November 2003	Do.	Do.	Do.
ICH Guidance for Industry: Q1A(R2) Stability Testing of New Drug Substances and Products	November 2003	Do.	Do.	Do.
WITHDRAWN GUIDANCES				
Draft Guidance for Industry: Application of Current Statutory Authority to Nucleic Acid Testing of Pooled Plasma	November 1999	Do.	N/A	
Draft Document Concerning the Regulation of Placental/Umbilical Cord Blood Hematopoietic Stem Cell Products Intended for Transplantation or Further Manufacturing Into Injectable Products	December 1995	Do.	Do.	

GUIDANCE DOCUMENTS ISSUED BY CBER—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
			Mailing Address	Internet Address
Draft Document Concerning the Regulation of Peripheral Blood Hematopoietic Stem Cell Products Intended for Transplantation or Further Manufacturing into Injectable Products	February 1996	Do.	Do.	
Draft Advertising and Promotional Labeling Staff Procedural Guidance	August 1994	Do.	Do.	
Draft Guidance for Industry: 21 CFR Part 11; Electronic Records; Electronic Signatures; Validation	August 2001	Do.	Do.	
Draft Guidance for Industry: 21 CFR Part 11; Electronic Records; Electronic Signatures; Glossary of Terms	August 2001	Do.	Do.	
Draft Guidance for Industry: 21 CFR Part 11; Electronic Records; Electronic Signatures; Time Stamps	February 2002	Do.	Do.	
Draft Guidance for Industry: 21 CFR Part 11; Electronic Records; Electronic Signatures, Maintenance of Electronic Records	July 2002	Do.	Do.	

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
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Aerosol Steroid Product Safety Information in Prescription Drug Advertising and Promotional Labeling	January 12, 1998	Advertising	Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573	*http://www.fda.gov/cder/guidance/index.htm*
Consumer-Directed Broadcast Advertisements	August 9, 1999	Do.	Do.	Do.
Industry-Supported Scientific and Educational Activities	December 3, 1997	Do.	Do.	Do.
Accelerated Approval Products—Submission of Promotional Materials	March 26, 1999	Advertising draft	Do.	Do.
Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements	February 10, 2004	Do.	Do.	Do.
"Help-Seeking" and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms	February 10, 2004	Do.	Do.	Do.
Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling	March 12, 1999	Do.	Do.	Do.
Promoting Medical Products in a Changing Healthcare Environment; I. Medical Product Promotion by Healthcare Organizations or Pharmacy Benefits Management Companies (PBMs)	January 5, 1998	Do.	Do.	Do.
Bioanalytical Method Validation	May 23, 2001	Biopharmaceutics	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CDER—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
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Bioavailability and Bioequivalence Studies for Orally Administered Drug Products—General Considerations	March 19, 2003	Do.	Do.	Do.
Cholestyramine Powder In Vitro Bioequivalence	July 15, 1993	Do.	Do.	Do.
Clozapine Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing	November 15, 1996	Do.	Do.	Do.
Corticosteroids, Dermatologic (topical) In Vivo	June 2, 1995	Do.	Do.	Do.
Dissolution Testing of Immediate Release Solid Oral Dosage Forms	August 25, 1997	Do.	Do.	Do.
Extended Release Oral Dosage Forms: Development, Evaluation, and Application of In Vitro/In Vivo Correlations	September 26, 1997	Do.	Do.	Do.
Food-Effect Bioavailability and Fed Bioequivalence Studies	December 2002	Do.	Do.	Do.
Metaproterenol Sulfate and Albuterol Metered Dose Inhalers In Vitro	June 27, 1989	Do.	Do.	Do.
Phenytoin/Phenytion Sodium (capsules, tablets, suspension) In Vivo Bioequivalence and In Vitro Dissolution Testing	March 4, 1994	Do.	Do.	Do.
Statistical Approaches to Establishing Bioequivalence	February 2, 2001	Do.	Do.	Do.
Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System	August 31, 2000	Do.	Do.	Do.
Antifungal (topical)	February 24, 1990	Biopharmaceutics draft	Do.	N/A
Antifungal (vaginal)	February 24, 1990	Do.	Do.	Do.
Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action	April 2003	Do.	Do.	*http://www.fda.gov/cder/guidance/index.htm*
Clozapine Tablets: In Vivo Bioequivalence and In Vitro Dissolution Testing	December 2003	Do.	Do.	Do.
Conjugated Estrogens, USP–LC–MS Method for Both Qualitative Chemical Characterization and Documentation of Qualitative Pharmaceutical Equivalence	March 2000	Do.	Do.	Do.
BACPAC I: Intermediates in Drug Substance Synthesis: Bulk Actives Postapproval Changes: Chemistry, Manufacturing, and Controls Documentation	February 16, 2001	Chemistry	Do.	*http://www.fda.gov/cder/guidance/index.htm*
Changes to an Approved Application for Specified Biotechnology and Specified Synthetic Biological Products	July 24, 1997	Do.	Do.	Do.
Changes to an Approved NDA or ANDA	April 2004	Do.	Do.	Do.
Changes to an Approved NDA or ANDA: Questions and Answers	January 22, 2001	Do.	Do.	Do.
Container Closure Systems for Packaging Human Drugs and Biologics	May 1999	Do.	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CDER—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
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Demonstration of Comparability of Human Biological Products, Including Therapeutic Biotechnology-Derived Products	April 1996	Do.	Do.	Do.
Development of New Stereoisomeric Drugs	May 1, 1992	Do.	Do.	Do.
Drug Master Files	September 1, 1989	Do.	Do.	Do.
Drug Master Files for Bulk Antibiotic Drug Substances	November 29, 1999	Do.	Do.	Do.
Environmental Assessment of Human Drug and Biologics Applications	July 27, 1998	Do.	Do.	Do.
Format and Content for the CMC Section of an Annual Report	September 1, 1994	Do.	Do.	Do.
Format and Content of the Chemistry, Manufacturing, and Controls Section of an Application	February 1, 1987	Do.	Do.	Do.
Format and Content of the Microbiology Section of an Application	February 1, 1987	Do.	Do.	Do.
IND Meetings for Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Information	May 25, 2001	Do.	Do.	Do.
INDs for Phase 2 and 3 Studies; Chemistry, Manufacturing, and Controls Information	May 20, 2003	Do.	Do.	Do.
Monoclonal Antibodies Used as Reagents in Drug Manufacturing	March 29, 2001	Do.	Do.	Do.
Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products—Chemistry, Manufacturing, and Controls Documentation	July 5, 2002	Do.	Do.	Do.
NDAs: Impurities in Drug Substances	February 25, 2000	Do.	Do.	Do.
PAC–ALTS: Postapproval Changes—Analytical Testing Laboratory Sites	April 28, 1998	Do.	Do.	Do.
Reviewer Guidance: Validation of Chromatographic Methods	November 1994	Do.	Do.	Do.
Submission Documentation for Sterilization Process Validation in Applications for Human and Veterinary Drug Products	November 1, 1994	Do.	Do.	Do.
Submission of Chemistry, Manufacturing, and Controls Information for Synthetic Peptide Substances	November 1994	Do.	Do.	Do.
Submitting Documentation for the Manufacturing of, and Controls for, Drug Products	February 1, 1987	Do.	Do.	Do.
Submitting Documentation for the Stability of Human Drugs and Biologics	February 1, 1987	Do.	Do.	Do.
Submitting Samples and Analytical Data for Methods Validation	February 1987	Do.	Do.	Do.
Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Products	February 1, 1987	Do.	Do.	N/A
Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Substances	February 1987	Do.	Do.	*http://www.fda.gov/cder/guidance/index.htm*

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
			Mailing Address	Internet Address
SUPAC IR—Immediate-Release Solid Oral Dosage Forms: Scale-Up and Postapproval Changes: Chemistry, Manufacturing and Controls, In Vitro Dissolution Testing, and In Vivo Bioequivalence Documentation	November 1995	Do.	Do.	Do.
SUPAC IR/MR: Immediate Release and Modified Release Solid Oral Dosage Forms Manufacturing Equipment Addendum	January 1999	Do.	Do.	Do.
SUPAC–IR Questions and Answers About SUPAC–IR Guidance	February 18, 1997	Do.	Do.	Do.
SUPAC–MR: Modified Release Solid Oral Dosage Forms Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls; In Vitro Dissolution Testing and In Vivo Bioequivalence Documentation	October 6, 1997	Do.	Do.	Do.
SUPAC–SS—Nonsterile Semisolid Dosage Forms Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls; In Vitro Release Testing and In Vivo Bioequivalence Documentation	May 1997	Do.	Do.	Do.
The Sourcing and Processing of Gelatin to Reduce the Potential Risk Posed by Bovine Spongiform Encephalopathy (BSE)	December 20, 2000	Do.	Do.	Do.
Analytical Procedures and Methods Validation: Chemistry, Manufacturing, and Controls Documentation	August 30, 2000	Chemistry draft	Do.	Do.
Botanical Drug Products	June 9, 2004	Do.	Do.	Do.
Comparability Protocols—Chemistry, Manufacturing, and Controls Information	February 25, 2003	Do.	Do.	Do.
Drug Product: Chemistry, Manufacturing, and Controls Information	January 28, 2003	Do.	Do.	Do.
Drug Substance: Chemistry, Manufacturing, and Controls Information	January 7, 2004	Do.	Do.	Do.
Drugs, Biologics, and Medical Devices Derived From Bioengineered Plants for Use in Humans and Animals	September 2002	Do.	Do.	Do.
Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations	July 1999	Do.		Do.
Liposome Drug Products: Chemistry, Manufacturing, and Controls; Human Pharmacokinetics and Bioavailability; and Labeling Documentation	August 2002	Do.	Do.	Do.
Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products; Chemistry, Manufacturing, and Controls Documentation	November 19, 1998	Do.	Do.	Do.
Stability Testing of Drug Substances and Drug Products	June 8, 1998	Do.	Do.	Do.
Submitting Supporting Chemistry Documentation in Radiopharmaceutical Drug Applications	November 1, 1991	Do.	Do.	N/A
SUPAC–SS: Nonsterile Semisolid Dosage Forms Manufacturing Equipment Addendum	January 5, 1999	Do.	Do.	*http://www.fda.gov/cder/guidance/index.htm*

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
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Antiretroviral Drugs Using Plasma HIV RNA Measurements—Clinical Considerations for Accelerated and Traditional Approval	October 2002	Clinical antimicrobial	Do.	Do.
Clinical Development and Labeling of Anti-Infective Drug Products	October 26, 1992	Do.	Do.	Do.
Clinical Evaluation of Anti-Infective Drugs (Systemic)	September 1, 1977	Do.	Do.	Do.
Preclinical Development of Antiviral Drugs	November 1990	Do.	Do.	Do.
Acute Bacterial Exacerbation of Chronic Bronchitis; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Clinical antimicrobial draft	Do.	Do.
Acute Bacterial Meningitis; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do.	Do.	Do.
Acute Bacterial Sinusitis; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do.	Do.	Do.
Acute or Chronic Bacterial Prostatitis; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do.	Do.	Do.
Acute Otitis Media; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do.	Do.	Do.
Bacterial Vaginosis; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do.	Do.	Do.
Catheter-Related Bloodstream Infections—Developing Antimicrobial Drugs for Treatment	October 18, 1999	Do.	Do.	Do.
Community Acquired Pneumonia; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do.	Do.	Do.
Complicated Urinary Tract Infections and Pylonephritis—Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do.	Do.	Do.
Developing Antimicrobial Drugs—General Considerations for Clinical Trials	July 22, 1998	Do.	Do.	Do.
Developing Drugs to Treat Inhalational Anthrax (Post-Exposure)	March 18, 2002	Do.	Do.	Do.
Empiric Therapy of Febrile Neutropenia—Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do.	Do.	Do.
Evaluating Clinical Studies of Antimicrobials in the Division of Anti-Infective Drug Products	February 1997	Do.	Do.	Do.
Lyme Disease—Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do.	Do.	Do.
Nosocomial Pneumonia—Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do.	Do.	Do.
Secondary Bacterial Infections of Acute Bronchitis—Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do.	Do.	Do.
Streptococcal Pharyngitis and Tonsillitis—Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do.	Do.	Do.
Uncomplicated and Complicated Skin and Skin Structure Infections—Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do.	Do.	Do.

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Uncomplicated Gonorrhea—Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do.	Do.	Do.
Uncomplicated Urinary Tract Infections—Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do.	Do.	Do.
Vaccinia Virus—Developing Drugs to Mitigate Complications From Smallpox Vaccination	March 2004	Do.	Do.	Do.
Vuvlovaginal Candidiasis—Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do.	Do.	Do.
Acceptance of Foreign Clinical Studies	March 2001	Clinical medical	Do.	Do.
Calcium DTPA and Zinc DTPA Drug Products—Submitting a New Drug Application	August 2004	Do.	Do.	Do.
Cancer Drug and Biological Products—Clinical Data in Marketing Applications	October 2001	Do.	Do.	Do.
Clinical Development Programs for Drugs, Devices, and Biological Products for the Treatment of Rheumatoid Arthritis (RA)	February 1999	Do.	Do.	Do.
Clinical Development Programs for MDI and DPI Drug Products	September 19, 1994	Do.	Do.	Do.
Clinical Evaluation of Anti-Inflammatory and Antirheumatic Drugs (adults and children)	April 1988	Do.	Do.	Do.
Clinical Evaluation of Antianxiety Drugs	September 1, 1977	Do.	Do.	Do.
Clinical Evaluation of Antidepressant Drugs	September 1, 1977	Do.	Do.	Do.
Clinical Evaluation of Antiepileptic Drugs (adults and children)	January 1, 1981	Do.	Do.	Do.
Clinical Evaluation of General Anesthetics	May 1, 1982	Do.	Do.	Do.
Clinical Evaluation of Hypnotic Drugs	September 1, 1977	Do.	Do.	Do.
Clinical Evaluation of Local Anesthetics	May 1982	Do.	Do.	Do.
Clinical Evaluation of Psychoactive Drugs in Infants and Children	July 1979	Do.	Do.	Do.
Content and Format for Pediatric Use Supplements	May 1996	Do.	Do.	Do.
Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-Derived Products	November 1995	Do.	Do.	Do.
Establishing Pregnancy Exposure Registries	August 2002	Do.	Do.	Do.
FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products	February 2, 1999	Do.	Do.	Do.
FDA Requirements for Approval of Drugs to Treat Non-Small Cell Lung Cancer	January 1991	Do.	Do.	Do.
Format and Content of the Clinical and Statistical Sections of an Application	July 1, 1988	Do.	Do.	Do.
Format and Content of the Summary for New Drug and Antibiotic Applications	February 1, 1987	Do.	Do.	Do.
Formatting, Assembling and Submitting New Drug and Antiobiotic Applications	February 1, 1987	Do.	Do.	Do.

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
			Mailing Address	Internet Address
General Considerations for the Clinical Evaluation of Drugs	December 1, 1978	Do.	Do.	Do.
General Considerations for the Clinical Evaluation of Drugs in Infants and Children	September 1, 1977	Do.	Do.	Do.
Guidance for the Development of Vaginal Contraceptive Drugs (NDA)	April 1995	Do.	Do.	Do.
IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer	January 15, 2004	Do.	Do.	Do.
Integration of Dose-Counting Mechanisms Into MDI Drug Products	March 2003	Do.	Do.	Do.
Levothyroxine Sodium Tablets—In Vivo Pharmacokinetic and Bioavailability Studies and In Vitro Dissolution Testing	March 8, 2001	Do.	Do.	Do.
Oncologic Drugs Advisory Committee Discussion on FDA Requirements for Approval of New Drugs for Treatment of Colon and Rectal Cancer	April 19, 1988	Do.	Do.	Do.
Oncologic Drugs Advisory Committee Discussion on FDA Requirements for Approval of New Drugs for Treatment of Ovarian Cancer	April 1988	Do.	Do.	Do.
Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products: Clarification of What to Report	August 27, 1997	Do.	Do.	Do.
Postmarketing Reporting of Adverse Drug Experiences	March 1, 1992	Do.	Do.	Do.
Preclinical Development of Immunomodulatory Drugs for Treatment of HIV Infection and Associated Disorders	September 1992	Do.	Do.	Do.
Preparation of Investigational New Drug Products (Human and Animal)	November 1, 1992	Do.	Do.	Do.
Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products	May 1998	Do.	Do.	Do.
Prussian Blue Drug Products—Submitting a New Drug Application	February 4, 2003	Do.	Do.	Do.
Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs	July 22, 1993	Do.	Do.	Do.
Study of Drugs Likely to be Used in the Elderly	November 1, 1989	Do.	Do.	Do.
Submission of Abbreviated Reports and Synopses in Support of Marketing Applications	September 13, 1999	Do.	Do.	Do.
Abuse Liability Assessment	July 1, 1990	Clinical medical draft	Do.	N/A
Allergic Rhinitis: Clinical Development Programs for Drug Products	June 21, 2000	Do.	Do.	*http://www.fda.gov/cder/guidance/index.htm*
Available Therapy	July 22, 2004	Do.	Do.	Do.
Chronic Cutaneous Ulcer and Burn Wounds—Developing Products for Treatment	June 28, 2000	Do.	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CDER—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
			Mailing Address	Internet Address
Clinical Development Programs for Drugs, Devices, and Biological Products Intended for the Treatment of Osteoarthritis (OA)	July 1999	Do.	Do.	Do.
Clinical Evaluation of Anti-Anginal Drugs	January 1, 1989	Do.	Do.	N/A
Clinical Evaluation of Anti-Arrhythmic Drugs	July 1, 1985	Do.	Do.	Do.
Clinical Evaluation of Antihypertensive Drugs	May 1, 1988	Do.	Do.	Do.
Clinical Evaluation of Drugs for the Treatment of Congestive Heart Failure	December 1, 1987	Do.	Do.	Do.
Clinical Evaluation of Lipid-Altering Agents in Adults and Children	September 1990	Do.	Do.	*http://www.fda.gov/cder/guidance/index.htm*
Clinical Evaluation of Weight-Control Drugs	September 24, 1996	Do.	Do.	Do.
Clinical Trial Sponsors on the Establishment and Operation of Clinical Trial Data Monitoring Committees	November 2001	Do.	Do.	Do.
Collection of Race and Ethnicity Data in Clinical Trials for FDA-Regulated Products	January 30, 2003	Do.	Do.	Do.
Developing Medical Imaging Drug and Biological Products—2nd draft	May 19, 2003	Do.	Do.	Do.
Development and Evaluation of Drugs for the Treatment of Psychoactive Substance Use Disorders	February 12, 1992	Do.	Do.	N/A
Development of Parathyroid Hormone for the Prevention and Treatment of Osteoporosis	May 2000	Do.	Do.	*http://www.fda.gov/cder/guidance/index.htm*
Drugs, Biologics, and Medical Devices Derived From Bioengineered Plants for Use in Humans and Animals	September 2002	Do.	Do.	Do.
Estrogen and Estrogen/Progestin Drug Products to Treat Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms—Recommendations for Clinical Evaluation	January 2003	Do.	Do.	Do.
Evaluation of Human Pregnancy Outcome Data	June 1999	Do.	Do.	Do.
Evaluation of the Effects of Orally Inhaled and Intranasal Corticosteroids on Growth in Children	November 6, 2001	Do.	Do.	Do.
Exercise-Induced Bronchospasm (EIB)—Development of Drugs to Prevent EIB	February 20, 2002	Do.	Do.	Do.
Female Sexual Dysfunction: Clinical Development of Drug Products for Treatment	May 19, 2000	Do.	Do.	Do.
Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research	March 2000	Do.	Do.	Do.
Inhalation Drug Products Packaged in Semipermeable Container Closure Systems	July 26, 2002	Do.	Do.	Do.
OTC Treatment of Herpes Labialis with Antiviral Agents	March 8, 2000	Do.	Do.	Do.
Pediatric Oncology Studies in Response to a Written Request	June 21, 2000	Do.	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CDER—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
			Mailing Address	Internet Address
Preclinical and Clinical Evaluation of Agents Used in the Prevention or Treatment of Postmenopausal Osteoporosis	April 1, 1994	Do.	Do.	Do.
Preparation of IND Applications for New Drugs Intended for the Treatment of HIV-Infected Individuals	September 1, 1991	Do.	Do.	N/A
Recommendations for Complying With the Pediatric Rule	November 2000	Do.	Do.	*http://www.fda.gov/cder/guidance/index.htm*
Drug Metabolism/Drug Interaction Studies in the Drug Development Process: Studies In Vitro	April 7, 1997	Clinical pharmacology	Do.	Do.
Exposure-Response Relationships—Study Design, Data Analysis, and Regulatory Applications	April 2003	Do.	Do.	Do.
Format and Content of the Human Pharmacokinetics and Bioavailability Section of an Application	February 1, 1987	Do.	Do.	Do.
In Vivo Metabolism/Drug Interaction Studies—Study Design, Data Analysis, and Recommendations for Dosing and Labeling	November 24, 1999	Do.	Do.	Do.
Pharmacokinetics in Patients With Impaired Hepatic Function; Study Design, Data Analysis, and Impact on Dosing and Labeling	May 30, 2003	Do.	Do.	Do.
Pharmacokinetics in Patients with Impaired Renal Function—Study Design, Data Analysis, and Impact on Dosing and Labeling	May 1998	Do.	Do.	Do.
Population Pharmacokinetics	February 10, 1999	Do.	Do.	Do.
General Considerations for Pediatric Pharmacokinetic Studies for Drugs and Biological Products	November 30, 1998	Clinical pharmacology draft	Do.	Do.
A Review of FDA's Implementation of the Drug Export Amendments of 1986	May 1990	Compliance	Do.	Do.
Compressed Medical Gases	February 1989	Do.	Do.	Do.
Computerized Systems Used in Clinical Trials	April 1999	Do.	Do.	Do.
Expiration Dating and Stability Testing of Solid Oral Dosage Form Drugs Containing Iron	June 27, 1997	Do.	Do.	Do.
General Principles of Process Validation	May 1987	Do.	Do.	Do.
Good Laboratory Practice Regulations Questions and Answers	June 1981	Do.	Do.	Do.
Guidance for Hospitals, Nursing Homes, and Other Health Care Facilities—FDA Public Health Advisory	March 2001	Do.	Do.	Do.
Guideline for Validation of Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices	December 1987	Do.	Do.	Do.
Monitoring of Clinical Investigations	January 1988	Do.	Do.	Do.
Nuclear Pharmacy Guideline Criteria for Determining When to Register as a Drug Establishment	May 1984	Do.	Do.	Do.
Pharmacy Compounding: Compliance Policy Guide	May 2002	Do.	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CDER—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
			Mailing Address	Internet Address
Possible Dioxin/PCB Contamination of Drug and Biological Products	August 23, 1999	Do.	Do.	Do.
Sterile Drug Products Produced by Aseptic Processing	June 1987	Do.	Do.	Do.
Street Drug Alternatives	March 2000	Do.	Do.	Do.
Current Good Manufacturing Practices for Medical Gases	May 6, 2003	Compliance draft	Do.	Do.
Good Manufacturing Practice for Positron Emission Tomography Drug Products	April 1, 2002	Do.	Do.	Do.
Guidance for IRBs, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research	May 12, 2000	Do.	Do.	Do.
Investigating Out of Specification (OOS) Test Results for Pharmaceutical Production	September 30, 1998	Do.	Do.	Do.
Manufacture, Processing, or Holding of Active Pharmaceutical Ingredients	April 17, 1998	Do.	Do.	Do.
Marketed Unapproved Drugs—Compliance Policy Guide	October 2003	Do.		Do.
Prescription Drug Marketing Act Regulations for Donation of Prescription Drug Samples to Free Clinics	June 27, 2002	Do.	Do.	Do.
Repackaging of Solid Oral Dosage Form Drug Products	February 1, 1992	Do.	Do.	N/A
Part 11, Electronic Records; Electronic Signatures—Scope and Application	August 2003	Current good manufacturing practices (CGMPs)	Do.	*http://www.fda.gov/cder/guidance/index.htm*
Comparability Protocols—Protein Drug Products and Biological Products—Chemistry, Manufacturing, and Controls Information	September 2003	CGMPs draft	Do.	Do.
Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practices	August 2003	Do.	Do.	Do.
Powder Blends and Finished Dosage Units—Stratified In-Process Dosage Unit Sampling and Assessment	November 7, 2003	Do.	Do.	Do.
Process Analytical Technology—A Framework for Innovative Pharmaceutical Manufacturing and Quality Assurance	October 4, 2004	Do.	Do.	Do.
Sterile Drug Products Produced by Aseptic Processing	October 4, 2004	Do.	Do.	Do.
Providing Electronic Submissions in Electronic Format—ANDAs	June 27, 2002	Electronic submissions	Do.	Do.
Regulatory Submissions in Electronic Format; General Considerations	January 28, 1999	Do.	Do.	Do.
Regulatory Submissions in Electronic Format; New Drug Applications	January 28, 1999	Do.	Do.	Do.
Providing Regulatory Submissions in Electronic Format—Annual Reports for NDAs and ANDAs	August 2003	Electronic submissions draft	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CDER—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
			Mailing Address	Internet Address
Providing Regulatory Submissions in Electronic Format—Content of Labeling	February 2004	Do.	Do.	Do.
Providing Regulatory Submissions in Electronic Format—General Considerations	October 22, 2003	Do.	Do.	Do.
Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Applications and Related Submissions	August 29, 2003	Do.	Do.	Do.
Providing Regulatory Submissions in Electronic Format—Postmarketing Expedited Safety Reports	May 4, 2001	Do.	Do.	Do.
Providing Regulatory Submissions in Electronic Format—Postmarketing Periodic Adverse Drug Experience Reports	June 2003	Do.	Do.	Do.
Providing Regulatory Submissions in Electronic Format, Prescription Drug Advertising and Promotional Labeling	January 31, 2001	Do.	Do.	Do.
180-Day Exclusivity When Multiple Abbreviated New Drug Applications Are Submitted on the Same Day	July 2003	Generics	Do.	
Alternate Source of Active Pharmaceutical Ingredients in Pending ANDAs	December 12, 2000	Do.	Do.	Do.
ANDAs: Impurities in Drug Substances	November 1999	Do.	Do.	Do.
Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act	March 2000	Do.	Do.	Do.
Letter announcing that the OGD will now accept the ICH long-term storage conditions as well as the stability studies conducted in the past	August 1995	Do.	Do.	Do.
Letter describing efforts by the CDER & the ORA to clarify the responsibilities of CDER chemistry review scientists and ORA field investigators in the new & abbreviated drug approval process in order to reduce duplication or redundancy in the process	October 1994	Do.	Do.	Do.
Letter on incomplete Abbreviated Applications, Convictions Under GDEA, Multiple Supplements, Annual Reports for Bulk Antibiotics, Batch Size for Transdermal Drugs, Bioequivalence Protocols, Research, Deviations from OGD Policy	April 1994	Do.	Do.	Do.
Letter on the provision of new information pertaining to new bioequivalence guidelines and refuse-to-file letters	July 1992	Do.	Do.	Do.
Letter on the provision of new procedures and policies affecting the generic drug review process	March 1989	Do.	Do.	Do.
Letter on the request for cooperation of regulated industry to improve the efficiency and effectiveness of the generic drug review process, by assuring the completeness and accuracy of required information and data submissions	November 1991	Do.	Do.	Do.
Letter on the response to 12/20/84 letter from the Pharmaceutical Manufacturers Association about the Drug Price Competition and Patent Term Restoration Act	March 1985	Do.	Do.	Do.

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
			Mailing Address	Internet Address
Letter to all ANDA and AADA applicants about the Generic Drug Enforcement Act of 1992 (GDEA), and the Office of Generic Drugs intention to refuse-to-file incomplete submissions as required by the new law	January 1993	Do.	Do.	Do.
Letter to regulated industry notifying interested parties about important detailed information regarding labeling, scale-up, packaging, minor/major amendment criteria, and bioequivalence requirements	August 1993	Do.	Do.	Do.
Major, Minor, and Telephone Amendments to Abbreviated New Drug Applications	December 2001	Do.	Do.	Do.
Organization of an ANDA	March 2, 1999	Do.	Do.	Do.
Revising ANDA Labeling Following Revision of the RLD Labeling	May 2000	Do.	Do.	Do.
Skin Irritation and Sensitization Testing of Generic Transdermal Drug Products	February 3, 2000	Do.	Do.	Do.
Variations in Drug Products that May Be Included in a Single ANDA	December 1998	Do.	Do.	Do.
ANDAs: Impurities in Drug Products	January 5, 1999	Generics draft	Do.	Do.
Handling and Retention of Bioavailability and Bioequivalence Testing Samples	May 26, 2004	Do.	Do.	Do.
Potassium Chloride Modified-Release Tablets and Capsules: In Vivo Bioequivalence and In Vitro Dissolution Testing (revised)	August 7, 2002	Do.	Do.	Do.
Pharmacology/Toxicology Review Format	May 2001	Good review practices (GRP)	Do.	Do.
Conducting a Clinical Safety Review of a New Product Application and Preparing a Report on the Review	November 22, 1996	GRP draft	Do.	Do.
Good Review Management Principles for Prescription Drug User Fee Act Products	July 28, 2003	Do.	Do.	Do.
E10—Choice of Control Group and Related Issues in Clinical Trials	May 14, 2001	ICH, efficacy	Do.	Do.
E11—Clinical Investigation of Medicinal Products in the Pediatric Population	December 15, 2000	Do.	Do.	Do.
E1A—The Extent of Population Exposure to Assess Clinical Safety: for Drugs Intended for Long-Term Treatment of Non-Life-Threatening Conditions	March 1995	Do.	Do.	Do.
E2A—Clinical Safety Data Management: Definitions and Standards for Expedited Reporting	March 1995	Do.	Do.	Do.
E2B—Data Elements for Transmission of Individual Case Safety Reports	January 15, 1998	Do.	Do.	Do.
E2BM—Data Elements for Transmission of Individual Case Safety Reports (revised)	April 3, 2002	Do.	Do.	Do.
E2BM—Data Elements for Transmission of Individual Case Safety Reports—Questions and Answers	May 2004	Do.	Do.	Do.
E2C—Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs	May 19, 1997	Do.	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CDER—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
			Mailing Address	Internet Address
E2C Addendum—Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs	February 5, 2004	Do.	Do.	Do.
E3—Structure and Content of Clinical Study Reports	July 1996	Do.	Do.	Do.
E4—Dose-Response Information to Support Drug Registration	November 1994	Do.	Do.	Do.
E5—Ethnic Factors in the Acceptability of Foreign Clinical Data	June 1998	Do.	Do.	Do.
E6—Good Clinical Practice: Consolidated Guideline	May 9, 1997	Do.	Do.	Do.
E7—Studies in Support of Special Populations: Geriatrics	August 1994	Do.	Do.	Do.
E8—General Considerations for Clinical Trials	December 24, 1997	Do.	Do.	Do.
E9—Statistical Principles for Clinical Trials	September 1998	Do.	Do.	Do.
M2 eCTD: Electronic Common Technical Document Specification	April 2, 2003	ICH, joint safety/efficacy (multidisciplinary)	Do.	Do.
M3—Nonclinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals	November 25, 1997	Do.	Do.	Do.
M4—Organization of the CTD	August 2004	Do.	Do.	Do.
M4—The CTD—Efficacy Questions and Answers	May 2004	Do.	Do.	Do.
M4—The CTD—General Questions and Answers	May 2004	Do.	Do.	Do.
M4—The CTD—Safety Questions and Answers	February 4, 2003	Do.	Do.	Do.
Q1A(R2)—Stability Testing of New Drug Substances and Products	November 21, 2003	ICH, quality	Do.	Do.
Q1B—Photostability Testing of New Drug Substances and Products	November 1996	Do.	Do.	Do.
Q1C—Stability Testing for New Dosage Forms	May 9, 1997	Do.	Do.	Do.
Q1D—Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products	January 16, 2003	Do.	Do.	Do.
Q1F—Stability Data Package for the Registration in Climatic Zones III and IV	June 2004	Do.	Do.	Do.
Q2A—Text on Validation of Analytical Procedures	March 1995	Do.	Do.	Do.
Q2B—Validation of Analytical Procedures: Methodology	May 19, 1997	Do.	Do.	Do.
Q3A—Impurities in New Drug Substances	February 2003	Do.	Do.	Do.
Q3B(R)—Impurities in Drug Products	November 14, 2003	Do.	Do.	Do.
Q3C—Impurities: Residual Solvents	December 24, 1997	Do.	Do.	Do.
Q3C—Tables and List (revised recommendations for N-Methylpyrrolidone and Tetrahydrofuran)	November 2003	Do.	Do.	Do.
Q5A—Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Origin	September 24, 1998	Do.	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CDER—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
			Mailing Address	Internet Address
Q5B—Quality of Biotechnology Products: Analysis of the Expression Construct in Cells Used for Production of r-DNA Derived Protein Products	February 1996	Do.	Do.	Do.
Q5C—Quality of Biotechnological Products: Stability Testing of Biotechnology/Biological Products	July 1996	Do.	Do.	Do.
Q5D—Quality of Biotechnological/Biological Products: Derivation and Characterization of Cell Substrates Used for Production of Biotechnological/Biological Products	September 21, 1998	Do.	Do.	Do.
Q6A—Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances	December 29, 2000	Do.	Do.	Do.
Q6B—Test Procedures and Acceptance Criteria for Biotechnological/Biological Products	August 18, 1999	Do.	Do.	Do.
Q7A—Good Manufacturing Practice for Active Pharmaceutical Ingredients	August 2001	Do.	Do.	Do.
S1A—The Need for Long-Term Rodent Carcinogenicity Studies of Pharmaceuticals	March 1996	ICH, safety	Do.	Do.
S1B—Testing for Carcinogenicity of Pharmaceuticals	July 1997	Do.	Do.	Do.
S1C—Dose Selection for Carcinogenicity Studies of Pharmaceuticals	March 1995	Do.	Do.	Do.
S1C(R)—Dose Selection for Carcinogenicity Studies of Pharmaceuticals: Addendum on a Limit Dose and Related Notes	December 4, 1997	Do.	Do.	Do.
S2A—Specific Aspects of Regulatory Genotoxicity Tests for Pharmaceuticals	April 1996	Do.	Do.	Do.
S2B—Genotoxicity: A Standard Battery for Genotoxicity Testing of Pharmaceuticals	November 21, 1997	Do.	Do.	Do.
S3A—Toxicokinetics: The Assessment of Systemic Exposure in Toxicity Studies	March 1995	Do.	Do.	Do.
S3B—Pharmacokinetics: Repeated Dose Tissue Distribution Studies	March 1995	Do.	Do.	Do.
S4A—Duration of Chronic Toxicity Testing in Animals (Rodent and Nonrodent Toxicity Testing)	June 25, 1999	Do.	Do.	Do.
S5A—Detection of Toxicity to Reproduction for Medicinal Products	September 22, 1994	Do.	Do.	Do.
S5B—Detection of Toxicity to Reproduction for Medicinal Products: Addendum on Toxicity to Male Fertility	April 1996	Do.	Do.	Do.
S6—Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals	November 18, 1997	Do.	Do.	Do.
S7A—Safety Pharmacology Studies for Human Pharmaceuticals	July 13, 2001	Do.	Do.	Do.
E2D—Postapproval Safety Data Management: Definitions and Standards for Expedited Reporting	July 2003	ICH draft, efficacy	Do.	Do.
E12A—Principles for Clinical Evaluation of New Antihypertensive Drugs	August 9, 2000	Do.	Do.	Do.

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M4—Common Technical Document—Quality: Questions and Answers/Location Issues	December 30, 2002	ICH draft, joint safety/efficacy (multidisciplinary)	Do.	Do.
Submitting Marketing Appilcations According to the ICH–CTD Format—General Considerations	September 5, 2001	Do.	Do.	Do.
Q1E—Evaluation of Stability Data	June 14, 2002	ICH draft, quality	Do.	Do.
S7B—The Nonclinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals	June 2004	ICH draft, safety	Do.	Do.
Content and Format of INDs for Phase 1 Studies of Drugs; Including Well-Characterized, Therapeutic, Biotechnology-Derived Products	November 1995	IND	Do.	Do.
A Revision in Sample Collection Under the Compliance Program Pertaining to Preapproval Inspections	July 15, 1996	Industry letters	Do.	N/A
Continuation of a series of letters communicating interim and informal generic drug policy and guidance. Availability of Policy and Procedure Guides, and further operational changes to the generic drug review program	March 2, 1998	Do.	Do.	*http://www.fda.gov/cder/guidance/index.htm*
Fifth of a series of letters providing informal notice about the Act, discussing the statutory mechanism by which ANDA applicants may make modifications in approved drugs where clinical data is required	April 1987	Do.	Do.	Do.
Fourth of a series of letters providing informal notice to all affected parties about policy developments and interpretations regarding the Act. Three year exclusivity provisions of Title I	October 1986	Do.	Do.	Do.
Implementation of the Drug Price Competition and Patent Term Restoration Act. Preliminary Guidance	October 1984	Do.	Do.	Do.
Implementation Plan USP injection nomenclature	October 1995	Do.	Do.	Do.
Instructions for Filing Supplements Under the Provisions of SUPAC–IR	April 11, 1996	Do.	Do.	N/A
Seventh of a series of letters about the Act providing guidance on the "180-day exclusivity" provision of section 505(j)(4)(B)(iv) of the FD&C Act	July 1988	Do.	Do.	*http://www.fda.gov/cder/guidance/index.htm*
Sixth of a series of informal notice letters about the Act discussing 3- and 5-year exclusivity provisions of sections 505(c)(3)(D) and 505(j)(4)(D) of the FD&C Act	April 1988	Do.	Do.	Do.
Streamlining Initiatives	December 24, 1996	Do.	Do.	N/A
Supplement to 10/11/84 letter about policies, procedures and implementation of the Act (Q & A format)	November 1984	Do.	Do.	*http://www.fda.gov/cder/guidance/index.htm*
Third of a series of letters regarding the implementation of the Act	May 1985	Do.	Do.	Do.
Year 2000 Letter from Dr. Janet Woodcock	October 19, 1998	Do.	Do.	Do.
Barbiturate, Single Entity-Class Labeling	March 1, 1981	Labeling	Do.	N/A

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
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Content and Format for Geriatric Labeling	October 5, 2001	Do.	Do.	*http://www.fda.gov/cder/guidance/index.htm*
Hypoglycemic Oral Agents	April 1, 1984	Do.	Do.	N/A
Labeling Over-the-Counter Human Drug Products; Updating Labeling in Reference Listed Drugs and Abbreviated New Drug Applications	October 18, 2002	Do.	Do.	*http://www.fda.gov/cder/guidance/index.htm*
Local Anesthetics—Class Labeling	September 1, 1982	Do.	Do.	N/A
Clinical Studies Section of Labeling for Prescription Drugs and Biologics—Content and Format	July 9, 2001	Labeling draft	Do.	*http://www.fda.gov/cder/guidance/index.htm*
Content and Format of the Adverse Reactions Section of Labeling for Human Prescription Drugs and Biologics	March 5, 2004	Do.	Do.	Do.
Labeling for Combined Oral Contraceptives	March 2004	Do.	Do.	Do.
Labeling for Noncontraceptive Estrogen Drug Products for the Treatment of Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms—Prescribing Information for Health Care Providers and Patient Labeling	February 2004	Do.	Do.	Do.
OTC Topical Drug Products for the Treatment of Vaginal Yeast Infections (Vulvovaginal Candidiasis)	June 1998	Do.	Do.	Do.
Referencing Discontinued Labeling for Listed Drugs in Abbreviated New Drug Applications	October 26, 2000	Do.	Do.	Do.
Enforcement Policy on Marketing OTC Combination Products (CPG 7132b.16)	May 1984	OTC	Do.	Do.
General Guidelines for OTC Combination Products	September 1978	Do.	Do.	Do.
Labeling OTC Human Drug Products Using a Column Format	December 19, 2000	Do.	Do.	Do.
Upgrading Category III Antiperspirants to Category I (43 FR 46728–46731)	October 1978	Do.	Do.	Do.
Labeling OTC Human Drug Products—Submitting Requests for Exemptions and Deferrals	December 19, 2000	OTC draft	Do.	Do.
Labeling OTC Human Drug Products Updating Labeling in ANDAs	February 2001	Do.	Do.	Do.
OTC Actual Use Studies	July 22, 1994	Do.	Do.	N/A
OTC Nicotine Substitutes	March 1, 1994	Do.	Do.	Do.
Time and Extent Applications	February 10, 2004	Do.	Do.	*http://www.fda.gov/cder/guidance/index.htm*
Carcinogenicity Study Protocol Submissions	May 2002	Pharmacology/Toxicology	Do.	Do.
Format and Content of the Nonclinical Pharmacology/Toxicology Section of an Application	February 1987	Do.	Do.	Do.
Immunotoxicology Evaluation of Investigational New Drugs	October 2002	Do.	Do.	Do.

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
			Mailing Address	Internet Address
Nonclinical Pharmacology/Toxicology Development of Topical Drugs Intended to Prevent the Transmission of Sexually Transmitted Diseases (STD) and/or for the Development of Drugs Intended to Act as Vaginal Contraceptives	October 1996	Do.	Do.	Do.
Photosafety Testing	May 7, 2003	Do.	Do.	Do.
Reference Guide for the Nonclinical Toxicity Studies of Antiviral Drugs Indicated for the Treatment of N/A Non-Life Threatening Disease: Evaluation of Drug Toxicity Prior to Phase I Clinical Studies	February 1989	Do.	Do.	Do.
Single Dose Acute Toxicity Testing for Pharmaceuticals	August 1996	Do.	Do.	Do.
Estimating the Safe Starting Dose in Clinical Trials for Therapeutics in Adult Healthy Volunteers	January 16, 2003	Pharmacology/ Toxicology draft	Do.	Do.
Integration of Study Results to Access Concerns About Human Reproductive and Developmental Toxicities	November 13, 2001	Do.	Do.	Do.
Nonclinical Safety Evaluation of Pediatric Drug Products	February 2003	Do.	Do.	Do.
Nonclinical Studies for Development of Pharmaceutical Excipients	October 2, 2002	Do.	Do.	Do.
Statistical Aspects of the Design, Analysis, and Interpretation of Chronic Rodent Carcinogenicity Studies of Pharmaceuticals	May 8, 2001	Do.	Do.	Do.
180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act	June 1998	Procedural	Do.	Do.
Continuous Marketing Applications: Pilot 1—Reviewable Units for Fast Track Products Under the PDUFA	October 2003	Do.	Do.	Do.
Continuous Marketing Applications: Pilot 2—Scientific Feedback and Interactions During Drug Development of Fast Track Products Under the PDUFA	October 2003	Do.	Do.	Do.
Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act	March 27, 2000	Do.	Do.	Do.
Disclosure of Materials Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Convened by the Center for Drug Evaluation and Research Beginning on January 1, 2000	November 30, 1999	Do.	Do.	Do.
Drug Products Containing Ensulizole, Hypromellose, Meradimate, Octinoxate, and Octisalate—Labeling Enforcement Policy	June 3, 2003	Do.	Do.	Do.
Enforcement Policy During Implementation of Section 503A of the Federal Food, Drug, and Cosmetic Act	November 23, 1998	Do.	Do.	Do.
Fast Track Drug Development Programs—Designation, Development, and Application Review	July 2004	Do.	Do.	Do.
Financial Disclosure by Clinical Investigators	March 2001	Do.	Do.	Do.
Formal Dispute Resolution: Appeals Above the Division Level	February 2000	Do.	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CDER—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
			Mailing Address	Internet Address
Formal Meetings With Sponsors and Applicants For PDUFA Products	February 2003	Do.	Do.	Do.
Implementation of Section 120 of the Food and Drug Administration Modernization Act of 1997—Advisory Committees	November 2, 1998	Do.	Do.	Do.
Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997—Elimination of Certain Labeling Requirements	July 21, 1998	Do.	Do.	Do.
Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions	January 27, 2004	Do.	Do.	Do.
Potassium Iodide in Radiation Emergencies—Questions and Answers	December 23, 2002	Do.	Do.	Do.
Potassium Iodide Tablets for Shelf Life Extension for Federal Agencies and State and Local Governments	March 8, 2004	Do.	Do.	Do.
Levothyroxine Sodium Products Enforcement of August 14, 2001, Compliance Date and Submission of New Applications	July 13, 2001	Do.	Do.	Do.
National Uniformity for Nonprescription Drugs—Ingredient Listing for OTC Drugs	April 9, 1998	Do.	Do.	Do.
Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies	December 11, 2001	Do.	Do.	Do.
Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act (revised)	September 1999	Do.	Do.	Do.
Refusal to File	July 12, 1993	Do.	Do.	Do.
Repeal of Section 507 of the Federal Food, Drug, and Cosmetic Act	May 1998	Do.	Do.	Do.
Special Protocol Assessment	May 17, 2002	Do.	Do.	Do.
Standards for the Prompt Review of Efficacy Supplements, Including Priority Efficacy Supplements	May 15, 1998	Do.	Do.	Do.
Guidance for FDA Staff: The Leveraging Handbook; an Agency Resource for Effective Collaborations	June 19, 2003	Do.	Do.	Do.
Women and Minorities Guidance Requirements	July 20, 1998	Do.	Do.	Do.
Applications Covered by Section 505(b)(2)	October 1999	Procedural draft	Do.	Do.
Clinical Trial Sponsors On the Establishment and Operation of Clinical Trial Data Monitoring Committees	November 2001	Do.	Do.	Do.
PET Drug Applications—Content and Format for NDAs and ANDAs	March 2000	Do.	Do.	Do.
Disclosing Information Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Related to the Testing or Approval of New Drugs and Convened by CDER, Beginning January 1, 2000	December 22, 1999	Do.	Do.	Do.
Disclosure of Conflicts of Interest for Special Government Employees Participating in FDA Product Specific Advisory Committees	February 14, 2002	Do.	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CDER—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
			Mailing Address	Internet Address
Forms for Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution	April 2001	Do.	Do.	Do.
Good Review Management Principles for PDUFA Products	July 28, 2003	Do.	Do.	Do.
Independent Consultants for Biotechnology Clinical Trial Protocols	May 7, 2003	Do.	Do.	Do.
Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions	January 27, 2004	Do.	Do.	Do.
Pharmacogenomic Data Submissions	January 27, 2004	Do.	Do.	Do.
Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines	March 12, 2001	Do.	Do.	Do.
Reports on the Status of Postmarketing Studies—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997	April 4, 2001	Do.	Do.	Do.
Submitting Debarment Certification Statements	October 2, 1998	Do.	Do.	Do.
Submitting Marketing Applications According to the ICH/CTD Format—General Considerations	September 5, 2001	Do.	Do.	Do.
The Use of Clinical Holds Following Clinical Investigator Misconduct	April 2002	Do.	Do.	Do.
Sterility Requirements for Aqueous-Based Drug Products for Oral Inhalation—Small Entity Compliance Guide	November 7, 2001	Small entity compliance guides	Do.	Do.
Applicability of User Fees to (1) Applications Withdrawn Before Filing, or (2) Applications the Agency Has Refused to File and That Are Resubmitted or Filed Over Protest (Attachment F)	July 12, 1993	User fee	Do.	Do.
Application, Product, and Establishment Fees: Common Issues and Their Resolution (revised) (attachment D) (I)	December 16, 1994	Do.	Do.	Do.
Classifying Resubmissions in Response to Action Letters	May 14, 1998	Do.	Do.	Do.
Fees-Exceed-the-Costs Waivers Under the Prescription Drug User Fee Act	June 1999	Do.	Do.	Do.
Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act	November 21, 2001	Do.	Do.	Do.
Submitting and Reviewing Complete Responses to Clinical Holds (revised)	October 26, 2000	Do.	Do.	Do.
Document for Waivers of and Reductions in User Fees (attachment G)	July 16, 1993	User fees draft	Do.	Do.
Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees	December 2000	Do.	Do.	Do.
WITHDRAWALS				
In Vivo Bioequivalence Studies on Population and Individual Bioequivalence Studies	December 30, 1987	Do.	Do.	
Clinical Evaluation of Antacid Drugs	April 1, 1978	N/A	N/A	
Clinical Evaluation of Antidiarrheal Drugs	September 1, 1977	Do.	Do.	

GUIDANCE DOCUMENTS ISSUED BY CDER—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
			Mailing Address	Internet Address
Clinical Evaluation of Gastric Secretory Depressant (GSD) Drugs	September 1, 1977	Do.	Do.	
Clinical Evaluation of Laxative Drugs	April 1, 1978	Do.	Do.	
Clinical Evaluation of Radiopharmaceutical Drugs	October 1, 1981	Do.	Do.	
FDA Requirements for Approval of Drugs to Treat Superficial Bladder Cancer	June 20, 1989	Do.	Do.	
ANDAs: Blend Uniformity Analysis	August 27, 1999	Do.	Do.	
Topical Dermatological Drug Products NDAs and ANDAs—In Vivo Bioavailability, Bioequivalence, In Vitro Release, and Associated Studies	June 18, 1998	Do.	Do.	
Clinical Evaluation of Combination Estrogen/Progestin-Containing Drug Products Used for Hormone Replacement Therapy of Postmenopausal Women	March 1, 1995	Do.	Do.	
Noncontraceptive Estrogen Drug Products—Prescribing Information for Healthcare Providers and Patient Labeling	September 27, 1999	Do.	Do.	
Chlordiazepoxide Hydrochloride Capsules	January 1, 1988	Do.	Do.	
Clorazepate Dipotassium Capsules/Tablets	March 1, 1993	Do.	Do.	
Cyproheptadine Hydrochloride Tablets/Syrup	December 1, 1986	Do.	Do.	
Dipivefrin Hydrochloride Ophthalmic Solution, 0.1%	November 2, 1998	Do.	Do.	
Ergoloid Mesylate Tablets	January 1, 1988	Do.	Do.	
Hydroxyzine Hydrochloride Injection	December 1, 1989	Do.	Do.	
Isoetharine Inhalation Solution	March 1, 1989	Do.	Do.	
Meclofenamate Sodium Capsules	July 1, 1992	Do.	Do.	
Naphazoline Hydrochloride Ophthalmic Solution	March 1, 1989	Do.	Do.	
Niacin Tablets	July 1, 1992	Do.	Do.	
Phendimetrazine Tartrate Capsules/Tablets and Extended-Release Capsules	February 1, 1991	Do.	Do.	
Phentermine Hydrochloride Capsules/Tablets	August 1, 1988	Do.	Do.	
Promethazine Hydrochloride Tablets	March 1, 1990	Do.	Do.	
Propantheline Bromide Tablets	August 1, 1988	Do.	Do.	
Pyridoxine Hydrochloride Injection	June 1, 1984	Do.	Do.	
Quinidine Sulfate Capsules USP	October 1, 1995	Do.	Do.	
Sulfamethoxazole and Phenazopyridine Hydrochloride Tablets	February 1, 1992	Do.	Do.	
Theophylline Immediate Release Oral Dosage Forms	February 1, 1995	Do.	Do.	
Thiamine Hydrochloride Injection	February 1, 1988	Do.	Do.	
Vitamin A Capsules	February 1, 1992	Do.	Do.	
Part 11; Electronic Records; Electronic Signatures, Electronic Copies of Electronic Records	November 12, 2002	Do.	Do.	

GUIDANCE DOCUMENTS ISSUED BY CDER—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
			Mailing Address	Internet Address
Clinical Evaluation of Analgesic Drugs	December 1, 1992	Do.	Do.	
Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements	April 23, 2001	Do.	Do.	

GUIDANCE DOCUMENTS ISSUED BY CDRH

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
Guidance for Industry, FDA Staff, and Third Parties; Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria	October 4, 2004	FDA, regulated industry, and third parties	Division of Small Manufacturers, International and Consumer Assistance, 1–800–638–2041 or 301–443–6597; or Facts-on-Demand,[1] 301–827–0111; or Internet at *http://www.fda.gov/cdrh/guidance.html*
Implementation of Third Party Programs Under the FDA Modernization Act of 1997; Final Guidance for Staff, Industry, and Third Parties	February 2, 2001	Do.	Do.
Mutual Recognition Agreement Between the European Union and the United States of America: Confidence Building Programme: Overview and Procedure; Medical Device Annex, Version 7, June 29, 2000; Draft	June 29, 2000	FDA and regulated industry	Do.
Draft Guidance for Industry and FDA; Medical Glove Guidance Manual	July 30, 1999	Do.	Do.
Guidance for Industry and FDA; Regulation of Medical Devices; Background Information for International Officials (entire document available on disk)	April 14, 1999	Do.	Do.
Guidance for Staff, Industry, and Third Parties; Third Party Programs Under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community (MRA)	January 6, 1999	Do.	Do.
Medical Device Appeals and Complaints: Guidance on Dispute Resolution	February 1998	Do.	Do.
Overview of FDA Modernization Act of 1997 Medical Device Provisions	February 19, 1998	Do.	Do.
Medical Device Reporting for Manufacturers	March 1997	Do.	Do.
In Vitro Diagnostic Devices: Guidance for the Preparation of 510(k) Submissions (FDA 97–4224)	January 1997	Do.	Do.
Medical Device Quality Systems Manual: A Small Entity Compliance Guide	April 14, 1999	Do.	Do.
Comparison Chart: 1996 Quality System Regulation vs. 1978 Good Manufacturing Practices Regulation vs. ANSI/ISO/ASQC Q9001–1994 and ISO/DIS 13485:1996	November 29, 1996	Do.	Do.
Premarket Notification: 510(k)—Regulatory Requirements for Medical Devices (FDA 95–4158)	August 1995	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
Labeling—Regulatory Requirements for Medical Devices	September 1, 1989	Do.	Do.
Impact Resistant Lenses: Questions and Answers (FDA 87–4002)	September 1987	Do.	Do.
CDRH Manual for the GGP Regulations; Final Guidance for FDA Staff	February 9, 2001	FDA	Do.
Human Factors Principles for Medical Device Labeling	September 1, 1993	FDA, regulated industry	Do.
Human Factors PTC for IDE Devices	January 17, 1997	Do.	Do.
Write It Right	August 1993	Do.	Do.
Do It By Design—An Introduction to Human Factors in Medical Devices	December 1996	Do.	Do.
Guidance for Industry and FDA Premarket and Design Control Reviewers; Medical Device Use—Safety: Incorporating Human Factors Engineering into Risk Management	July 18, 2000	Do.	Do.
Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers	April 19, 2001	Do.	Do.
Medical Device Reporting for User Facilities	April 1996	FDA and user facilities	Do.
Frequently-Asked Questions About the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors; Final Guidance for Industry and FDA Staff	July 6, 2001	FDA, regulated industry, third party, and hospital reprocessors	Do.
Frequently-Asked Questions About the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors; Three Additional Questions	July 16, 2003	Do.	Do.
Continuing Education Credit for Reading/Writing Articles/Papers and Presenting Courses/Lectures (incorporated into the Policy Guidance Help System (PGHS))	March 17, 1998	FDA, accreditation bodies, and mammography facilities	Do.
Guidance for Submission of Request for Reconsideration of Adverse Decisions on Accreditation of Mammography Facilities Under the Mammography Quality Standards Acts, 42 U.S.C. 263(b)/4/8, 1998 (incorporated into PGHS)	March 26, 1998	Do.	Do.
Guidance for Review of Requests for Reconsideration of Adverse Decisions on Accreditation of Mammography Facilities Under the Mammography Quality Standards Act, 42 U.S.C. 263(b)/4/8, 1998 (incorporated into PGHS)	March 26, 1998	Do.	Do.
Policy and Standard Operating Procedures When Mammography Facilities in States That Have Accreditation Bodies Intend to Change Accreditation Bodies (incorporated into PGHS)	April 15, 1998	Do.	Do.
Guidance for Industry; Requalification for Interpreting Physician's Continuing Experience Requirement (incorporated into PGHS)	May 28, 1998	Do.	Do.
Guidance; The Mammography Quality Standards Act Final Regulations; Document #1 (incorporated into PGHS)	March 19, 1999	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
Compliance Guidance; The Mammography Quality Standards Act Final Regulations Motion of Tube-Image Receptor Assembly (incorporated into PGHS)	March 23, 1999	Do.	Do.
Guidance for Request and Issuance of Interim Notice Letters for Mammography Facilities Under the Mammography Quality Standards Act, 42 U.S.C. Section 263(b) (incorporated into PGHS)	May 4, 1999	Do.	Do.
Compliance Guidance; The Mammography Quality Standards Act Final Regulations Quality Assurance Documentation (incorporated into PGHS)	December 7, 1999	Do.	Do.
Compliance Guidance; The Mammography Quality Standards Act Final Regulations; Document #2 (incorporated into PGHS)	February 25, 2000	Do.	Do.
The Mammography Quality Standards Act Final Regulations Modifications to the Policy Guidance Help System #1; Guidance for Industry and FDA (incorporated into PGHS)	July 5, 2000	Do.	Do.
Compliance Guidance; The Mammography Quality Standards Act Final Regulations; Document #3 (incorporated into PGHS)	July 18, 2000	Do.	Do.
Compliance Guidance; Mammography Facility Survey, Equipment Evaluation, and Medical Physicist Qualification Requirements Under MQSA; Final (incorporated into PGHS)	November 6, 2000	Do.	Do.
The Mammography Quality Standards Act Final Regulations; Modifications and Additions to Policy Guidance Help System #2; Final Guidance for Industry and FDA (incorporated into PGHS)	January 24, 2001	Do.	Do.
The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #4; Guidance for Industry and FDA (incorporated into PGHS)	May 23, 2001	Do.	Do.
The Mammography Quality Standards Act Final Regulations Modifications to the Policy Guidance Help System Due to the September 11, 2002, Terrorist Attacks; Final Guidance for Industry and FDA (incorporated into PGHS)	October 5, 2001	Do.	Do.
The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #3; Guidance for Industry and FDA (incorporated into PGHS)	November 5, 2001	Do.	Do.
Compliance Guidance; The Mammography Quality Standards Act Final Regulations—Preparing for MQSA Inspections (incorporated into PGHS)	November 5, 2001	Do.	Do.
The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #4; Guidance for Industry and FDA (incorporated into PGHS)	March 25, 2002	Do.	Do.
The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #5; Guidance for Industry and FDA (incorporated into PGHS)	July 8, 2002	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #7; Guidance for Industry and FDA (incorporated into PGHS)	January 28, 2003	Do.	Do.
The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #6 (incorporated into PGHS)	August 19, 2003	Do.	Do.
Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations to State and Local Agencies	August 13, 1998	FDA, State and local agencies	Do.
Office of Device Evaluation			
FY 2004 MDUFMA Small Business Qualification Worksheet and Certification; Guidance for Industry and FDA	August 1, 2003	Office of Device Evaluation	Do.
Premarket Assessment of Pediatric Medical Devices; Draft Guidance for Industry and FDA Staff	July 24, 2003	Do.	Do.
Pediatric Expertise for Advisory Panels; Guidance for Industry and FDA Staff	June 3, 2003	Do.	Do.
Premarket Approval Application Filing Review; Guidance for Industry and FDA Staff	May 1, 2003	Do.	Do.
Guidance for Industry and FDA; FY 2003 MDUFMA Small Business Qualification Worksheet and Certification	March 27, 2003	Do.	Do.
Assessing User Fees: PMA Supplement Definitions, Modular PMA Fees, BLA and Efficacy Supplement Definitions, Bundling Multiple Devices in a Single Application, and Fees for Combination Products	February 21, 2003	Do.	Do.
Determination of Intended Use for 510(k) Devices; Guidance for CDRH Staff	December 3, 2002	Do.	Do.
The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles; Final Guidance for FDA and Industry	October 4, 2002	Do.	Do.
Medical Devices Made With Polyvinylchloride (PVC) Using the Plasticizer di-(2-Ethylhexyl)phthalate (DEHP); Draft Guidance for Industry and FDA	September 6, 2002	Do.	Do.
Updated 510(k) Sterility Review Guidance K90–1; Final Guidance for Industry and FDA	August 30, 2002	Do.	Do.
Availability of Information Given to Advisory Committee Members in Connection With CDRH Open Public Panel Meetings; Draft Guidance for Industry and FDA Staff	July 18, 2001	Do.	Do.
Humanitarian Device Exemptions (HDE) Regulation: Questions and Answers; Final Guidance for Industry	July 12, 2001	Do.	Do.
Changes or Modifications During the Conduct of a Clinical Investigation; Final Guidance for Industry and CDRH Staff	May 29, 2001	Do.	Do.
Early Collaboration Meetings Under the FDA Modernization Act (FDAMA); Final Guidance for Industry and for CDRH Staff	February 28, 2001	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
Deciding When To Submit a 510(k) for a Change to an Existing Wireless Telemetry Medical Device; Final Guidance for FDA Reviewers and Industry	November 30, 2000	Do.	Do.
Guidance on Section 216 of the Food and Drug Administration Modernization Act of 1997	August 9, 2000	Do.	Do.
Guidance on Amended Procedures for Advisory Panel Meetings; Final	July 22, 2000	Do.	Do.
Guidance on the Use of Standards in Substantial Equivalence Determinations; Final	March 12, 2000	Do.	Do.
Guidance for Off-the-Shelf Software Use in Medical Devices; Final	September 9, 1999	Do.	Do.
Draft Guidance on Evidence Models for the Least Burdensome Means to Market	September 1, 1999	Do.	Do.
Medical Devices Containing Materials Derived from Animal Sources (Except In Vitro Diagnostic Devices); Final Guidance for FDA Reviewers and Industry	November 16, 1998	Do.	Do.
Guidance for the Medical Device Industry on PMA Shell Development and Modular Review; Final	November 6, 1998	Do.	Do.
Guidance for Industry; General/Specific Intended Use; Final	November 4, 1998	Do.	Do.
Frequently Asked Questions on the New 510(k) Paradigm; Final	October 22, 1998	Do.	Do.
Modifications to Devices Subject to Premarket Approval—The PMA Supplement Decision Making Process; Draft	August 6, 1998	Do.	Do.
Guidance for Industry; Contents of a Product Development Protocol; Draft	July 27, 1998	Do.	Do.
New Model Medical Device Development Process; Final	July 21, 1998	Do.	Do.
Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices; Final	May 29, 1998	Do.	Do.
Guidance to Industry Supplements to Approved Applications for Class III Medical Devices: Use of Published Literature, Use of Previously Submitted Materials, and Priority Review; Final	May 20, 1998	Do.	Do.
A New 510(k) Paradigm—Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications	March 20, 1998	Do.	Do.
PMA/510(k) Expedited Review; Guidance for Industry and CDRH Staff; Final	March 20, 1998	Do.	Do.
PMA/510(k) Expedited Review G94–4 (blue book memo)	March 20, 1998	Do.	Do.
30-Day Notices and 135-Day PMA Supplements for Manufacturing Method or Process Changes; Guidance for Industry and CDRH (Docket No. 98D–0080); Final	February 19, 1998	Do.	Do.
Guidance on PMA Interactive Procedures for Day-100 Meetings and Subsequent Deficiencies—for Use by CDRH and Industry; Final	February 19, 1998	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
New section 513(f)(2)--Evaluation of Automatic Class III Designation; Guidance for Industry and CDRH Staff; Final	February 19, 1998	Do.	Do.
Procedures for Class II Device Exemptions from Premarket Notification Guidance for Industry and CDRH Staff; Final	February 19, 1998	Do.	Do.
Guidance on IDE Policies and Procedures; Final	January 20, 1998	Do.	Do.
Distribution and Public Availability of PMA Summary of Safety and Effectiveness Data Packages	October 10, 1997	Do.	Do.
Kit Certification for 510(k)s	July 1, 1997	Do.	Do.
Convenience Kits Interim Regulatory Guidance	May 20, 1997	Do.	Do.
Real-Time Review Program for Premarket Aproval Application (PMA) Supplements	April 22, 1997	Do.	Do.
Deciding When to Submit a 510(k) for a Change to an Existing Device (K97–1)	January 10, 1997	Do.	Do.
Questions and Answers for the FDA Reviewer Guidance: Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities	September 3, 1996	Do.	Do.
Memorandum of Understanding Regarding Patient Labeling Review (blue book memo #G96–3)	August 9, 1996	Do.	Do.
Continued Access to Investigational Devices During PMA Preparation and Review (blue book memo #D96–1)	July 15, 1996	Do.	Do.
Document Review by the Office of the Chief Counsel (blue book memo G96–1)	June 6, 1996	Do.	Do.
Format for IDE Progress Reports	June 1, 1996	Do.	Do.
Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance	April 1, 1996	Do.	Do.
510(k) Quality Review Program (blue book memo)	March 29, 1996	Do.	Do.
Suggested Content for Original IDE Application Cover Letter	February 27, 1996	Do.	Do.
Indications for Use Statement	January 2, 1996	Do.	Do.
Letter—Vascular Graft Industry (Philip Phillips)	November 22, 1995	Do.	Do.
Cover Letter: 510(k) Requirements During Firm-Initiated Recalls; Attachment A: Guidance on Recall and Premarket Notification Review Procedures During Firm-Initiated Recalls of Legally Marketed Devices (blue book memo #K95–1)	November 21, 1995	Do.	Do.
Color Additives for Medical Devices (Snesko)	November 15, 1995	Do.	Do.
#D95–2, Attachment A (Interagency Agreement between FDA and HCFA)	September 15, 1995	Do.	Do.
#D95–2, Attachment B (Criteria for Categorization of Investigational Devices (HCFA))	September 15, 1995	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
HCFA Reimbursement Categorization Determinations for FDA-Approved IDEs	September 15, 1995	Do.	Do.
Implementation of the FDA/HCFA Interagency Agreement Regarding Reimbursement Categorization of Investigational Devices, Attachment A Interagency Agreement, Attachment B Criteria for Catergorization of Investigational Devices, and Attachment C—List (blue book memo #D95–2)	September 15, 1995	Do.	Do.
Goals and Initiatives for the IDE Program (blue book memo #D95–1)	July 12, 1995	Do.	Do.
Memorandum: Electromagnetic Compatibility for Medical Devices: Issues and Solutions	June 13, 1995	Do.	Do.
Use of International Standard ISO–10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" (replaces #G87–1 #8294) (blue book memo)	May 1, 1995	Do.	Do.
Premarket Approval Application (PMA) Closure (blue book memo #P94–2)	July 8, 1994	Do.	Do.
510(k) Sign-Off Procedures (blue book memo #K94–2)	June 3, 1994	Do.	Do.
Letter to Industry, Powered Wheelchair/Scooter or Accessory/Component Manufacturer from Susan Alpert, Ph.D., M.D.	May 26, 1994	Do.	Do.
510(k) Refuse to Accept Procedures (blue book memo #K94–1)	May 20, 1994	Do.	Do.
IDE Refuse to Accept Procedures (blue book memo #D94–1)	May 20, 1994	Do.	Do.
PMA/510(k) Triage Review Procedures (blue book memo #G94–1)	May 20, 1994	Do.	Do.
Preamendments Class III Strategy	April 19, 1994	Do.	Do.
Premarket Notification (510(k)) Status Request Form	March 7, 1994	Do.	Do.
Documentation and Resolution of Differences of Opinion on Product Evaluations (blue book memo #G93–1)	December 23, 1993	Do.	Do.
510(k) Additional Information Procedures (blue book memo #K93–1)	July 23, 1993	Do.	Do.
CDRH's Investigational Device Exemption (IDE) Refuse to Accept Policy	June 30, 1993	Do.	Do.
CDRH's Premarket Notification (510(k)) Refuse to Accept Policy (updated checklist March 14, 1995)	June 30, 1993	Do.	Do.
Proposal for Establishing Mechanisms for Setting Review Priorities Using Risk Assesment and Allocating Review Resources	June 30, 1993	Do.	Do.
Classified Convenience Kits	April 30, 1993	Do.	Do.
Telephone Communications Between ODE Staff and Manufacturers (blue book memo #I93–1)	January 29, 1993	Do.	Do.
Preamendment Class III Devices	March 11, 1992	Do.	Do.
Nondisclosure of Financially Sensitive Information (blue book memo #I92–1)	March 5, 1992	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
Document Review Processing (blue book memo #I91–1)	February 12, 1992	Do.	Do.
4-of-a-Kind PMAs	October 1, 1991	Do.	Do.
Review of 510(k)s for Computer Controlled Medical Devices (blue book memo #K91–1)	August 29, 1991	Do.	Do.
Review of Final Draft Medical Device Labeling (blue book memo #P91–4)	August 29, 1991	Do.	Do.
Integrity of Data and Information Submitted to ODE (blue book memo #I91–2)	May 29, 1991	Do.	Do.
Clinical Utility and Premarket Approval (blue book memo #P91–1)	May 3, 1991	Do.	Do.
Panel Review of Premarket Approval Applications (blue book memo #P91–2)	May 3, 1991	Do.	Do.
PMA Compliance Program (blue book memo #P91–3)	May 3, 1991	Do.	Do.
Shelf Life of Medical Devices	April 1, 1991	Do.	Do.
Device Labeling Guidance (blue book memo #G91–1)	March 8, 1991	Do.	Do.
Review and Approval of PMAs of Licensees (blue book memo #P86–4)	October 22, 1990	Do.	Do.
Consolidated Review of Submissions for Diagnostic Ultrasound Equipment, Accessories and Related Measurement Devices (blue book memo #G90–2)	October 19, 1990	Do.	Do.
Consolidated Review of Submissions for Lasers and Accessories (blue book memo #G90–1)	October 19, 1990	Do.	Do.
Assignment of Review Documents (blue book memo #I90–2)	August 24, 1990	Do.	Do.
PMA Supplements: ODEs Letter to Manufacturers; Identifies Situations Which May Require the Submission of a PMA Supplement (When PMA Supplements Are Required) (blue book memo #P90–1)	April 24, 1990	Do.	Do.
Policy Development and Review Procedures (blue book memo #I90–1)	February 15, 1990	Do.	Do.
Substantial Equivalence (SE) Decision Making Documentation Attached: "SE" Decision Making Process (detailed); i.e., The Decision Making Tree	January 1, 1990	Do.	Do.
Threshold Assessment of the Impact of Requirements for Submission of PMAs for 31 Medical Devices Marketed Prior to May 28, 1976	January 1, 1990	Do.	Do.
Meetings with the Regulated Industry (blue book memo #I89–3)	November 20, 1989	Do.	Do.
FDA Policy for The Regulation of Computer Products; Draft	November 13, 1989	Do.	Do.
Toxicology Risk Assessment Committee (blue book memo #G89–1)	August 9, 1989	Do.	Do.
Review of IDEs for Feasibility Studies (blue book memo #D89–1)	May 17, 1989	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
Premarket Notification—Consistency of Reviews (blue book memo #K89–1)	February 28, 1989	Do.	Do.
Review of Laser Submissions (blue book memo #G88–1)	April 15, 1988	Do.	Do.
PMA Review Schedules (P87–1); replaced by P94–2	March 31, 1988	Do.	Do.
Guideline on Validation of the Limulus Amebocyte Lysate (LAL) Test as an End-Product Endotoxin Test	December 1, 1987	Do.	Do.
Necessary Information for Diagnostic Ultrasound 510(k); Draft	November 24, 1987	Do.	Do.
Limulus Amebocute Lysate; Reduction of Samples for Testing	October 23, 1987	Do.	Do.
ODE Executive Secretary Guidance Manual G87–3	August 7, 1987	Do.	Do.
Guideline on Sterile Drug Products Produced by Aseptic Processing	June 1, 1987	Do.	Do.
Master Files Part III; Guidance on Scientific and Technical Information	June 1, 1987	Do.	Do.
ODE Regulatory Information for the Office of Compliance—Information Sharing Procedures (blue book memo #G87–2)	May 15, 1987	Do.	Do.
Guideline on General Principles of Process Validation	May 1, 1987	Do.	Do.
Industry Representatives on Scientific Panel	March 27, 1987	Do.	Do.
Panel Review of "Me-Too" Devices (blue book memo #P86–6)	July 1, 1986	Do.	Do.
Guidance on CDRH's Premarket Notification Review Program (blue book memo #K86–3)	June 30, 1986	Do.	Do.
Panel Report and Recommendations on PMA Approvals (blue book memo #P86–5)	April 18, 1986	Do.	Do.
Criteria for Panel Review of PMA Supplements (blue book memo #P86–3)	January 30, 1986	Do.	Do.
PMAs—Early Review and Preparation of Summaries of Safety and Effectiveness (blue book memo #P86–1)	January 27, 1986	Do.	Do.
PTC in the Characterization of Cell Lines Used to Produce Biological Products	June 1, 1984	Do.	Do.
Application of the Device Good Manufacturing Practice (GMP) Regulation to the Manufacture of Sterile Devices	December 1, 1983	Do.	Do.
Methods for Conducting Recall Effectiveness Checks	June 16, 1978	Do.	Do.
Guidance for Submitting Reclassification Petition	1997	Do.	Do.
Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme; Draft	February 8, 2000	Do.	Do.
Class II Special Controls Guidance Document: Apnea Monitors; Guidance for Industry and FDA	July 17, 2002	Do.	Do.
Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide (PcCo2) and Oxygen (PcO2) Monitors; Guidance for Industry and FDA	December 13, 2002	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
Class II Special Controls Guidance Document: Indwelling Blood Gas Analyzers; Final Guidance for Industry and FDA	October 5, 2001	Do.	Do.
Heated Humidifier Review Guidance	August 30, 1991	Do.	Do.
Class II Special Controls Guidance Document: Optical Impression Systems for Computer Assisted Design and Manufacturing (CAD/CAM) of Dental Restorations; Guidance for Industry and FDA	April 22, 2003	Do.	Do.
Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA	November 12, 2002	Do.	Do.
Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices; Draft Guidance for Industry and FDA Reviewers	August 14, 2002	Do.	Do.
Class II Special Controls Guidance Document: Root-Form Endosseous Dental Implants and Abutments; Draft Guidance for Industry and FDA	May 14, 2002	Do.	Do.
Special Control Guidance Document on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling; Draft Guidance for Industry and FDA	February 20, 2002	Do.	Do.
Overview of Information Necessary for Premarket Notification Submissions for Endosseous Implants; Final	April 21, 1999	Do.	Do.
Guidance for the Preparation of Premarket Notifications for Dental Composites	November 27, 1998	Do.	Do.
Dental Cements—Premarket Notification; Final	August 18, 1998	Do.	Do.
Dental Impression Materials—Premarket Notification; Final	August 17, 1998	Do.	Do.
OTC Denture Cushions, Pads, Reliners, Repair Kits, and Partially Fabricated Denture Kits; Final	August 17, 1998	Do.	Do.
Draft Guidance Document for the Preparation of Premarket Notification 510(k)s for Dental Alloys	March 3, 1997	Do.	Do.
Information Necessary for Premarket Notification Submissions for Screw-Type Endosseous Implants	December 9, 1996	Do.	Do.
Guidance Document on Dental Handpieces	July 1, 1995	Do.	Do.
Guidance for the Arrangement and Content of a Premarket Approval (PMA) Application for an Endosseous Implant for Prosthetic Attachment	May 16, 1989	Do.	Do.
Supplementary Guidance on Premarket Notifications for Medical Devices With Sharps Injury Prevention Features; Guidance for Industry and FDA	December 31, 2002	Do.	Do.
Guidance on Premarket Notifications for Intravascular Administration Sets	October 12, 2000	Do.	Do.
Neonatal and Neonatal Transport Incubators—Premarket Notifications; Final	September 18, 1998	Do.	Do.
Guidance on the Content of Premarket Notification (510(k)) Submissions for Protective Restraints	December 1, 1995	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
Guidance on Premarket Notification (510(k)) Submissions for Short-Term and Long-Term Intravascular Catheters	March 16, 1995	Do.	Do.
Guidance on the Content of Premarket Notification (510(k)) Submissions for Hypodermic Single Lumen Needles	April 1, 1993	Do.	Do.
Guidance on the Content of Premarket Notification (510(k)) Submissions for Piston Syringes	April 1, 1993	Do.	Do.
Guidance on the Content of Premarket Notification (510(k)) Submissions for Clinical Electronic Thermometers	March 1, 1993	Do.	Do.
Guidance on the Content of Premarket Notification (510(k)) Submissions for External Infusion Pumps	March 1, 1993	Do.	Do.
Guidance on 510(k) Submissions for Implanted Infusion Ports	October 1, 1990	Do.	Do.
Surgical Masks—Premarket Notification (510(k)) Submissions; Draft Guidance	May 15, 2003	Do.	Do.
Regulatory Status of Disinfectants Used to Process Dialysate Delivery Systems and Water Purification Systems for Hemodialysis; Guidance for Industry and FDA	August 30, 2002	Do.	Do.
Premarket Notification (510(k)) Submissions for Medical Sterilization Packaging Systems in Health Care Facilities; Draft Guidance for Industry and FDA	March 7, 2002	Do.	Do.
Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors; Guidance for the Medical Device Industry and FDA Review Staff	February 7, 2002	Do.	Do.
Premarket Guidance: Reprocessing and Reuse of Single-Use Devices; Draft Guidance for Industry and FDA Staff	June 1, 2001	Do.	Do.
Premarket Notifications (510(k)) for Biological Indicators Intended to Monitor Sterilizers Used in Health Care Facilities; Draft Guidance for Industry and FDA Reviewers	May 21, 2001	Do.	Do.
Premarket Approval Applications (PMA) for Sharps Needle Destruction Devices; Final Guidance for Industry and FDA	March 2, 2001	Do.	Do.
Guidance on the Content and Format of Premarket Notification (510(k)) Submissions for Liquid Chemical Sterilants and High Level Disinfectants; Final	January 3, 2000	Do.	Do.
Guidance for Conducting Stability Testing to Support an Expiration Date Labeling Claim for Medical Gloves; Draft	November 16, 1999	Do.	Do.
Premarket Notification (510(k)) Submissions for Testing for Skin Sensitization to Chemicals in Natural Rubber Products; Final	January 13, 1999	Do.	Do.
CDRH Regulatory Guidance for Washers and Washer-Disinfectors Intended for Use in Processing Reusable Medical Devices	June 2, 1998	Do.	Do.
Testing for Sensitizing Chemicals in Natural Rubber Latex Medical Devices (addendum to 944)	July 28, 1997	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
Addendum to Guidance on Premarket Notification (510(k)) Submissions for Sterilizers Intended for Use in Health Care Facilities	September 19, 1995	Do.	Do.
Guidance on the Content and Format of Premarket Notification (510(k)) Submissions for Sharps Containers	October 1, 1993	Do.	Do.
Guidance on Premarket Notification (510(k)) Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities	August 1, 1993	Do.	Do.
Guidance on Premarket Notification (510(k)) Submissions for Surgical Gowns and Surgical Drapes	August 1, 1993	Do.	Do.
Guidance on Premarket Notification 510(k) for Sterilizers Intended for Use in Health Care Facilities	March 1, 1993	Do.	Do.
Battery Guidance	January 1, 1994	Do.	Do.
Policy for Expiration Dating (DCRND RB92–G)	October 30, 1992	Do.	Do.
Balloon Valvuloplasty Guidance for the Submission of an IDE Application and a PMA Application	January 1, 1989	Do.	Do.
Cardiac Ablation Catheters Generic Arrhythmia Indications for Use; Guidance for Industry	July 1, 2002	Do.	Do.
Investigational Device Exemption (IDE) Study Enrollment for Cardiac Ablation of Typical Atrial Flutter; Final Guidance for Industry and FDA Reviewers	November 8, 2000	Do.	Do.
Recommended Clinical Study Design for Ventricular Tachycardia Ablation	May 7, 1999	Do.	Do.
Non-Automated Sphygmomanometer (Blood Pressure Cuff) Guidance Version 1; Final	November 19, 1998	Do.	Do.
Non-Invasive Blood Pressure (NIBP) Monitor Guidance	March 10, 1997	Do.	Do.
Electrocardiograph (ECG) Electrode	February 11, 1997	Do.	Do.
Electrocardiograph (ECG) Lead Switching Adapter	February 11, 1997	Do.	Do.
Electrocardiograph (ECG) Surface Electrode Tester	February 11, 1997	Do.	Do.
Draft Version Cardiac Ablation Preliminary Guidance (Data To Be Submitted to the FDA in Support Investigation Device Exemption Application)	March 1, 1995	Do.	Do.
Draft Version Electrode Recording Catheter Preliminary Guidance (Data To Be Submitted to the FDA in Support of Premarket Notifications)	March 1, 1995	Do.	Do.
Guidance for Annuloplasty Rings 510(k) Submissions; Final Guidance for Industry and FDA Staff	January 31, 2001	Do.	Do.
Guidance for Cardiopulmonary Bypass Arterial Line Blood Filter 510(k) Submissions; Final Guidance for Industry and FDA	November 29, 2000	Do.	Do.
Guidance for Extracorporeal Blood Circuit Defoamer 510(k) Submissions; Final Guidance for Industry and FDA	November 29, 2000	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions; Final Guidance for Industry and FDA Staff	November 13, 2000	Do.	Do.
Draft Replacement Heart Valve Guidance	October 14, 1994	Do.	Do.
Draft Guidance; Human Heart Valve Allografts	June 21, 1991	Do.	Do.
Guidance for the Preparation of the Annual Report to the PMA Approved Heart Valve Prostheses	April 1, 1990	Do.	Do.
Draft Intravascular Brachytherapy—Guidance for Data To Be Submitted to FDA in Support of Investigational Device Exemption (IDE) Applications	May 24, 1996	Do.	Do.
Draft Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices: PTCA Catheters, Atherectomy Catheters, Lasers, Intravascular Stents	May 1, 1995	Do.	Do.
Draft Percutaneous Transluminal Coronary Angioplasty Package Insert Template	February 7, 1995	Do.	Do.
Coronary and Cerebrovascular Guidewire Guidance	January 1, 1995	Do.	Do.
Guidance for the Submission of Research and Marketing Applications for Permanent Pacemaker Leads and for Pacemaker Lead Adaptor 510(k) Submissions	November 1, 2000	Do.	Do.
Draft Guidance for Implantable Cardioverter-Defibrillators	June 19, 1996	Do.	Do.
Implantable Pacemaker Testing Guidance	January 12, 1990	Do.	Do.
Guidance Document for Vascular Prostheses 510(k) Submissions	November 1, 2000	Do.	Do.
Guidance for Cardiovascular Intravascular Filter 510(k) Submissions; Final	November 26, 1999	Do.	Do.
Carotid Stent—Suggestions for Content of Submissions to FDA in Support of Investigational Devices Exemption (IDE) Applications	October 26, 1996	Do.	Do.
Draft Guidance for the Preparation of Research and Marketing Applications for Vascular Graft Prostheses	August 1, 1993	Do.	Do.
Guidance Document for Powered Suction Pump 510(k)s	September 30, 1998	Do.	Do.
Guidance Document for Surgical Lamp 510(k)s; Final	July 13, 1998	Do.	Do.
Electroencephalograph Devices Draft Guidance for 510(k) Content	November 3, 1997	Do.	Do.
Guidelines for Reviewing Premarket Notifications That Claim Substantial Equivalence to Evoked Response Stimulators	February 1, 1997	Do.	Do.
Guidance Document for the Preparation of Premarket Notification (510(k)) Applications for Electromyograph Needle Electrodes	July 26, 1995	Do.	Do.
Guidance on the Content and Organization of a Premarket Notification for a Medical Laser	June 1, 1995	Do.	Do.

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
Draft 510(k) Guideline for General Surgical Electrosurgical Devices	May 10, 1995	Do.	Do.
Guidance for the Preparation of a Premarket Notification for Extended Laparoscopy Devices	August 30, 1994	Do.	Do.
Galvanic Skin Response Measurement Devices; Draft Guidance for 510(k) Content	August 23, 1994	Do	Do.
Draft Version 1; Biofeedback Devices; Draft Guidance for 510(k) Content	August 1, 1994	Do.	Do.
Draft Version Cranial Perforator Guidance	July 13, 1994	Do.	Do.
Draft Version Neuro Endoscope Guidance	July 7, 1994	Do.	Do.
Draft Premarket Notification Review Guidance for Evoked Response Somatosensory Stimulators	June 1, 1994	Do.	Do.
Draft Guidance for Arthroscope and Accessory 510(k)s	May 1, 1994	Do.	Do.
Class II Special Controls Guidance Document; Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA	January 16, 2003	Do.	Do.
Class II Special Controls Guidance Document; Polymethylmethacrylate (PMMA) Bone Cement; Guidance for Industry and FDA	July 17, 2002	Do.	Do.
Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis	April 30, 2002	Do.	Do.
Class II Special Controls Guidance: Shoulder Joint Metal/Polymer/Metal Nonconstrained or Semiconstrained Porous-Coated Uncemented Prosthesis	October 31, 2000	Do.	Do.
Guidance for Spinal System 510(k)s	September 27, 2000	Do.	Do.
Guidance Document for the Preparation of IDEs for Spinal Systems	January 13, 2000	Do.	Do.
Guidance Document for Industry and CDRH Staff for the Preparation of Investigational Device Exemptions and Premarket Approval Applications for Bone Growth Stimulator Devices; Draft	March 18, 1998	Do.	Do.
Draft Guidance Document for the Preparation of Premarket Notification (510(k)) Applications for Orthopedic Devices—The Basic Elements	July 16, 1997	Do.	Do.
ORDB 510(k) Sterility Review Guidance	July 3, 1997	Do.	Do.
Calcium Phosphate (Ca-P) Coating Draft Guidance for Preparation of FDA Submissions for Orthopedic and Dental Endosseous Implants	February 21, 1997	Do.	Do.
Reviewers Guidance Checklist for Intramedullary Rods	February 21, 1997	Do.	Do.
Reviewers Guidance Checklist for Orthopedic External Fixation Devices	February 21, 1997	Do.	Do.
510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants	February 20, 1997	Do.	Do.

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
Guidance Document for Testing Biodegradable Polymer Implant Devices	April 20, 1996	Do.	Do.
Guidance Document for Testing Bone Anchor Devices	April 20, 1996	Do.	Do.
Draft Guidance Document for Femoral Stem Prostheses	August 1, 1995	Do.	Do.
Draft Guidance Document for Testing Acetabular Cup Prostheses	May 1, 1995	Do.	Do.
Guidance Document for Testing Non-Articulating, "Mechanically Locked," Modular Implant Components	May 1, 1995	Do.	Do.
Draft Data Requirements for Ultrahigh Molecular Weight Polyethylene (Uhmupe) Used in Orthopedic Devices	March 28, 1995	Do.	Do.
Guidance Document for the Preparation of Premarket Notification for Ceramic Ball Hip Systems	January 10, 1995	Do.	Do.
Guidance Document for Testing Orthopedic Implants With Modified Metallic Surfaces Apposing Bone or Bone Cement	April 28, 1994	Do.	Do.
Draft Guidance for the Preparation of Premarket Notifications (510(k)s) for Cemented, Semiconstrained Total Knee Prostheses	April 1, 1993	Do.	Do.
Guidance Document for the Preparation of IDE and PMA Applications for Intra-Articular Prothetic Knee Ligament Devices	February 18, 1993	Do.	Do.
Class II Special Controls Guidance Document; Surgical Sutures; Guidance for Industry and FDA	June 3, 2003	Do.	Do.
Guidance for Saline, Silicone Gel, and Alternative Breast Implants; Guidance for Industry and FDA	February 11, 2003	Do.	Do.
Class II Special Controls Guidance Document; Human Dura Mater; Draft Guidance for Industry and FDA	October 22, 2002	Do.	Do.
Guidance for Resorbable Adhesion Barrier Devices for Use in Abdominal and/or Pelvic Surgery; Guidance for Industry	June 18, 2002	Do.	Do.
Guidance Document for Dura Substitute Devices; Final Guidance for Industry	November 9, 2000	Do.	Do.
Guidance for Neurological Embolization Devices	November 1, 2000	Do.	Do.
Guidance for the Preparation of a Premarket Notification Application for Processed Human Dura Mater; Final	October 14, 1999	Do.	Do.
Guidance for Dermabrasion Devices; Final	March 2, 1999	Do.	Do.
Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh; Final	March 2, 1999	Do.	Do.
Guidance for Content of Premarket Notifications for Esophageal and Tracheal Prostheses; Final	April 28, 1998	Do.	Do.
Guidance for Testing MR Interaction With Aneurysm Clips	May 22, 1996	Do.	Do.

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
Draft Guidance for the Preparation of IDE Submission for Interactive Wound and Burn Dressing	April 4, 1995	Do.	Do.
Draft Guidance for the Preparation of a Premarket Notification for a Non-Interactive Wound and Burn Dressing	March 31, 1995	Do.	Do.
Draft Version; Guidance on Biocompatibility Requirements for Long Term Neurological Implants: Part 3—Implant Model	September 12, 1994	Do.	Do.
Protocol for Dermal Toxicity Testing for Devices in Contact With Skin; Draft	January 1, 1985	Do.	Do.
Class II Special Controls Guidance Document; Resorbable Calcium Salt Bone Void Filler Device; Guidance for Industry and FDA	June 2, 2003	Do.	Do.
Guidance Document for Powered Muscle Stimulator 510(k)s; Final	June 9, 1999	Do.	Do.
Guidance Document for the Preparation of Notification (510(k)) Applications for Therapeutic Massagers and Vibrators	July 26, 1995	Do.	Do.
Guidance Document for the Preparation of Premarket Notification (510(k)) Applications for Beds	July 26, 1995	Do.	Do.
Guidance Document for the Preparation of Premarket Notification (510(k)) Applications for Communications Systems (Powered and Nonpowered) and Powered Environmental Control Systems	July 26, 1995	Do.	Do.
Guidance Document for the Preparation of Premarket Notification (510(k)) Applications for Exercise Equipment	July 26, 1995	Do.	Do.
Guidance Document for the Preparation of Premarket Notification (510(k)) Applications for Heating and Cooling Devices	July 26, 1995	Do.	Do.
Guidance Document for the Preparation of Premarket Notification (510(k)) Applications for Immersion Hydrobaths	July 26, 1995	Do.	Do.
Guidance Document for the Preparation of Premarket Notification (510(k)) Applications for Powered Tables and Multifunctional Physical Therapy Tables	July 26, 1995	Do.	Do.
Guidance Document for the Preparation of Premarket Notification (510(k)) Applications for Submerged (Underwater) Exercise Equipment	July 26, 1995	Do.	Do.
Guidance Document for the Preparation of Premarket Notification (510(k)) Applications for Mechanical and Powered Wheelchairs, and Motorized Three-Wheeled Vehicles	July 26, 1995	Do.	Do.
Guide for TENS 510(k) Content; Draft	August 1, 1994	Do.	Do.
Draft Version Guidance for Clinical Data To Be Submitted for Premarket Approval Application for Cranial Electrotherapy Stimulators	August 20, 1992	Do.	Do.
Draft Guidance for Cortical Electrode 510(k) Content	August 10, 1992	Do.	Do.
Guidance for Studies for Pain Therapy Devices—General Consideration in the Design of Clinical Studies for Pain-Alleviating Devices	May 12, 1988	Do.	Do.

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
Accountability Analysis for Clinical Studies for Ophthalmic Devices; Draft	August 4, 1999	Do.	Do.
Guidance Document for Nonprescription Sunglasses; Final	October 9, 1998	Do.	Do.
Ophthalmoscope Guidance	July 8, 1998	Do.	Do.
Retinoscope Guidance; Final	July 8, 1998	Do.	Do.
Slit Lamp Guidance; Final	July 8, 1998	Do.	Do.
Discussion Points for Expansion of the "Checklist of Information Usually Submitted in an Investigational Device Exemption (IDE) Application for Refractive Surgery Lasers;" Draft Document	September 5, 1997	Do.	Do.
Third Party Review Guidance for Phacofragmentation System Device Premarket Notification (510(k))	January 31, 1997	Do.	Do.
Third Party Review Guidance for Vitreous Aspiration and Cutting Device Premarket Notification (510(k))	January 31, 1997	Do.	Do.
Checklist of Information Usually Submitted in an Investigational Device Exemptions (IDE) Application for Refractive Surgery Lasers (excimer)	October 10, 1996	Do.	Do.
Guidance for Manufacturers Seeking Marketing Clearance of Ear, Nose, and Throat Endoscope Sheaths Used as Protective Barriers; Final	March 12, 2000	Do.	Do.
Tympanostomy Tubes, Submission Guidance for a 510(k) Premarket Notification; Final	January 14, 1998	Do.	Do.
Guidance for the Arrangement and Content of a Premarket Approval (PMA) Application for a Cochlear Implant in Children Ages 2 through 17 Years	May 1, 1990	Do.	Do.
Guideline for the Arrangement and Content of a Premarket Approval (PMA) Application for a Cochlear Implant in Adults at Least 18 Years of Age	May 1, 1990	Do.	Do.
Refractive Implants: Guidance for Investigational Device Exemptions (IDE) and Premarket Approval (PMA) Applications; Draft	August 1, 2000	Do.	Do.
Intraocular Lens Guidance Document; Draft	October 14, 1999	Do.	Do.
Guidance on 510(k) Submissions for Keratoprostheses; Final	March 3, 1999	Do.	Do.
Aqueous Shunts—510(k) Submissions; Final	November 16, 1998	Do.	Do.
FDA Guidelines for Multifocal Intraocular Lens IDE Studies and PMAs	May 29, 1997	Do.	Do.
Important Information About Rophae Intraocular Lenses	August 20, 1992	Do.	Do.
Guidance for Premarket Submissions of Orthokeratology Rigid Gas Permeable Contact Lenses; Final	April 10, 2000	Do.	Do.
Revised Procedures for Adding Lens Finishing Laboratories to Approved Premarket Approval Applications for Class III Rigid Gas Permeable Contact Lenses for Extended Wear; Final	August 11, 1998	Do.	Do.

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
Premarket Notification 510(k) Guidance for Contact Lens Care Products	May 1, 1997	Do.	Do.
Premarket Notification (510(k)) Guidance Document for Class II Daily Wear Contact Lenses	June 28, 1994	Do.	Do.
New FDA Recommendations and Results of Contact Lens Study (7-day letter)	May 30, 1989	Do.	Do.
Class II Special Controls Guidance Document; Ingestible Telemetric Gastrointestinal Capsule Imaging System; Final Guidance for Industry and FDA	November 28, 2001	Do.	Do.
Class II Special Controls Guidance Document; Tissue Culture Media for Human Ex Vivo Tissue and Cell Culture Processing Applications; Final Guidance for Industry and FDA Reviewers	May 16, 2001	Do.	Do.
Guidance for Investigational Device Exemptions for Solutions for Hypothermic Flushing, Transport, and Storage of Organs for Transplantation; Final Guidance for Industry and FDA Reviewers	January 16, 2001	Do.	Do.
Guidance for Industry and CDRH Reviewers on the Content of Premarket Notifications for Hemodialysis Delivery Systems; Final	August 7, 1998	Do.	Do.
Guidance for the Content of Premarket Notification for Conventional and High Permeability Hemodialyzers; Final	August 7, 1998	Do.	Do.
Guidance for the Content of Premarket Notifications for Metal Expandable Biliary Stents; Final	February 5, 1998	Do.	Do.
Guidance for the Content of Premarket Notifications for Water Purification Components and Systems for Hemodialysis	May 30, 1997	Do.	Do.
Draft Guidance for Hemodialyzer Reuse Labeling	October 6, 1995	Do.	Do.
Class II Special Controls Guidance Document; Breast Lesion Documentation System; Guidance for Industry and FDA Staff	July 28, 2003	Do.	Do.
Class II Special Controls Guidance for Home Uterine Activity Monitors; Final Guidance for Industry and FDA Reviewers	March 9, 2001	Do.	Do.
Class II Special Controls Guidance Document for Clitoral Engorgement Devices	July 3, 2000	Do.	Do.
Draft Guidance for Industry; Electro-optical Sensors for the In Vivo Detection of Cervical Cancer and Its Precursors: Submission Guidance for an IDE/PMA	August 25, 1999	Do.	Do.
Devices Used for In Vitro Fertilization and Related Assisted Reproduction Procedures; Draft	September 10, 1998	Do.	Do.
Latex Condoms for Men—Information for 510(k) Premarket Notifications: Use of Consensus Standards for Abbreviated Submissions	July 23, 1998	Do.	Do.
Uniform Contraceptive Labeling; Final	July 23, 1998	Do.	Do.
Intrapartum Continuous Monitors for Fetal Oxygen Saturation and Fetal pH; Submission Guidance for a PMA; Draft Document	June 14, 1997	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
Letter to Manufacturers of Prescription Home Monitors for Nonstress Tests	September 6, 1996	Do.	Do.
Letter to Manufacturers of Falloposcopes	September 5, 1996	Do.	Do.
Thermal Endometrial Ablation Devices (Submission Guidance for an IDE)	March 14, 1996	Do.	Do.
Hysteroscopes and Gynecology Laparoscopes (Submission Guidance for a 510(k))	March 7, 1996	Do.	Do.
Hysteroscopes and Laparoscopic Insufflators (Submission Guidance for a 510(k))	August 1, 1995	Do.	Do.
Testing Guidance for Male Condoms Made From New Material (Nonlatex)	June 29, 1995	Do.	Do.
Draft Guidance for the Content of Premarket Notifications for Menstrual Tampons	May 25, 1995	Do.	Do.
Information for a Latex Condom 510(k) Submission for Obstetrics-Gynecology Devices Branch; Draft	April 13, 1994	Do.	Do.
Premarket Testing Guidelines for Falloposcopes	November 20, 1992	Do.	Do.
Draft Guidance for the Content of Premarket Notifications for Loop and Rollerball Electrodes for GYN Electrosurgical Excisions	July 29, 1991	Do.	Do.
Premarket Testing Guidelines for Female Barrier Contraceptive Devices Also Intended to Prevent Sexually Transmitted Diseases	April 4, 1990	Do.	Do.
Guidance ("Guidelines") for Evaluation of Hysteroscopic Sterilization Devices	May 10, 1978	Do.	Do.
Guidance ("Guidelines") for Evaluation of Laparoscopic Bipolar and Thermal Coagulators (and Accessories)	May 1, 1978	Do.	Do.
Guidance ("Guidelines") for Evaluation of Tubal Occlusion Devices	November 22, 1977	Do.	Do.
Guidance ("Guidelines") for Evaluation of Fetal Clip Electrode	March 8, 1977	Do.	Do.
Guidelines for Evaluation of Nondrug IUDs	September 28, 1976	Do.	Do.
Criteria for Significant Risk Investigations of Magnetic Resonance Diagnostic Devices; Guidance for Industry and FDA Staff	July 14, 2003	Do.	Do.
Bone Sonometer PMA Applications; Final Guidance for Industry and FDA	June 21, 2001	Do.	Do.
Premarket Applications for Digital Mammography Systems; Final Guidance for Industry and FDA	February 16, 2001	Do.	Do.
Guidance for the Submission of Premarket Notifications for Photon-Emitting Brachytherapy Sources	August 2, 2000	Do.	Do.
Guidance for the Submission of Premarket Notifications for Medical Image Management Devices	July 27, 2000	Do.	Do.
Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices; Final	August 6, 1999	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
Guidance for the Submission of Premarket Notifications for Emission Computed Tomography Devices and Accessories (SPECT and PET) and Nuclear Tomography Systems; Final	December 3, 1998	Do.	Do.
Guidance for the Submission of Premarket Notifications for Radionuclide Dose Calibrators; Final	November 20, 1998	Do.	Do.
Harmonic Imaging With/Without Contrast—Premarket Notification; Final	November 16, 1998	Do.	Do.
Guidance for the Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices; Final	November 14, 1998	Do.	Do.
Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers	September 30, 1997	Do.	Do.
Letter: Notice to Manufacturers of Bone Mineral Densitometers	September 25, 1997	Do.	Do.
Simplified 510(k) Procedures for Certain Radiology Devices: 12/21/93 letter from L. Yin, ODE/DRAERD, to NEMA	December 21, 1993	Do.	Do.
Draft Guidance for Review of Bone Densitometer 510(k) Submissions	November 9, 1992	Do.	Do.
Reviewer Guidance for Automatic X-Ray Film Processor 510(k)	February 1, 1990	Do.	Do.
Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi	August 9, 2000	Do.	Do.
Guidance for the Content of Premarket Notifications for Penile Rigidity Implants; Final	January 16, 2000	Do.	Do.
Guidance for the Content of Premarket Notifications for Intracorporeal Lithotripters; Final	November 30, 1998	Do.	Do.
CDRH Interim Regulatory Policy for External Penile Rigidity Devices	September 10, 1997	Do.	Do.
Draft Guidance for Preclinical and Clinical Investigations of Urethral Bulking Agents Used in the Treatment of Urinary Incontinence	November 29, 1995	Do.	Do.
Draft Guidance for the Clinical Investigation of Urethral Stents	November 2, 1995	Do.	Do.
Draft 510(k) Checklist for Endoscopic Electrosurgical Unit (ESU) and Accessories Used in Gastroenterology and Urology	August 16, 1995	Do.	Do.
Draft 510(k) Checklist for Urological Irrigation System and Tubing Set	August 1, 1995	Do.	Do.
Draft 510(k) Checklist for Endoscopic Light Sources Used in Gastroenterology and Urology	June 22, 1995	Do.	Do.
Draft 510(k) Checklist for Non-Implanted Electrical Stimulators Used for the Treatment of Urinary Incontinence	June 6, 1995	Do.	Do.
Draft Guidance for Preparation of PMA Applications for the Implanted Mechanical/Hydraulic Urinary Continence Device (Artificial Urinary Sphincter)	May 1, 1995	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
Draft Guidance for the Content of Premarket Notifications for Endoscopes Used in Gastroenterology and Urology	March 17, 1995	Do.	Do.
Draft 510(k) Checklist for Condom Catheters	February 23, 1995	Do.	Do.
Draft Guidance for Clinical Investigations of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH)	November 11, 1994	Do.	Do.
Checklist for Mechanical Lithotripters and Stone Dislodgers Used in Gastroenterology and Urology	November 1, 1994	Do.	Do.
510(k) Checklist for Sterile Lubricating Jelly Used With Transurethral Surgical Instruments	September 19, 1994	Do.	Do.
Guidance for the Content of Premarket Notifications for Conventional and Antimicrobial Foley Catheters	September 12, 1994	Do.	Do.
Guidance for the Content of Premarket Notifications for Urodynamic/Uroflowmetry Systems	July 29, 1994	Do.	Do.
Guidance for the Content of Premarket Notifications for Urine Drainage Bags	June 7, 1994	Do.	Do.
Draft Guidance Outline—PTC for Clinical Studies for Vasovasostomy Devices	November 30, 1993	Do.	Do.
Draft Guidance for Preparation of PMA Applications for Penile Inflatable Implants	March 16, 1993	Do.	Do.
Draft Guidance for Preparation of PMA Applications for Testicular Prostheses	March 16, 1993	Do.	Do.
Guidance for the Content of Premarket Notifications for Biopsy Devices Used in Gastroenterology and Urology	February 10, 1993	Do.	Do.
Guidance for the Content of Premarket Notifications for Ureteral Stents	February 10, 1993	Do.	Do.
Draft Guidance for the Content of Premarket Notifications for Urological Balloon Dilatation Cathethers	January 24, 1992	Do.	Do.
Draft of Suggested Information for Reporting Extracorporeal Shock Wave Lithotripsy Device Shock Wave Measurements	January 18, 1991	Do.	Do.
Draft Guidance to Firms on Biliary Lithotripsy Studies	August 2, 1990	Do.	Do.
Office of In Vitro Diagnostic Device Evaluation and Safety			
Analyte Specific Reagents; Small Entity Compliance Guidance; Guidance for Industry	February 26, 2003	Do.	Do.
Assessing the Safety/Effectiveness of Home-Use In Vitro Diagnostic Devices (IVDs): Draft PTC Regarding Labeling and Premarket Submissions	October 1, 1988	Do.	Do.
Data for Commercialization of Original Equipment Manufacturer, Secondary and Generic Reagents for Automated Analyzers	June 10, 1996	Do.	Do.
Determination of Intended Use for 510(k) Devices; Guidance for CDRH Staff	December 3, 2002	Do.	Do.
Guidance for Administrative Procedures for CLIA Categorization	August 14, 2000	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
Guidance for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Criteria for Waiver; Draft Guidance for Industry and FDA	March 1, 2001	Do.	Do.
Guidance for Industry; Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final	February 22, 1999	Do.	Do.
Guidance on Labeling for Laboratory Tests; Draft	June 24, 1999	Do.	Do.
Letter to IVD Manufacturers on Streamlined PMA; Final	December 22, 1997	Do.	Do.
PTC for Collection of Data in Support of In Vitro Device Submissions for 510(k) Clearance	September 26, 1994	Do.	Do.
PTC for Review of Calibration and Quality Control Labeling for In Vitro Diagnostic Devices (cover letter dated March 14, 1996)	February 1, 1996	Do.	Do.
PTC Guidance Document on Assayed and Unassayed Quality Control Material; Draft	February 3, 1999	Do.	Do.
Premarket Approval Application Filing Review; Guidance for Industry and FDA Staff	May 1, 2003	Do.	Do.
Breath Nitric Oxide Test System; Class II Special Controls Guidance Document	July 7, 2003	Do.	Do.
Class II Special Control Guidance Document for B-Type Natriuretic Peptide Premarket Notifications; Final Guidance for Industry and FDA Reviewers	November 30, 2000	Do.	Do.
Class II Special Controls Guidance Document; Cyclosporine and Tacrolimus Assays; Guidance for Industry and FDA	September 16, 2002	Do.	Do.
Draft Guidance for Prescription Use of Drugs of Abuse Assays Premarket Notifications	November 14, 2000	Do.	Do.
Draft Guidance on the Labeling for Over-the-Counter Sample Collection Systems for Drugs of Abuse Testing	December 21, 1999	Do.	Do.
Guidance for 510(k)s on Cholesterol Tests for Clinical Laboratory, Physicians' Office Laboratory, and Home Use	July 14, 1995	Do.	Do.
Guidance for Industry In Vitro Diagnostic Bicarbonate/Carbon Dioxide Test System; Final	July 6, 1998	Do.	Do.
Guidance for Industry In Vitro Diagnostic Chloride Test System; Final	July 6, 1998	Do.	Do.
Guidance for Industry In Vitro Diagnostic Creatinine Test System; Final	July 2, 1998	Do.	Do.
Guidance for Industry In Vitro Diagnostic Glucose Test System; Final	July 6, 1998	Do.	Do.
Guidance for Industry In Vitro Diagnostic Potassium Test System; Final	July 6, 1998	Do.	Do.
Guidance for Industry In Vitro Diagnostic Sodium Test System; Final	July 6, 1998	Do.	Do.
Guidance for Industry In Vitro Diagnostic Urea Nitrogen Test System; Final	July 6, 1998	Do.	Do.
Guidance for Industry; In Vitro Diagnostic C-Reactive Protein Immunological Test System	July 20, 1998	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
Guidance for Over-the-Counter (OTC) Human Chorionic Gonadotropin (hCG) 510(k)s	July 22, 2000	Do.	Do.
Guidance for Over-the-Counter (OTC) Ovulation Predictor 510(k)s	July 22, 2000	Do.	Do.
Over-the-Counter (OTC) Screening Tests for Drugs of Abuse; Guidance for Premarket Notifications	November 14, 2000	Do.	Do.
PTC for Portable Blood Glucose Monitoring Devices Intended for Bedside Use in the Neonate Nursery	February 20, 1996	Do.	Do.
Review Criteria for Assessment of In Vitro Diagnostic Devices for Drugs of Abuse Assays Using Various Methodologies	August 31, 1995	Do.	Do.
Review Criteria for Assessment of Portable Blood Glucose In Vitro Diagnostic Devices Using Glucose Oxidase, Dehydrogenase, or Hexokinase Methodology	February 14, 1996	Do.	Do.
Review Criteria for Assessment of Professional Use Human Chorionic Gonadotropin (hCG) In Vitro Diagnostic Devices (IVDs)	November 6, 1996	Do.	Do.
510(k) Submissions for Coagulation Instruments; Guidance for Industry and FDA Staff	June 19, 2003	Do.	Do.
Class II Special Control Guidance Document for Anti-*Saccharomyces cerevisia* (*S. cerevisiae*) Antibody (ASCA) Premarket Notifications	August 23, 2000	Do.	Do.
Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells; Final Guidance for Industry and FDA	December 4, 2001	Do.	Do.
Document for Special Controls for Erythropoietin Assay Premarket Notifications (510(k)s); Final	April 28, 1999	Do.	Do.
Draft Guidance Document for 510(k) Submission of Fecal Occult Blood Tests	July 29, 1992	Do.	Do.
Draft Guidance Document for 510(k) Submission of Glycohemoglobin (Glycated or Glycosylated) Hemoglobin for IVDs	September 30, 1991	Do.	Do.
Draft Guidance Document for 510(k) Submission of Immunoglobulins A, G, M, D and E Immunoglobulin System In Vitro Devices	September 1, 1992	Do.	Do.
Draft Guidance for 510(k) Submission of Lymphocyte Immunophenotyping IVDs Using Monoclonal Antibodies	September 26, 1991	Do.	Do.
Draft; Premarketing Approval Review Criteria for Premarket Approval of Estrogen (ER) or Progesterone (PGR) Receptors In Vitro Diagnostic Devices Using Steroid Hormone Binding (SBA) with Dextran-Coated Charcoal (DCC) Separation, Histochemical Receptor Bind	September 10, 1992	Do.	Do.
Guidance Document for the Submission of Tumor Associated Antigen Premarket Notification (510(k)) to FDA	September 19, 1996	Do.	Do.
Guidance for Submission of Immunohistochemistry Applications to the FDA; Final	June 3, 1998	Do.	Do.
In Vitro Diagnostic Fibrin Monomer Paracoagulation Test; Final	April 27, 1999	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
Multiplex Tests for Heritable DNA Markers, Mutations, and Expression Patterns; Draft Guidance for Industry and FDA Reviewers	February 27, 2003	Do.	Do.
PTC for Cervical Cytology Devices	July 25, 1994	Do.	Do.
PTC for Hematology Quality Control Materials	September 30, 1997	Do.	Do.
Radioallergosorbent Test (RAST) Methods for Allergen-Specific Immunoglobulin E (IgE) 510(k)s; Final Guidance for Industry and FDA	August 22, 2001	Do.	Do.
Review Criteria for Assessment of Alpha-Fetoprotein (AFP) In Vitro Diagnostic Devices for Fetal Open Neural Tube Defects Using Immunological Test Methodologies	July 15, 1994	Do.	Do.
Review Criteria for Assessment of Cytogenetic Analysis Using Automated and Semi-Automated Chromosome Analyzers	July 15, 1991	Do.	Do.
Review Criteria for Assessment of Rheumatoid Factor (RF) In Vitro Diagnostic Devices Using Enzyme-Linked Immunoassay (EIA), Enzyme Linked Immunosorbent Assay (ELISA), Particle Agglutination Tests, and Laser and Rate Nephelometry	February 21, 1997	Do.	Do.
Review Criteria for Blood Culture Systems	August 12, 1991	Do.	Do.
Review Criteria for In Vitro Diagnostic Devices for Detection of IGM Do Antibodies to Viral Agents	August 1, 1992	Do.	Do.
Review Criteria for In Vitro Diagnostic Devices for the Assessment of Thyroid Autoantibodies Using Indirect Immunofluorescence Assay (IFA), Indirect Hemagglutination Assay (IHA), Radioimmunoasay (RIA), and Enzyme Linked Immunosorbent Assay (ELISA)	February 1, 1994	Do.	Do.
Review Criteria for In Vitro Diagnostic Devices That Utilize Cytogenetic In Situ Hybridization Technology for the Detection of Human Genetic Mutations (Germ Line and Somatic)	February 15, 1996	Do.	Do.
Review Criteria for the Assessment of Anti-Nuclear Antibodies (ANA) In Vitro Diagnostic Devices Using Indirect Immunofluorescence Assay (IFA), Immunodiffusion (IMD), and Enzyme Linked Immunosorbant Assay (ELISA)	September 1, 1992	Do.	Do.
Class II Special Controls Guidance Document; Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA	February 5, 2003	Do.	Do.
Draft Review Criteria for Nucleic Acid Amplification Based In Vitro Diagnostic Devices for Direct Detection of Infectious Microorganisms	June 14, 1993	Do.	Do.
Premarket Approval Applications for In Vitro Diagnostic Devices Pertaining to Hepatitis C Viruses (HCV): Assays Intended for Diagnosis, Prognosis, or Monitoring of HCV Infection, Hepatitis C, or Other HCV-Associated Disease; Draft Guidance for Industry and FDA	April 27, 2001	Do.	Do.
Review Criteria for Assessment of Antimicrobial Susceptibility Test Discs	October 30, 1996	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
Review Criteria for Assessment of In Vitro Diagnostic Devices for Direct Detection of Chlamydiae in Clinical Specimens	January 1, 1992	Do.	Do.
Review Criteria for Assessment of In Vitro Diagnostic Devices for Direct Detection of *Mycobacterium* Spp. (Tuberculosis (TB))	July 6, 1993	Do.	Do.
Review Criteria for Assessment of Laboratory Tests for the Detection of Antibodies to *Helicobacter pylori*	September 17, 1992	Do.	Do.
Review Criteria for Devices Assisting in the Diagnosis of *C. Difficile* Associated Diseases	May 31, 1990	Do.	Do.
Review Criteria for Devices Intended for the Detection of Hepatitis B 'e' Antigen and Antibody to HBe	December 30, 1991	Do.	Do.
Review Criteria for Premarket Approval of In Vitro Diagnostic Devices for Detection of Antibodies to Parvovirus B19	May 15, 1992	Do.	Do.
Office of Surveillance and Biometrics			
PMA Review Statistical Checklist	(no date available)	Do.	Do.
Statistical Aspects of Submissions to FDA: A Medical Device Perspective (also includes as appendix the article "Observed Uses and Abuses of Statistical Procedures in Medical Device Submissions")	June 1, 1984	Do.	Do.
Statistical Guidance for Clinical Trials of Nondiagnostic Medical Devices	January 1, 1996	Do.	Do.
MDR Guidance Document: Remedial Action Exemption; Final	September 26, 2001	Industry and FDA	Do.
Guidance on Adverse Event Reporting for Hospitals That Reprocess Devices Intended by the Original Equipment Manufacturer for Single Use	April 24, 2001	Industry	Do.
MDR Guidance Document No. 1—IOL—E1996004; Final	August 7, 1996	Do.	Do.
Common Problems: Baseline Reports and Medwatch Form 3500A	January 1, 1997	Do.	Do.
Medical Device Reporting: An Overview; Final	April 1, 1996	Do.	Do.
Instructions for Completing FDA Form 3500A With Coding Manual for Form 3500A (MEDWATCH) (MDR); Final	December 15, 1995	Do.	Do.
MEDWATCH FDA Form 3500A for Use by User Facilities, Distributors and Manufacturers for Mandatory Reporting (MDR); Final	June 1, 1993	Industry and user facilities	Do.
Variance from Manufacturer Report Number Format (MDR letter); Final	July 16, 1996	Industry	Do.
Instructions for Completing Form 3417: Medical Device Reporting Baseline Report (MDR); Final	March 31, 1997	Do.	Do.
Medical Device Reporting—Alternative Summary Reporting (ASR) Program; Guidance for Industry	October 19, 2000	Do.	Do.
Addendum to the Instructions for Completing FDA Form 3500A With Coding Manual (MEDWATCH) (MDR); Final	June 9, 1999	Do.	Do.

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
Needlesticks—Medical Device Reporting Guidance	November 12, 2002	Industry and user facilities	Do.
Guidance to Sponsors on the Development of a Discretionary Postmarket Surveillance Study for Permanent Implantable Cardiac Pacemaker Electrodes (Leads)	June 9, 1993	Industry and FDA reviewers	Do.
Guidance on Criteria and Approaches for Postmarket Surveillance	November 2, 1998	Do.	Do.
Guidance on Procedures to Determine Application of Postmarket Surveillance Strategies (FDAMA); Final	February 19, 1998	FDA reviewers	Do.
Guidance on Procedures for Review of Postmarket Surveillance Submissions (FDAMA); Final	February 19, 1998	Do.	Do.
Guidance for Industry and FDA Staff; SMDA to FDAMA: Guidance on FDA's Transition Plan for Existing Postmarket Surveillance Protocols (FDAMA); Final	November 2, 1998	Industry and FDA reviewers	Do.
Amendment to Guidance on Discretionary Postmarket Surveillance on Pacemaker Leads; Final	March 30, 1994	Do.	Do.
Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket	February 2, 2000	Do.	Do.
Office of Compliance			
Commercial Distribution/Exhibit Letter	March 11, 1992	Do.	Do.
FDA Guide for Validation of Biological Indicator Incubation Time	January 1, 1986	Do.	Do.
Guide for Establishing and Maintaining a Calibration Constancy Intercomparison System for Microwave Oven Compliance Survey Instruments (FDA 88–8264)	March 1, 1988	Do.	Do.
General Principles of Software Validation; Draft Guidance	January 11, 2002	Do.	Do.
Guidance on Medical Device Tracking (FDAMA); Guidance for Industry and FDA Staff	May 23, 2003	Do.	Do.
Compliance Program Guidance Manual: Inspection of Medical Devices; Draft	February 7, 2001	Do.	Do.
Procedures for Laboratory Compliance Testing of Television Revivers—Part of TV Packet	May 1, 1986	Do.	Do.
Guidance on Quality System Regulation Information for Various Premarket Submissions; Draft	February 3, 2003	Do.	Do.
Surveillance and Detention Without Physical Examination of Surgeons' and/or Patient Examination Gloves; Guidance for Industry	July 26, 2000	Do.	Do.
Manufacturers/Assemblers of Diagnostic X-Ray Systems: Enforcement Policy for Positive-Beam Limitation (PBL) Requirements in 21 CFR 1020.31(g)	October 13, 1993	Do.	Do.
Guidance for the Submission of Initial Reports on Diagnostic X-Ray Systems and Their Major Components	January 1, 1982	Do.	Do.

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
Exemption From Reporting and Recordkeeping Requirements for Certain Sunlamp Product Manufacturers	September 16, 1981	Do.	Do.
Letter to Medical Device Industry on Endoscopy and Laparoscopy Accessories (Galdi)	May 17, 1993	Do.	Do.
Clarification of Radiation Control Regulations for Diagnostic X-Ray Equipment (FDA 89–8221)	March 1, 1989	Do.	Do.
CPG 7133.19: Retention of Microwave Oven Test Record/Cover Letter: August 24, 1981; Retention of Records Required by 21 CFR 1002	March 1, 1995	Do.	Do.
A Guidance for the Submission of Abbreviated Radiation Safety Reports on Cephalometric X-Ray Devices: Defined as Dental Units With an Attachment for Mandible Work That Holds a Cassette and Beam Limiting Device	March 1, 1996	Do.	Do.
A Guide for the Submission of an Abbreviated Radiation Safety Report on X-Ray Tables, Cradles, Film Changers or Cassette Holders Intended for Diagnostic Use	March 1, 1996	Do.	Do.
A Guide for the Submission of Abbreviated Radiation Safety Reports on Image Receptor Support Devices for Mammography X-Ray Systems	March 1, 1996	Do.	Do.
Compliance Program Guidance Manual; Field Compliance Testing of Diagnostic (Medical) X-Ray Equipment; Guidance for FDA Staff	March 15, 2000	Do.	Do.
Information Disclosure by Manufacturers to Assemblers for Diagnostic X-Ray Systems; Final Guidance for Industry and FDA	April 2, 2001	Do.	Do.
Guide for Submission of Information on Accelerators Intended to Emit X-Radiation Required Pursuant to 21 CFR 1002.10	April 1, 1971	Do.	Do.
Abbreviated Report on Radiation Safety for Microwave Products (Other Than Microwave Ovens)—e.g., Microwave Heating, Microwave Diathermy, RF Sealers, Induction, Dielectric Heaters, Security Systems	August 1, 1995	Do.	Do.
Guide for Preparing Reports on Radiation Safety of Microwave Ovens	March 1, 1985	Do.	Do.
Reporting Guide for Laser Light Shows and Displays (21 CFR 1002) (FDA 88–8140)	September 1, 1995	Do.	Do.
Guide for Filing Annual Reports for X-Ray Components and Systems	July 1, 1980	Do.	Do.
Reporting and Compliance Guide for Television Products Including Product Report, Supplemental Report, Radiation Safety Abbreviated Report, Annual Report, Information, and Guidance	October 1, 1995	Do.	Do.
Revised Guide for Preparing Annual Reports on Radiation Safety Testing of Laser and Laser Light Show Products (replaces FDA 82–8127)	September 1, 1995	Do.	Do.
Guide for Preparing Abbreviated Reports of Microwave and RF Emitting Electronic Products Intended for Medical Use	September 1, 1996	Do.	Do.

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Letter to Manufacturers and Importers of Microwave Ovens: Information Requirements for Cookbooks and User and Service Manuals	October 31, 1988	Do.	Do.
Abbreviated Report on Radiation Safety of Nonmedical Ultrasonic Products	August 1, 1995	Do.	Do.
Guide for Preparing Product Reports for Medical Ultrasound Products	September 1, 1996	Do.	Do.
Letter to Manufacturers, Distributors, and Importers of Condom Products	February 23, 1994	Do.	Do.
Letter to Manufacturers, Importers, and Repackagers of Condoms for Contraception or Sexually-Transmitted Disease Prevention (Holt)	February 13, 1989	Do.	Do.
Letter to Condom Manufacturers and Distributors	April 5, 1994	Do.	Do.
Letter to Manufacturers/Repackers Using Cotton	April 22, 1994	Do.	Do.
Guide for Preparing Product Reports for Lasers and Products Containing Lasers	September 1, 1995	Do.	Do.
Compliance Guide for Laser Products (FDA 86–8260)	September 1, 1985	Do.	Do.
Condoms: Inspection and Sampling at Domestic Manufacturers and of All Repackers; Sampling From All Importers (Damaska memo to field on April 8, 1987)	April 8, 1987	Do.	Do.
Dental Hand Piece Sterilization (dear doctor letter)	September 28, 1992	Do.	Do.
Latex Labeling Letter (Johnson)	March 18, 1993	Do.	Do.
Pesticide Regulation Notice 94–4: Interim Measures for the Registration of Antimicrobial Products/Liquid Chemical Germicides With Medical Device Use Claims Under the Memorandum of Understanding Between EPA and FDA	June 30, 1994	Do.	Do.
Letter to Industry, Powered Wheelchair Manufacturers, from RM Johnson	May 10, 1993	Do.	Do.
Hazards of Volume Ventilators and Heated Humidifiers	September 15, 1993	Do.	Do.
Manufacturers and Initial Distributors of Sharps Containers and Destroyers Used by Health Care Professionals	February 3, 1994	Do.	Do.
Ethylene Oxide; Ethylene Chlorohydrin; and Ethylene Glycol: Proposed Maximum Residue Limits and Maximum Levels of Exposure	June 23, 1978	Do.	Do.
Letter to Manufacturers and Users of Lasers for Refractive Surgery (excimer)	October 10, 1996	Do.	Do.
Shielded Trocars and Needles Used for Abdominal Access During Laparoscopy	August 23, 1996	Do.	Do.
Surveillance and Detention Without Physical Examination of Condoms; Draft Guidance for Industry	August 14, 2000	Do.	Do.
All U.S. Condom Manufacturers, Importers, and Repackagers	April 7, 1987	Do.	Do.
Manufacturers and Initial Distributors of Hemodialyzers	May 23, 1996	Do.	Do.

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
Laser Light Show Safety—Who's Responsible? (FDA 86–8262)	May 1, 1986	Do.	Do.
Suggested State Regulations for Control of Radiation; Volume II; Nonionizing Radiation—Lasers (FDA Pub. No. 83–8220)	January 1, 1982	Do.	Do.
Letter to All Foreign Manufacturers and Importers of Electronic Products For Which Applicable FDA Performance Standards Exist	May 28, 1981	Do.	Do.
Guide for Submission of Information on Industrial X-Ray Equipment Required Pursuant to 21 CFR 1002.10	March 1, 1973	Do.	Do.
Guide for Submission of Information on Analytical X-Ray Equipment Required Pursuant to 21 CFR 1002.10	April 30, 1974	Do.	Do.
Guidance for the Submission of Cabinet X-Ray System Reports Pursuant to 21 CFR 1020.40	February 1, 1975	Do.	Do.
Guide for Preparing Annual Reports in Radiation Safety Testing of Electronic Products (General)	October 1, 1987	Do.	Do.
Computerized Devices/Processes Guidance—Application of the Medical Device GMP to Computerized Devices and Manufacturing Processes	May 1, 1992	Do.	Do.
Guide for Preparing Product Reports for Ultrasonic Therapy Products (Physical Therapy Only)	August 1, 1996	Do.	Do.
Guide for Submission of Information on Industrial Radiofrequency Dielectric Heater and Sealer Equipment Pursuant to 21 CFR 1002.10 and 1002.12 (FDA 81–8137)	November 1, 1980	Do.	Do.
Guide for Preparing Annual Reports for Ultrasonic Therapy Products	September 1, 1996	Do.	Do.
Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products (replaces FDA 82–8127)	September 1, 1995	Do.	Do.
Guide for Preparing Annual Reports on Radiation Safety Testing of Mercury Vapor (replaces FDA 82–8127)	September 1, 1995	Do.	Do.
Quality Control Guide for Sunlamp Products (FDA 88–8234)	September 1, 1984	Do.	Do.
Guide for the Submission of Initial Reports on Computed Tomography X-Ray Systems	December 1, 1985	Do.	Do.
Guide for Preparing Product Reports on Sunlamps and Sunlamp Products (21 CFR 1002)	September 1, 1995	Do.	Do.
Letter: Policy on Maximum Timer Interval and Exposure Schedule for Sunlamp Products	June 25, 1985	Do.	Do.
Reporting Guide for Product Reports on High Intensity Mercury Vapor Discharge Lamps (21 CFR 1002)	September 1, 1995	Do.	Do.
Quality Control Practices for Compliance With the Federal Mercury Vapor Lamp Performance Standard	May 1, 1980	Do.	Do.
Keeping Up With the Microwave Revolution (FDA Publication No. 91–4160)	March 1, 1990	Do.	Do.

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
Quality Assurance Guidelines for Hemodialysis Devices	February 1, 1991	Do.	Do.
Letter to Manufacturers and Importers of Microwave Ovens—Open Door Operation of Microwave Ovens as a Result of Oven Miswiring	March 28, 1980	Do.	Do.
Reporting of New Model Numbers to Existing Model Families	June 14, 1983	Do.	Do.
Import: Radiation-Producing Electronic Products (FDA 89–8008)	November 1, 1988	Do.	Do.
Unsafe Patient Lead Wires and Cables	September 3, 1993	Do.	Do.
Application of a Variance From 21 CFR 1040.11(c) for a Laser Light Show, Display, or Device (form FDA 3147)	July 1, 1998	Do.	Do.
Letter to Trade Association: Reuse of Single-Use or Disposable Medical Devices	December 27, 1995	Do.	Do.
Design Control Guidance for Medical Device Manufacturers	March 11, 1997	Do.	Do.
Keeping Medical Devices Safe from Electromagnetic Interference	July 1, 1995	Do.	Do.
Safety of Electrically Powered Products: Letter to Medical Devices and Electronic Products Manufacturers from Lilliam Gill and BHB Correction Memo	September 18, 1996	Do.	Do.
Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals; Guidance for Industry and for FDA Staff	August 14, 2000	Do.	Do.
Labeling for Electronic Anti-theft Systems; Final Guidance for Industry	August 15, 2000	Do.	Do.
Wireless Medical Telemetry Risks and Recommendations; Final Guidance for Industry	September 27, 2000	Do.	Do.
Policy on Warning Label Required on Sunlamp Products	June 25, 1985	Do.	Do.
Policy on Lamp Compatibility (Sunlamps)	September 2, 1986	Do.	Do.
Office of Science and Technology			
Guidance on Frequently Asked Questions on Recognition of Consensus Standards (FDAMA)	December 21, 1998	Do.	Do.
Guidance on the Recognition and Use of Consensus Standards; appendix A (FDAMA)	February 19, 1998	Do.	Do.
CDRH Standard Operating Procedures for the Identification and Evaluation of Candidate Consensus Standard for Recognition	August 6, 1999	Do.	Do.
Guidance for Industry and FDA Reviewers: Guidance on Immunotoxicity Testing	May 6, 1999	Do.	Do.
WITHDRAWN GUIDANCES			
Medical Devices Made With Polyvinylchloride (PVC) Using the Plasticizer di-(2-Ethylhexyl)phthalate (DEHP); Draft Guidance for Industry and FDA	September 6, 2002	N/A	N/A

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
Draft Guidance on Evidence Models for the Least Burdensome Means to Market	September 1, 1999	Do.	Do.
Modifications to Devices Subject to Premarket Approval—The PMA Supplement Decision Making Process; Draft	August 6, 1998	Do.	Do.
Guidance for Industry; Contents of a Product Development Protocol; Draft	July 27, 1998	Do.	Do.
New Model Medical Device Development Process; Final	July 21, 1998	Do.	Do.
Document Review by the Office of the Chief Counsel (blue book memo G96–1)	June 6, 1999	Do.	Do.
Letter: Vascular Graft Industry (Philip Phillips)	November 22, 1995	Do.	Do.
Color Additives for Medical Devices (Snesko)	November 15, 1995	Do.	Do.
PMA/510(k) Triage Review Procedures (blue book memo #G94–1)	May 20, 1994	Do.	Do.
Proposal for Establishing Mechanisms for Setting Review Priorities Using Risk Assessment and Allocating Review Resources	June 30, 1993	Do.	Do.
4-of-a-Kind PMAs	October 1, 1999	Do.	Do.
Review of 510(k)s for Computer Controlled Medical Devices (blue book memo #K91–1)	August 29, 1991	Do.	Do.
Review of Final Draft Medical Device Labeling (blue book memo #P91–4)	August 29, 1991	Do.	Do.
Clinical Utility and Premarket Approval (blue book memo #P91–1)	May 3, 1991	Do.	Do.
Review and Approval of PMAs of Licensees (blue book memo #P86–4)	October 22, 1990	Do.	Do.
PMA Supplements: ODEs Letter to Manufacturers; Identifies Situation Which May Require the Submission of a PMA Supplement (blue book memo #P90–1)	April 24, 1990	Do.	Do.
FDA Policy for the Regulation of Computer Products; Draft	November 13, 1989	Do.	Do.
PMA Review Schedules (P87–1) (replaced by P94–2)	March 31, 1988	Do.	Do.
Necessary Information for Diagnostic Ultrasound 510(k); Draft	November 24, 1987	Do.	Do.
Guideline on Sterile Drug Products Produced by Aseptic Processing	June 1, 1987	Do.	Do.
ODE Regulatory Information for the Office of Compliance; Information Sharing Procedures (blue book memo #G87–2)	May 15, 1987	Do.	Do.
Panel Review of "Me-Too" Devices (blue book memo #P86–6)	July 1, 1986	Do.	Do.
Criteria for Panel Review of PMA Supplements (blue book memo #P86–3)	January 30, 1986	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
PMAs-Early Review and Preparation of Summaries of Safety and Effectiveness (blue book memo #P86–1)	January 27, 1986	Do.	Do.
Draft Guidance for the Preparation of Premarket Notification 510(k)s for Dental Alloys	March 3, 1997	Do.	Do.
Premarket Guidance; Reprocessing and Reuse of Single-Use Devices; Draft	June 1, 2001	Do.	Do.
Guidance for Conducting Stability Testing to Support an Expiration Date Labeling Claim for Medical Gloves; Draft	November 16, 1999	Do.	Do.
Draft Version Cardiac Ablation Preliminary Guidance (Data To Be Submitted to the FDA in Support Investigation Device Exemption Application)	March 1, 1995	Do.	Do.
Draft Version Electrode Recording Catheter Preliminary Guidance (Data To Be Submitted to the FDA in Support of Premarket Notifications)	March 1, 1995	Do.	Do.
Draft Replacement Heart Valve Guidance	October 14, 1994	Do.	Do.
Draft Guidance on Human Heart Valve Allografts	June 21, 1991	Do.	Do.
Draft Intravascular Brachytherapy—Guidance for Data To Be Submitted to FDA in Support of Investigational Device Exemption (IDE) Applications	May 24, 1996	Do.	Do.
Draft Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices: PTCA Catheters, Atherectomy Catheters, Lasers, Intravascular Stents	May 1, 1995	Do.	Do.
Draft Percutaneous Transluminal Coronary Angioplasty Package Insert Template	February 7, 1995	Do.	Do.
Draft Guidance for Implantable Cardioverter-Defibrillators	June 19, 1996	Do.	Do.
Draft Guidance for the Preparation of Research and Marketing Applications for Vascular Graft Prostheses	August 1, 1993	Do.	Do.
Electroencephalograph Devices Draft Guidance for 510(k) Content	November 3, 1997	Do.	Do.
Draft 510(k) Guideline for General Surgical Electrosurgical Devices	May 10, 1995	Do.	Do.
Galvanic Skin Response Measurement Devices; Draft Guidance for 510(k) Content	August 23, 1994	Do.	Do.
Draft Version 1; Biofeedback Devices; Draft Guidance for 510(k) Content	August 1, 1994	Do.	Do.
Draft Version Cranial Perforator Guidance	July 13, 1994	Do.	Do.
Draft Version Neuro Endoscope Guidance	July 7, 1994	Do.	Do.
Draft Premarket Notification Review Guidance for Evoked Response Somatosensory Stimulators	June 1, 1994	Do.	Do.
Draft Guidance for Arthroscope and Accessory 510(k)s	May 1, 1994	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
Guidance Document for Industry and CDRH Staff for the Preparation of Investigational Device Exemptions and Premarket Approval Applications for Bone Growth Stimulator Devices; Draft	March 18, 1998	Do.	Do.
Draft Guidance for Preparation of Premarket Notification (510(k)) Applications for Orthopedic Devices: The Basic Elements	July 16, 1997	Do.	Do.
Calcium Phosphate (Ca-P) Coating Draft Guidance for Preparation of FDA Submission for Orthopedic and Dental Endosseous Implants	February 21, 1997	Do.	Do.
Draft Guidance Document for Femoral Stem Prostheses	August 1, 1995	Do.	Do.
Draft Guidance Document for Testing Acetabular Cup Prostheses	May 1, 1995	Do.	Do.
Draft Data Requirements for Ultrahigh Molecular Weight Polyethylene (Uhmupe) Used in Orthopedic Devices	March 23, 1995	Do.	Do.
Draft Guidance for the Preparation of Premarket Notifications (510(k)s) for Cemented, Semiconstrained Total Knee Prostheses	April 1, 1993	Do.	Do.
Draft Guidance for the Preparation of IDE Submission for Interactive Wound and Burn Dressing	April 4, 1995	Do.	Do.
Draft Guidance for the Preparation of a Premarket Notification for a Non-Interactive Wound and Burn Dressing	March 31, 1995	Do.	Do.
Draft Version; Guidance on Biocompatibility Requirements for Long Term Neurological Implants: Part 3—Implant Model	September 12, 1994	Do.	Do.
Protocol for Dermal Toxicity Testing for Devices in Contact with Skin; Draft	January 1, 1985	Do.	Do.
Guide for TENS 510(k) Content; Draft	August 1, 1994	Do.	Do.
Draft Version Guidance for Clinical Data To Be Submitted for Premarket Approval Application for Cranial Electrotherapy Stimulators	August 20, 1992	Do.	Do.
Draft Guidance for Cortical Electrode 510(k) Content	August 10, 1999	Do.	Do.
Accountability Analysis for Clinical Studies for Ophthalmic Devices; Draft	August 4, 1999	Do.	Do.
Refractive Implants: Guidance for Investigational Device Exemptions (IDE) and Premarket Approval (PMA) Applications; Draft	August 1, 2000	Do.	Do.
Intraocular Lens Guidance Document; Draft	October 14, 1999	Do.	Do.
Draft Guidance for Hemodialyzer Reuse Labeling	October 6, 1995	Do.	Do.
Draft Guidance for Industry: Electro-Optical Sensors for the In Vivo Detection of Cervical Cancer and its Precursors; Submission Guidance for an IDE/PMA	August 25, 1999	Do.	Do.
Devices Used for In Vitro Fertilization and Related Assisted Reproduction Procedures; Draft	September 10, 1988	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
Intrapartum Continuous Monitors for Fetal Oxygen Saturation and Fetal pH; Submission Guidance for a PMA; Draft Document	June 14, 1997	Do.	Do.
Draft Guidance for the Content of Premarket Notifications for Menstrual Tampons	May 25, 1995	Do.	Do.
Information for a Latex Condom 510(k) Submission for Obstetrics-Gynecology Devices Branch; Draft	April 13, 1994	Do.	Do.
Premarket Testing Guidelines for Falloscopes	November 20, 1992	Do.	Do.
Draft Guidance for the Content of Premarket Notifications for Loop and Rollerball Electrodes for GYN Electrosurgical Excisions	July 29, 1991	Do.	Do.
Draft Guidance for Review of Bone Densitometer 510(k) Submissions	November 9, 1992	Do.	Do.
Draft Guidance for Preclinical and Clinical Investigations of Urethral Bulking Agents Used in the Treatment of Urinary Incontinence	November 29, 1995	Do.	Do.
Draft Guidance for Clinical Investigation of Urethral Stents	November 2, 1995	Do.	Do.
Draft 510(k) Checklist for Endoscopic Electrosurgical Unit (ESU) and Accessories Used in Gastroenterology and Urology	August 16, 1995	Do.	Do.
Draft 510(k) Checklist for Urological Irrigation System and Tubing Set	August 1, 1995	Do.	Do.
Draft 510(k) Checklist for Endoscopic Light Sources Used in Gastroenterology and Urology	June 22, 1995	Do.	Do.
Draft 510(k) Checklist for Non-Implanted Electrical Stimulators Used for the Treatment of Urinary Incontinence	June 6, 1995	Do.	Do.
Draft Guidance for Preparation of PMA Applications for the Implanted Mechanical/Hydraulic Urinary Continence Device (Artificial Urinary Sphincter)	May 1, 1995	Do.	Do.
Draft Guidance for the Content of Premarket Notifications for Endoscopes Used in Gastroenterology and Urology	March 17, 1995	Do.	Do.
Draft 510(k) Checklist for Condom Catheters	February 23, 1995	Do.	Do.
Draft Guidance for Clinical Investigations of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH)	November 11, 1994	Do.	Do.
Draft Guidance Outline; PTC for Clinical Studies for Vasovasostomy Devices	November 30, 1993	Do.	Do.
Draft Guidance for Preparation of PMA Applications for Penile Inflatable Implants	March 16, 1993	Do.	Do.
Draft Guidance for Preparation of PMA Applications for Testicular Prostheses	March 16, 1993	Do.	Do.
Draft Guidance for the Content of Premarket Notifications for Urological Balloon Dilatation Catheters	January 24, 1992	Do.	Do.
Draft of Suggested Information for Reporting Extracorporeal Shock Wave Lithotripsy Device Shock Wave Measurements	January 18, 1991	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
Draft Guidance to Firms on Biliary Lithotripsy Studies	August 2, 1990	Do.	Do.
Statistical Aspects of Submissions to FDA: A Medical Device Perspective (also includes as appendix the article "Observed Uses and Abuses of Statistical Procedures in Medical Device Submissions")	June 1, 1984	Do.	Do.
Guidance to Sponsors on the Development of a Discretionary Postmarket Surveillance Study for Permanent Implantable Cardiac Pacemaker Electrodes (Leads)	June 9, 1993	Do.	Do.
Amendment to Guidance on Discretionary Postmarket Surveillance on Pacemaker Leads; Final	March 30, 1994	Do.	Do.
Premarketing Approval Review Criteria for Premarket Approval of Estrogen (ER) or Progesterone (PGR) Receptors In Vitro Diagnostic Devices Using Steroid Hormone Binding (SBA) With Dextran-Coated Charcoal (DCC) Separation, Histochemical Receptor Bind; Draft	September 10, 1992	Do.	Do.
Premarket Approval Applications for In Vitro diagnostic Devices Pertaining to Hepatitis C Viruses (HCV): Assays Intended for Diagnosis, Prognosis, or Monitoring of HCV Infection, Hepatitis C, Other HCV-Associated Disease; Draft Guidance for Industry and FDA	April 27, 2001	Do.	Do.
Premarket Approval (PMA) Manual	January 1998	Do.	Do.
SMDA Changes—PMA Manual Insert	April 17, 1992	Do.	Do.
Investigational Device Exemptions (IDE) Manual (FDA 96–4159)	June 1, 1996	Do.	Do.
510(k) Manual—Premarket Notification: 510(k)—Regulatory Requirements for Medical Devices	August 1, 1995	Do.	Do.
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Beds	July 26, 1995	Do.	Do.

[1]See Internet address for Facts-on-Demand number.

GUIDANCE DOCUMENTS ISSUED BY CFSAN

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
Compliance Policy Guides Manual	August 2000; updated in April 2001	General publications	*http://www.cfsan.fda.gov/guidance.html*
Compliance Programs Guidance Manual	March 1995	Do.	Do.
FDA Recall Policy	2002	Do.	Do.
Guidance for FDA Staff; The Leveraging Handbook; An Agency Resource for Effective Collaborations	2003	Do.	Do.
Guidance for Small Businesses; Submission of Comments for CFSAN Rulemaking	2002	Do.	Do.
Investigations Operations Manual	May 1996	Do.	Do.
Regulatory Procedures Manual	August 1997	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CFSAN—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
Draft Guidance: Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals, For Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental Protection Agency	July 2003	Chemical and pesticide contaminants publications	Do.
Channels of Trade Policy for Commodities With Vinclozolin Residues	June 2002	Do.	Do.
FDA Recommendations for Sampling and Testing Yellow Corn and Dry-Milled Yellow Corn Shipments for Cry9C Protein Residues	January 2001	Do.	Do.
Channels of Trade Policy for Commodities With Methyl Parathion Residues	December 2000	Do.	Do.
Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed	2000	Do.	Do.
Pesticides Analytical Manual	1999	Do.	Do.
FDA Advisory for Deoxynivanol (DON) in Finished Wheat Products Intended for Human Consumption and in Grain and Grain By-Products for Animal Feed	September 1993	Do.	Do.
FDA's Cosmetic Labeling Manual	October 1991	Cosmetic publications	Do.
Draft Guidance: Labeling for Topically Applied Cosmetic Products Containing Alpha Hydroxy Acids as Ingredients	December 2, 2002	Do.	Do.
Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements	July 10, 2003	Dietary supplements publications	Do.
Interim Evidence-Based Ranking System for Scientific Data	July 10, 2003	Do.	Do.
Structure/Function Claims: Small Entity Compliance Guide	January 9, 2002	Do.	Do.
Statement of Identity, Nutrition Labeling, and Ingredient Labeling of Dietary Supplements Small Entity Compliance Guide	January 1999	Do.	Do.
Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements	December 1999	Do.	Do.
Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body	July 1998	Do.	Do.
Iron-Containing Supplements and Drugs: Label Warning Statements: Small Entity Compliance Guide	October 17, 2003	Do.	Do.
Providing Regulatory Submissions in Electronic Format; General Considerations	July 2001	Food and color additives publications	Do.
Providing Food and Color Additive Petitions in Electronic Format	July 2001	Do.	Do.
Electronic Submission Forms	July 2001	Do.	Do.
FDA's Policy for Foods Developed by Biotechnology	1995	Do.	Do.
Partial List of Enzyme Preparations That Are Used in Foods	2001	Do.	Do.
Partial List of Microorganisms and Microbial-Derived Ingredients That Are Used in Food	2001	Do.	Do.
Use of Antibiotic Resistance Marker Genes in Transgenic Plants	September 1998	Do.	Do.
Enzyme Preparations: Chemistry Recommendations for Food Additive and GRAS Affirmation Petitions	January 1993	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CFSAN—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
Guidance for Submitting Requests Under 21 CFR 170.39; Threshold of Regulation for Substances Used in Food Contact Articles	1996	Do.	Do.
PTC for the Use of Recycled Plastics in Food Packaging: Chemistry Considerations	December 1992	Do.	Do.
How to Submit a GRAS Notice	April 17, 1997	Do.	Do.
Recommendations for Submission of Chemical and Technological Data for Direct Food Additive and GRAS Food Ingredient Petitions	May 1993	Do.	Do.
Statement of Policy; Foods Derived from New Plant Varieties; Notice	May 1992	Do.	Do.
Guidelines for the Preparation of Petition Submissions	1996	Do.	Do.
Guidelines for Approval of Color Additives in Contact Lenses Intended as Colors	1996	Do.	Do.
FDA Recommendations for Submission of Chemical and Technological Data on Color Additives for Food, Drug, or Cosmetic Use	January 1997	Do.	Do.
Estimating Exposure to Direct Food Additive and Chemical Contaminants in the Diet	September 1995	Do.	Do.
Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food (also known as redbook I)	1982	Do.	Do.
Toxicological Principles for the Safety of Food Ingredients (redbook 2000)	April 2004	Do.	Do.
Draft Guidance; Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to CFSAN	September 17, 2003	Do.	Do.
Environmental Assessment Technical Handbook	March 1987	Do.	Do.
Toxicological Testing of Food Additives	1983	Do.	Do.
Guidance on Consultation Procedures Foods Derived From New Plant Varieties	October 1997	Do.	Do.
Bovine Spongiform Encephalopathy (BSE) in Products for Human Use	1997	Do.	Do.
Food Additive Petition Expedited Review; Guidance for Industry and CFSAN	January 1999	Do.	Do.
Antimicrobial Food Additives Guidance	July 1999	Do.	Do.
Preparation of Premarket Notifications for Food Contact Substances (Food Contact Notifications (FCN)): Administrative Recommendations	May 2002	Do.	Do.
Preparation of Food Contact Notifications and Food Additive Petitions for Food Contact Substances: Chemistry Recommendations	April 2002	Do.	Do.
Preparation of Premarket Notifications for Food Contact Substances: Toxicology Recommendations	April 2002	Do.	Do.
A Food Labeling Guide	May 1997	Food labeling publications	Do.
Food Labeling: *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims; Small Entity Compliance Guide	August 20, 2003	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CFSAN—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements	December 18, 2002	Do.	Do.
Draft Guidance; Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering	January 2001	Do.	Do.
Small Business Food Labeling Exemption	June 1996	Do.	Do.
Food Labeling: Questions and Answers (volume I)	August 1994	Do.	Do.
Food Labeling: Questions and Answers (volume II)	February 1996	Do.	Do.
Fair Packaging and Labeling Act Manual	June 1978	Do.	Do.
Implementation of Section 10809 of the Farm Security and Investment Act of 2002, Public Law No. 107–171, § 10809 (2002), Regarding the Petition Process to Request Approval of Labeling for Foods That Have Been Treated by Irradiation	2002	Do.	Do.
FDA Nutrition Labeling Manual—A Guide for Developing and Using Databases	March 1998	Do.	Do.
Guidelines for Determining Metric Equivalents of Household Measures	October 1, 1993	Do.	Do.
Food Labeling—Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution; Small Entity Compliance Guide	July 2001	Do.	Do.
Exemptions From the Warning Label Requirement for Juice—Recommendations for Effectively Achieving a 5-Log Pathogen Reduction	October 7, 2002	Do.	Do.
Food Labeling—Serving Sizes Reference Amount for Baking Powder, Baking Soda, Pectin; Small Entity Compliance Guide	July 2001	Do.	Do.
Bacteriological Analytical Manual (7th ed.)	1992	Food processing publicatons	Do.
Bacteriological Analytical Manual Online	2001	Do.	Do.
Questions and Answers Regarding Registration of Food Facilities (4th ed.)	August 6, 2004	Food and cosmetic security publications	Do.
Cosmetics Processors and Transporters: Cosmetics Security Preventive Measures Guidance	December 17, 2003	Do.	Do.
Retail Food Stores and Food Service Establishments: Food Security Preventive Measures Guidance	December 17, 2003	Do.	Do.
What You Need to Know About Registration of Food Facilities	November 25, 2003	Do.	Do.
What You Need to Know About Prior Notice of Imported Food Shipments	November 25, 2003	Do.	Do.
Necessity of the Use of Food Product Categories in Registration of Food Facilities	July 17, 2003	Do.	Do.
Dairy Farms, Bulk Milk Transporters, Bulk Milk Transfer Stations, and Fluid Milk Processors: Food Security Preventive Measures Guidance	July 11, 2003	Do.	Do.
Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance	March 21, 2003	Do.	Do.
Importers and Filers: Food Security Preventive Measures Guidance	March 21, 2003	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CFSAN—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
Compliance Policy Guide; Guidance for FDA Staff on Registration of Food Facilities	2003	Do.	Do.
Compliance Policy Guide; Guidance for FDA Staff on Prior Notice of Imported Foods	2003	Do.	Do.
Prior Notice of Imported Food Questions and Answers (2nd ed.)	May 2004	Imports and exports publications	Do.
Prior Notice of Imported Food: Harmonized Tariff Schedule Codes Flagged With Prior Notice Indicators	August 2004	Do.	Do.
Guidance for Industry and FDA; Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors With Interest in Exporting to Chile	May 23, 2003	Do.	Do.
FDA Food Importer's Guide for Low-Acid Canned and Acidified Foods	1985	Do.	Do.
Guidance for Industry; FDA Export Certificates	2002	Do.	Do.
Draft Guidance; Regulatory Procedures Manual, chapter 9, subchapter: Guidance Concerning Recommending Customs' Seizure and Destruction of Imported Human and Animal Food That Has Not Been Reconditioned	November 5, 2002	Do.	Do.
Guidelines Concerning Notification and Testing of Infant Formula	1985	Infant formula publications	Do.
Guidelines for Evaluation of the Safety and Suitability of New Infant Formulas for Feeding Preterm Infants	1988	Do.	Do.
Clinical Testing of Infant Formulas With Respect to Nutritional Suitability for Term Infants	1988	Do.	Do.
Guidelines for Evaluation of the Safety and Suitability of Infant Formulas for Feeding Infants With Allergic Diseases	1990	Do.	Do.
Guidelines for the Clinical Evaluation of New Products Used in the Dietary Management of Infants, Children, and Pregnant Women With Metabolic Disorders	1987	Do.	Do.
The Juice HACCP Regulation: Questions and Answers	September 4, 2003	Juice publications	Do.
Standardized Training Curriculum for Application of HACCP Principles to Juice Processing	June 2003	Do.	Do.
Bulk Transport of Juice Concentrates and Certain Shelf Stable Juices	April 24, 2002	Do.	Do.
Juice HACCP Small Entity Compliance Guide	April 4, 2003	Do.	Do.
Draft Guidance; Juice HACCP Hazards and Control Guidance (1st ed.)	March 3, 2004	Do.	Do.
Apple Juice, Apple Juice Concentrates, and Apple Juice Products—Adulteration With Patulin	October 2001	Do.	Do.
The Juice HACCP Regulation: Questions and Answers	August 31, 2001	Do.	Do.
FDA Food Importer's Guide for Low-Acid Canned and Acidified Foods	1985	Low-acid and acidified foods publications	Do.
Grade "A" Pasteurized Milk Ordinance (2001 revision)	May 15, 2002	Milk sanitation publications	Do.
Importation of PMO Defined Dairy Products (M–I–00–4)	April 11, 2000	Do.	Do.
Evaluation of Milk Laboratories	1995	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CFSAN—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
Methods of Making Sanitation Ratings of Milk Supplies	1999	Do.	Do.
Procedures Governing the Cooperative State-Public Health Service/FDA Program for Certification of Interstate Milk Shippers	1999	Do.	Do.
Frozen Dessert Processing Guidelines	1989	Do.	Do.
Dry Milk Ordinance	1995	Do.	Do.
Pasteurized Milk Ordinance	1999	Do.	Do.
Fumonisin Levels in Human Foods and Animal Feeds	November 9, 2001	Natural toxins publications	Do.
List of Products for Each Product Category	October 8, 1992	Nutrition and food science publications	Do.
Label Declaration of Allergenic Substances in Foods; Notice to Manufacturers	June 10, 1996	Do.	Do.
Guidance on Labeling of Foods That Need Refrigeration by Consumers	February 24, 1997	Do.	Do.
Interim Guidance on the Voluntary Labeling of Milk and Milk Products That Have Not Been Treated With Recombinant Bovine Somatropin	February 10, 1994	Do.	Do.
Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables	October 26, 1998	Produce publications	Do.
Reducing Microbial Food Safety Hazards for Sprouted Seeds	October 1999	Do.	Do.
Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production	October 1999	Do.	Do.
Retail Food Stores and Food Service Establishments: Food Security Preventive Measures Guidance	December 17, 2003	Retail food protection publications	Do.
Foods—Adulteration Involving Hard or Sharp Foreign Objects	February 1999	Sanitation publications	Do.
Defect Action Levels (DALs)	May 1998	Do.	Do.
Action Levels for Poisonous or Deleterious Substances in Human Food and Feed	2000	Do.	Do.
Refusal of Inspection or Access to HACCP Records Pertaining to the Safe and Sanitary Processing of Fish and Fishery Products	July 2001	Seafood publications	Do.
Seafood HACCP Transition Policy	December 1999	Do.	Do.
Seafood List	1993	Do.	Do.
Fish and Fisheries Products Hazards and Control Guide (3rd ed.)	2001	Do.	Do.
HACCP Regulation for Fish and Fishery Products: Questions and Answers	1998	Do.	Do.
Implementation of Section 403(t) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(t)) Regarding the Use of the Term "Catfish"	December 2002	Do.	Do.
Letter to Various Seafood Trade Associations Regarding the Labeling of Catfish	February 28, 2003	Do.	Do.
WITHDRAWN GUIDANCES			

GUIDANCE DOCUMENTS ISSUED BY CFSAN—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
Guidance for Industry: Fumonisin Levels in Human Foods and Animal Feeds, Draft (replaced by Guidance for Industry: Fumonisin Levels in Human Foods and Animal Feeds; Final (November 2001)	June 2000	N/A	N/A
Guidance for Industry Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements (replaced by Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements and Interim Evidence-Based Ranking System for Scientific Data (July 2003))	December 2002	Do.	Do.
Guidance for Industry Preparation of Premarket Notifications for Food Contact Substances: Administrative; Draft (replaced by Guidance for Industry Preparation of Premarket Notifications for Food Contact Substances: Administrative; Final (May 2002))	June 2000	Do.	Do.
Guidance for Industry Preparation of Premarket Notifications for Food Contact Substances: Chemistry Recommendations, Draft (replaced by Guidance for Industry Preparation of Food Contact Notifications for Food Contact Substances: Chemistry Recommendations; Final (April 2002))	May 2000	Do.	Do.
Recommendations for Chemistry Data for Indirect Food Additive Petitions (replaced by Guidance for Industry Preparation of Food Contact Notifications for Food Contact Substances: Chemistry Recommendations; Final (April 2002))	June 1995	Do.	Do.
Guidance for Industry Preparation of Premarket Notifications for Food Contact Substances: Toxicology Recommendations (replaced by Guidance for Industry Preparation of Food Contact Notifications for Food Contact Substances: Toxicology Recommendations; Final (April 2002))	September 1999	Do.	Do.
Iron-Containing Supplements and Drugs: Label Warning and Unit Dose Packaging Small Entity Compliance Guide (replaced by Guidance for Industry; Iron-Containing Supplements and Drugs: Label Warning Statements; Small Entity Compliance Guide (October 2003))	November 1997	Do.	Do.
Guidance for Industry Channels of Trade Policy for Commodities With Vinclozolin Residues; Draft (replaced by Guidance for Industry Channels of Trade Policy for Commodities With Vinclozolin Residues; Final (June 2002))	July 2001	Do.	Do.
Guidance for Industry Refusal of Inspection or Access to HACCP Records Pertaining to the Safe and Sanitary Processing of Fish and Fishery Products; Draft (replaced by Guidance for Industry Refusal of Inspection or Access to HACCP Records Pertaining to the Safe and Sanitary Processing of Fish and Fishery Products; Final (July 2001))	November 2000	Do.	Do.
Guidance Document for Arsenic	1993	Do.	Do.
Guidance Document for Cadmium	1993	Do.	Do.
Guidance Document for Chromium	1993	Do.	Do.
Guidance Document for Lead	1993	Do.	Do.
Guidance Document for Nickel	1993	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CVM

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
#159 Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish a Microbiological ADI (VICH GL36)	November 12, 2003	FDA personnel and regulated industry	Internet via *http://www.fda.gov/cvm/guidance/published.htm*, or Communications Staff (HFV–12), FDA/CVM, 7519 Standish Pl., Rockville, MD, 301–827–3800, FAX: 301–827–4065
#158 Use of Material From Deer and Elk in Animal Feed; Final	September 15, 2003	Regulated industry	Do.
#156 Comparability Protocols; Chemistry, Manufacturing, and Controls Information; Draft	February 2003	Do.	Do.
#153 Drugs, Biologics, and Medical Devices Derived From Bioengineered Plants for Use in Humans and Animals; Draft	September 2002	Do.	Do.
#152 Evaluating the Safety of Antimicrobial New Animal Drugs With Regard to Their Microbiological Effects on Bacteria of Human Health Concern	October 23, 2003	Do.	Do.
#151 FDA Export Certificates	July 2004	Do.	Do.
#150 Status of Clove Oil and Eugenol for Anesthesia of Fish	June 11, 2002	Do.	Do.
#149 Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Testing (VICH GL33)	May 18, 2004	Do.	Do.
#148 Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Developmental Toxicity Testing (VICH GL32); Final Guidance	March 19, 2004	Do.	Do.
#147 Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food; Repeat Dose (90-day) Toxicity Testing (VICH GL31)	November 12, 2003	Do.	Do.
#145 Bioanalytical Method Validation	May 2001	Do.	Do.
#144 Pre-Approval Information for Registration of New Veterinary Medicinal Products for Food-producing Animals with Respect to Antimicrobial Resistance (VICH GL27); Final Guidance	April 27, 2004	Do.	Do.
#143 Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms (VICH GL30); Draft Guidance	February 1, 2002	Do.	Do.
#142 Pharmacovigilance of Veterinary Medicinal Products: Management of Periodic Summary Update Reports (PSUs) (VICH GL29); Draft Guidance	December 12, 2001	Do.	Do.
#141 Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Carcinogenicity Testing (VICH GL28); Final Guidance	May 24, 2004	Do.	Do.
#132 The Administrative New Animal Drug Application Process; Draft	November 6, 2002	Do.	Do.
#126 BACPAC I: Intermediates in Drug Substance Synthesis; Bulk Actives Postapproval Changes: Chemistry, Manufacturing, and Controls Documentation	February 2001	Do.	Do.
#124 Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Draft	January 2001	Do.	Do.
#122 Manufacture and Labeling of Raw Meat Foods for Companion and Captive Noncompanion Carnivores and Omnivores	November 9, 2004	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CVM—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
#121 Expedited Review for New Animal Drug Applications for Human Pathogen Reduction Claims	March 6, 2001	Do.	Do.
# 120 Veterinary Feed Directive Regulation	March 1, 2001	Do.	Do.
# 119 How CVM Intends to Handle Deficient Submissions Filed During the Investigation of a New Animal Drug; Final Guidance	August 29, 2002	Do.	Do.
#118 Mass Spectrometry for Confirmation of the Identity of Animal Drug Residues; Final Guidance	May 1, 2003	Do.	Do.
#117 Pharmacovigilance of Veterinary Medical Products: Management of Adverse Event Reports (AERs) (VICH GL24); Draft Guidance	December 12, 2000	Do.	Do.
#116 Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Genotoxicity Testing (VICH GL23); Final Guidance	January 3, 2002	Do.	Do.
#115 Safety Studies for Veterinary Drug Residues in Human Food; Reproduction Toxicity Testing (VICH GL22); Final Guidance	January 3, 2002	Do.	Do.
#114 Effectiveness of Anthelmintics: Specific Recommendations for Poultry-*Gallus Gallus* (VICH GL21); Final Guidance	June 19, 2002	Do.	Do.
#113 Effectiveness of Anthelmintics: Specific Recommendations for Feline (VICH GL20); Final Guidance	June 19, 2002	Do.	Do.
#112 Fumonisin Levels in Human Foods and Animal Feeds; Final Guidance	November 9, 2001	Do.	Do.
#111 Effectiveness of Anthelmintics: Specific Recommendations for Canine (VICH GL19); Final Guidance	June 27, 2002	Do.	Do.
#110 Effectiveness of Anthelmintics: Specific Recommendations for Porcine (VICH GL16); Final Guidance	June 27, 2002	Do.	Do.
#109 Effectiveness of Anthelmintics: Specific Recommendations for Equine (VICH GL15); Final Guidance	June 27, 2002	Do.	Do.
#108 How to Submit Information in Electronic Format by E-mail	May 21, 2004	Do.	Do.
#107 How to Submit a Protocol in Electronic Format by E-mail	May 21, 2004	Do.	Do.
#106 The Use of Published Literature in Support of New Animal Drug Approval	August 31, 2000	Do.	Do.
#105 Computerized Systems Used in Clinical Trials	September 2004	Do.	Do.
#104 Content and Format of Effectiveness and Target Animal Safety Technical Sections and Final Study Reports for Submission to the Division of Therapeutic Drugs for Nonfood Animals	July 10, 2001	Do.	Do.
#103 Possible Dioxin/PCB Contamination of Drug and Biological Products	August 1999	Do.	Do.
#102 Manufacture and Distribution of Unapproved Piperazine Products; Revised	August 27, 1999	Do.	Do.
#100 Impurities: Residual Solvents in New Veterinary Medicinal Products, Active Substances and Excipients (VICH GL18); Final Guidance	May 15, 2001	Do.	Do.
#99 Stability Testing of New Biotechnological/Biological Veterinary Medicinal Products (VICH GL17); Final Guidance	March 26, 2001	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CVM—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
#98 Dioxin in Anticaking Agents Used in Animal Feed and Feed Ingredients; Revised	April 14, 2000	Do.	Do.
#97 Effectiveness of Anthelmintics: Specific Recommendations for Caprine (VICH GL14); Final Guidance	March 26, 2001	Do.	Do.
#96 Effectiveness of Anthelmintics: Specific Recommendations for Ovine (VICH GL13); Final Guidance	March 26, 2001	Do.	Do.
#95 Efficacy of Anthelmintics: Specific Recommendations for Bovines; (VICH GL12); Final Guidance	March 26, 2001	Do.	Do.
#93 Impurities in New Veterinary Medical Products (VICH GL11)	May 1, 2000	Do.	Do.
#92 Impurities in New Veterinary Drug Substances (VICH GL10)	May 1, 2000	Do.	Do.
#91 Stability Testing for Medicated Premixes (VICH GL8); Final Guidance	March 2000	Do.	Do.
#90 Effectiveness of Anthelmintics: General Recommendations (VICH GL7); Final Guidance (replaces March 26, 2001)	October 11, 2001	Do.	Do.
#89 Environmental Impact Assessments (EIAs) for Veterinary Medicinal Products (VMPs)—Phase I (VICH GL6); Final Guidance	March 7, 2001	Do.	Do.
#88 How to Submit a Request for a Meeting or Teleconference in Electronic Format by E-mail	May 21, 2004	Do.	Do.
#87 How to Submit a Notice of Intent to Slaughter for Human Food Purposes in Electronic Format by E-mail	May 21, 2004	Do.	Do.
#86 How to Submit a Notice of Final Disposition of Investigational Animals Not Intended for Immediate Slaughter in Electronic Format by E-mail	May 21, 2004	Do.	Do.
#85 Good Clinical Practice (VICH GL9); Final Guidance	May 9, 2001	Do.	Do.
#84 Product Name Placement, Size and Prominence in Advertising and Promotional Labeling; Draft Guidance	January 1999	Do.	Do.
#83 Chemistry, Manufacturing, and Controls Changes to an Approved NADA or ANADA; Draft Guidance	June 1999	Do.	Do.
#82 Development of Supplemental Applications for Approved New Animal Drugs; Final Guidance	October 28, 2002	Do.	Do.
#80 Studies to Evaluate the Utility of Anti-*Salmonella* Chemical Food Additives in Feeds	November 21, 2002	Do.	Do.
#79 Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by CVM; Draft Guidance	May 16, 2003	Do.	Do.
#78 Consideration of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals	December 13, 1999	Do.	Do.
#76 Questions and Answers: BSE Feed Regulation	July 1998	Do.	Do.
#75 Stability Testing: Photostability Testing of New Veterinary Drug Substances and Medicinal Products; Final Guidance	September 1999	Do.	Do.
#74 Stability Testing of New Veterinary Dosage Forms (VICH GL4); Final Guidance	September 1999	Do.	Do.
#73 Stability Testing of New Veterinary Drug Substances and Medicinal Products (VICH GL3); Final Guidance	September 1999	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CVM—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
#72 GMPs for Medicated Feed Manufacturers Not Required to Register and Be Licensed With FDA	May 1998	Do.	Do.
#70 Para Alimentadores de Animales Rumiantes Sin Operaciones de Mezclado de Alimentos en la Granja	February 1998	Do.	Do.
#70 Small Entities Compliance Guide for Feeders of Ruminant Animals Without On-Farm Feed Mixing Operations	February 1998	Do.	Do.
#69 Para Alimentadores de Animales Rumiantes Con Operaciones de Mezclado de Alimentos en la Granja	February 1998	Do.	Do.
#69 Small Entities Compliance Guide for Feeders of Ruminant Animals With On-Farm Feed Mixing Operations	February 1998	Do.	Do.
#68 Para Mezcladores de Proteínas, Fabricantes de Alimentos para Animales y Distribuidores	February 1999	Do.	Do.
#68 Small Entities Compliance Guide for Protein Blenders, Feed Manufacturers, and Distributors	February 1998	Do.	Do.
#67 Para Extractores de Grasa por Fusion	February 1998	Do.	Do.
#67 Small Entities Compliance Guide for Renderers	February 1998	Do.	Do.
#65 Industry-Supported Scientific and Educational Activities	November 1997	Do.	Do.
#64 Validation of Analytical Procedures: Methodology; Final Guidance	July 1999	Do.	Do.
#63 Validation of Analytical Procedures: Definition and Terminology	July 1999	Do.	Do.
#62 Consumer-Directed Broadcast Advertisements; Final Guidance	August 1999	Do.	Do.
#61 FDA Approval of New Animal Drugs for Minor Uses and for Minor Species	April 1999	Do.	Do.
#59 How to Submit a Notice of Claimed Investigational Exemption in Electronic Format by E-mail	May 21, 2004	Do.	Do.
#57 Guidance for Industry for the Preparation and Submission of Veterinary Master Files	1995	Do.	Do.
#56 Protocol Development Guideline for Clinical Effectiveness and Target Animal Safety Trials	July 10, 2001	Do.	Do.
#55 Supportive Data for Cat Food Labels Bearing "Reduces Urinary pH" Claims: Guideline in Protocol Development	June 1994	Do.	Do.
#54 Draft Guideline for Utility Studies for Anti-*Salmonella* Chemical Food Additives in Animal Feeds (see final guidance #80)	June 22, 1994	Do.	Do.
#53 Guideline for the Evaluation of the Utility of Food Additives in Diets Fed to Aquatic Animals	May 1994	Do.	Do.
#52 Assessment of the Effects of Antimicrobial Drug Residues From Food of Animal Origin on the Human Intestinal Flora	February 18, 2004	Do.	Do.
#50 Draft Guideline for Target Animal and Human Food Safety, Drug Efficacy, Environmental and Manufacturing Studies for Teat Antiseptic Products	February 1, 1993	Do.	Do.
#49 Guidance Document for Target Animal Safety and Drug Effectiveness Studies for Antimicrobial Bovine Mastitis Products (Lactating and Nonlactating Cow Products)	April 4, 1996	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CVM—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
#48 Guidance for Industry for the Submission Documentation for Sterilization Process Validation in Applications for Human and Veterinary Drug Products	November 1994	Do.	Do.
#45 Guideline for Uniform Labeling of Drugs for Dairy and Beef Cattle	August 1993	Do.	Do.
#43 Guidance on Generic Animal Drug Products Containing Fermentation-Derived Drug Substances	October 1995	Do.	Do.
#42 Animal Drug Manufacturing Guidelines	1994	Do.	Do.
#41 Draft Guideline for Formatting, Assembling, and Submitting New Animal Drug Applications	June 1992	Do.	Do.
#40 Draft Guideline for the Evaluation of the Efficacy of Anticoccidial Drugs and Anticoccidial Drug Combinations in Poultry	April 1992	Do.	Do.
#38 Guideline for Effectiveness Evaluation of Topical/OTIC Animal Drugs	August 21, 1984	Do.	Do.
#37 Guidelines for Evaluation of Effectiveness of New Animal Drugs for Use in Poultry Feeds for Pigmentation	March 1984	Do.	Do.
#36 Guideline for Efficacy Evaluation of Canine/Feline Anthelmintics	July 18, 1985	Do.	Do.
#35 Bioequivalence Guideline	Revised October 9, 2002	Do.	Do.
#33 Target Animal Safety Guidelines for New Animal Drugs	June 1989	Do.	Do.
#31 Guidelines for the Evaluation of Bovine Anthelmintics	July 1981	Do.	Do.
#29 Guidelines for the Effectiveness Evaluation of Swine Anthelmintics	September 30, 1980	Do.	Do.
#28 Animal Drug Applications Expedited Review Guideline (see Policy and Procedures Guide 1240.3135)	December 3, 1997	Do.	Do.
#27 New Animal Drug Determination (see Policy and Procedures Guide 1240.3500)	July 1989	Do.	Do.
#24 Guideline for Drug Combinations for Use in Animals	October 1983	Do.	Do.
#23 Medicated Free-Choice Feeds-Manufacturing Controls	July 1, 1985	Do.	Do.
#22 Labeling of Arecoline Base Drugs Intended for Animal Use		Do.	Do.
#21 Nutritional Ingredients in Animal Drugs and Feeds (see Policy and Procedures Guide 1240.3420)	March 1993	Do.	Do.
#16 Freedom of Information Summary Guidelines	May 10, 1985	Do.	Do.
#13 Guidelines for Evaluation and Effectiveness of New Animal Drugs for Use in Free-Choice Feeds (revision of The Cattle Medicated Block Guideline)	January 1985	Do.	Do.
#10 Amendment of Section II(G)(1)(b)(4) of the Preclearance Guidelines	October 1975	Do.	Do.
#9 Preclearance Guidelines for Production Drugs	Withdrawn pending revisions	Do.	Do.
#6 Guideline for Submitting NADAs for Generic Drugs Reviewed by NAS/NRC	October 20, 1971; revised March 19, 1976	Do.	Do.
#5 Drug Stability Guidelines	December 1, 1990	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY CVM—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
#3 General Principles for Evaluating the Safety of Compounds Used in Food-Producing Animals (revised) (see guidance #118 for update to Section V.B.1)	July 1994	Do.	Do.
WITHDRAWN DOCUMENTS			
#58 Guidance for Industry; Good Target Animal Study Practices: Clinical Investigators and Monitors	May 1997	N/A	N/A
#155 Guidance for Industry; 21 CFR Part 11; Electronic Records; Electronic Signatures, Electronic Copies of Electronic Records	March 1997/February 2003	Do.	Do.
#154 Draft Guidance for Industry on Part 11; Electronic Records, Electronic Signatures—Scope and Application	March 1997/February 2003	Do.	Do.
#77 Interpretation of On-Farm Feed Manufacturing and Mixing Operations	September 1998/June 2003	Do.	Do.
#66 Professional Flexible Labeling of Antimicrobial Drugs	August 1998/January 2002	Do.	Do.
#20 Antibacterial Drugs in Animal Feeds: Antibacterial Effectiveness Criteria	December 2004	Do.	Do.
#19 Antibacterial Drugs in Animal Feeds: Animal Health Safety Criteria	December 2004	Do.	Do.
#18 Antibacterial Drugs in Animal Feeds: Human Health Safety Criteria	December 2004	Do.	Do.
#15 Guideline for Reporting the Details of Clinical Trials Using an Investigational New Animal Drug in Non-Food Producing Animals	February 1977/December 2004	Do.	Do.
#14 Guideline for Reporting the Details of Clinical Trials Using an Investigational New Animal Drug in Food-Producing Animals	December 2004	Do.	Do.
#4 Guideline for Efficacy Studies for Systemic Sustained Release Sulfonamide Boluses for Cattle	December 2004	Do.	Do.
#2 Anthelmintics	December 2004	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY THE OFFICE OF THE COMMISSIONER AND THE OFFICE OF POLICY

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
FDA Information Sheets for Institutional Review Boards and Clinical Investigators	September 1998	Regulated industry	Internet via *http://www.fda.gov/oc/ohrt/irbs/default.htm* or Good Clinical Practice Programs (HF–34), Food and Drug Administration, 5600 Fishers Lane, rm. 9C–24, Rockville, MD 20857, 301–827–3340, *http://www.fda.gov/oc/gcp/guidance.html*
Guidance for Industry; Computerized Systems Used in Clinical Trials	April 1999	Do.	Internet via *http://www.fda.gov/ora/compliance_ref/bimo/ffinalcct.pdf* or Good Clinical Practice Programs (HF–34), Food and Drug Administration, 5600 Fishers Lane, rm. 9C–24, Rockville, MD 20857, 301–827–3340, *http://www.fda.gov/oc/gcp/guidance.htm*
Draft Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exceptions From Informed Consent Requirements for Emergency Research	March 30, 2000	Do.	Internet via *http://www.fda.gov/ora/compliance_ref/bimo/err_guide.htm* or Good Clinical Practice Programs (HF–34), Food and Drug Administration, 5600 Fishers Lane, rm. 9C–24, Rockville, MD 20857, 301–827–3340

GUIDANCE DOCUMENTS ISSUED BY THE OFFICE OF THE COMMISSIONER AND THE OFFICE OF POLICY—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
Draft Guidance for Industry on Exports and Imports Under the FDA Export Reform and Enhancement Act of 1996	February 1998	Do.	Internet via *http://www.fda.gov/opacom/fedregister/frexport.html*
Guidance for FDA and Industry: Direct Final Rule Procedures	November 21, 1997	FDA personnel	Internet via *http://www.fda.gov/opacom/morechoices/industry/guidance.htm*, or Office of Policy, 301–827–3360
International Harmonization; Policy on Standards	October 11, 1995	Regulated industry and FDA personnel	60 FR 53078, October 11, 1995; or Office of International Programs, 301–827–4480

GUIDANCE DOCUMENTS ISSUED BY ORA

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
			Mailing Address	Internet Address
Compliance Policy Guides Manual (replaces Compliance Policy Guide—January 1996)	Updated December 12, 2003	FDA staff	National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22161	*http://www.fda.gov/ora/cpgm*
Compliance Policy Guide, Section 615.115: Extra-Label Use of Medicated Feeds for Minor Species	April 2001	Do.	Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0420	*http://www.fda.gov/ora/compliance_ref/revisions.htm*
Compliance Policy Guide, Section 608.400: Compounding of Drugs for Use in Animals	July 2003	Do.	Do.	Do.
Compliance Policy Guide, Section 555.600: Filth From Insects, Rodents, and Other Pests in Foods	November 14, 2002	Do.	Do.	Do.
Compliance Policy Guide, Section 460.200: Pharmacy Compounding	May 29, 2002	Do.	Do.	Do.
Compliance Policy Guide, Section 575.100: Pesticide Residues in Food and Feed—Enforcement Criteria (CPG 7141.01) (revised)	May 16, 2002	Do.	Do.	Do.
Compliance Policy Guide, Section 230.150: Blood Donor Classification Statement, Paid or Volunteer Donor	May 7, 2002	Do.	Do.	Do.
Compliance Policy Guide, Section 510.150: Apple Juice, Apple Juice Concentrates, and Apple Juice Products—Adulteration With Patulin	October 2001	Do.	Do.	Do.
Compliance Policy Guide, Section 555.250: Statement of Policy for Labeling and Preventing Cross-Contact of Common Food Allergens	April 2001	Do.	Do.	Do.
Compliance Policy Guide, Section 220.100: Interstate Shipment of Biological Products for Use in Medical Emergencies	Reformatted March 2001	Do.	Do.	*http://www.fda.gov/ora/compliance_ref/cpg/*

GUIDANCE DOCUMENTS ISSUED BY ORA—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
			Mailing Address	Internet Address
Compliance Policy Guide, Section 270.100: Final Container Labels—Allergenic Extracts Containing Glycerin; Reporting Changes	Reformatted March 2001	Do.	Do.	Do.
Compliance Policy Guide, Section 230.150: Blood Donor Incentives; Draft	December 2000	Do.	Do.	Do.
Compliance Policy Guide, Section 7150.09: Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities	July 1991	FDA staff and regulated industry	Do.	*http://www.fda.gov/ora/compliance_ref/cpg/cpggenl/cpg120-100.html*
Glossary of Computerized System and Software Development Terminology	August 1995	Do.	National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22161 (NTIS Order No. PB96–127352)	*http://www.fda.gov/ora/inspect_ref/igs/gloss.html*
Guidelines for Entry Review of Radiation-Emitting Electronic Devices	March 12, 1999	FDA staff	Division of Import Operations and Policy (HFC–170), Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–1218	N/A
Laboratory Procedures Manual	June 1994	Do.	Division of Field Science (HFC–141), Food and Drug Administration, 5600 Fishers Lane, rm. 12–41, Rockville, MD 20857	*http://www.fda.gov/ora/science_ref/*
Laboratory Procedures Manual; ch. 10: Method Validation Samples	May 1999	Do.	Do.	Do.
Memorandum: ORA Investigational Strategy on Gamma-Butyrolactone (GBL) and Related Products	May 15, 2000	Do.	Division of Field Investigations, Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857	N/A
IOM: Investigations Operations Manual	March 2004	Do.	National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22161 (NTIS Order No. PB2001–913399)	*http://www.fda.gov/ora/inspect_ref/*
Regulatory Procedures Manual	March 2004	Do.	Do (NTIS Order No. PB97–196182)	*http://www.fda.gov/ora/compliance_ref/rpm/default.htm*
Regulatory Procedures Manual; ch. 5–7–10: Civil Money Penalty Reduction Policy for Small Entities	March 2004	Do.	Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0420	Do.
Regulatory Procedures Manual; ch. 10–9: Application Integrity Policy	March 2004	Do.	Do.	Do.

GUIDANCE DOCUMENTS ISSUED BY ORA—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
			Mailing Address	Internet Address
Regulatory Procedures Manual; ch. 9: Import Operations/Actions	September 2002	Do.	Do.	Do.
Regulatory Procedures Manual; ch. 6–1: Seizure	March 2004	Do.	Do.	Do.
Regulatory Procedures Manual; ch. 6–6: Civil Penalties—Electronic Product Radiation Control	March 2004	Do.	Do.	Do.
Regulatory Procedures Manual; ch. 4–1: Warning Letters	March 2004	Do.	Do.	*http://www.fda.gov/ora/compliance_ref/rpm_new2/ch4.html*
Guide to Inspections of Bulk Pharmaceutical Chemicals	May 1994	Do.	National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22161 (NTIS Order No. PB96–127154)	*http://www.fda.gov/ora/inspect_ref/igs/iglist.html*
Guide to Inspections of Pharmaceutical Quality Control Laboratories	July 1993	Do.	Do (NTIS Order No. PB96–127279)	Do.
Guide to Inspections of Microbiological Pharmaceutical Quality Control Laboratories	July 1993	Do.	Do (NTIS Order No. PB96–127287)	Do.
Guide to Inspections of Validation of Cleaning Processes	July 1993	Do.	Do (NTIS Order No. PB96–127246)	Do.
Guide to Inspections of Lyophilization of Parenterals	July 1993	Do.	Do (NTIS Order No. PB96–127253)	Do.
Guide to Inspections of High Purity Water Systems	July 1993	Do.	Do (NTIS Order No. PB96–127261)	Do.
Guide to Inspections of Dosage Form Drug Manufacturers—CGMPs	October 1993	Do.	Do (NTIS Order No. PB96–127212)	Do.
Guide to Inspections of Oral Solid Dosage Forms Pre/Post Approval Issues for Development and Validation	January 1994	Do.	Do (NTIS Order No. PB96–127345)	Do.
Guide to Inspections of Topical Drug Products	July 1994	Do.	Do (NTIS Order No. PB96–127394)	Do.
Guide to Inspections of Sterile Drug Substance Manufacturers	July 1994	Do.	Do (NTIS Order No. PB96–127295)	Do.
Guide to Inspections of Oral Solutions and Suspensions	August 1994	Do.	Do (NTIS Order No. PB96–127147)	Do.
Guide to Nutritional Labeling and Education Act (NLEA) Requirements	February 1995	Do.	Do (NTIS Order No. PB96–127378)	Do.
Guide to Inspections of Interstate Carriers and Support Facilities	April 1995	Do.	Do (NTIS Order No. PB96–127386)	Do.
Guide to Inspections of Dairy Product Manufacturers	April 1995	Do.	Do (NTIS Order No. PB96–127329)	Do.
Guide to Inspections of Manufacturers of Miscellaneous Foods—vol. 1	May 1995	Do.	Do (NTIS Order No. PB97–127220)	Do.
Guide to Inspections of Manufacturers of Miscellaneous Food Products—vol. 2	September 1996	Do.	Do (NTIS Order No. PB97–196133)	Do.

GUIDANCE DOCUMENTS ISSUED BY ORA—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
			Mailing Address	Internet Address
Guide to Inspections of Cosmetic Product Manufacturers	February 1995	Do.	Do (NTIS Order No. PB96–127238)	Do.
Guide to Inspections of Low Acid Canned Food Manufacturers, Part 1—Administrative Procedures/Scheduled Processes	November 1996	Do.	Do (NTIS Order No. PB97–196141)	Do.
Guide to Inspections of Low Acid Canned Food Manufacturers, Part 2—Manufacturing Processes/Procedures	April 1997	Do.	Do (NTIS Order No. PB97–196158)	Do.
Guide to Inspections of Low Acid Canned Food Manufacturers, Part 3—Container/Closures	November 1998	FDA staff	Do (NTIS Order No. PB00–133795)	N/A
Guide to Inspections of Blood Banks	September 1994	Do.	Do (NTIS Order No. PB96–127303)	*http://www.fda.gov/ora/inspect_ref/igs/iglist.html*
Guide to Inspections of Source Plasma Establishments	Revised April 2001	Do.	N/A	Do.
Guide to Inspections of Infectious Disease Marker Testing Facilities	October 1996	Do.	National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22161 (NTIS Order No. PB96–199476)	Do.
Biotechnology Inspection Guide Reference Materials and Training Aids	November 1991	Do.	Do (NTIS Order No. PB96–127402)	Do.
Guide to Inspection of Computerized Systems in Drug Processing	February 1983	Do.	Do (NTIS Order No. PB96–127337)	Do.
Guide to Inspections of Foreign Medical Device Manufacturers	September 1995	Do.	Do (NTIS Order No. PB96–127311)	Do.
Guide to Inspections of Foreign Pharmaceutical Manufacturers	May 1996	Do.	Do (NTIS Order No. PB96–199468)	Do.
Guide to Inspections of Medical Device Manufacturers	December 1997	Do.	Do (NTIS Order No. PB 98–127145)	Do.
Mammography Quality Standards Act (MQSA) Auditor's Guide	January 1998	Do.	Do (NTIS Order No. PB98–127178)	Do.
Guide to Inspections of Electromagnetic Compatibility Aspects of Medical Device Quality Systems	December 1997	Do.	Do (NTIS Order No. PB98–127152)	Do.
Guide to Inspections of Acidified Food Manufacturers	May 1998	Do.	N/A	Do.
Guide to Inspection of Aseptic Processing and Packaging for the Food Industry	February 2001	Do.	Division of Field Investigations, Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857	N/A
Guide to Inspections of Grain Product Manufacturers	July 2003	Do.	Do (NTIS Order No. PB98–137128)	Do.
Guide to Bioresearch Monitoring Inspections of In Vitro Diagnostic Devices	February 1998	Do.	Do (NTIS Order No. PB98–137151)	Do.
Guide to Inspections of Viral Clearance Processes for Plasma Derivatives	March 1998	Do.	Do (NTIS Order No. PB–98137144)	Do.

GUIDANCE DOCUMENTS ISSUED BY ORA—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
			Mailing Address	Internet Address
Guide to Traceback of Fresh Fruits and Vegetables Implicated in Epidemiological Investigations	April 2001	Do.	N/A	Do.
Guide to Inspections of Computerized Systems in the Food Processing Industry	August 1998	Do.	National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22161 (NTIS Order No. PB98–137136)	Do.
Guide to International Inspections and Travel (revision) (formerly FDA/ORA International Inspection Manual and Travel Guide)	November 2002	Do.	N/A	*http://www.fda.gov/ora/inspect_ref/giit/default.htm*
Guide to Inspections of Quality Systems	August 1999	Do.	N/A	*http://www.fda.gov/ora/inspect_ref/igs/qsit/QSITGUIDE.PDF*
Guide to Inspection of Firms Producing Food Products Susceptible to Contamination With Allergenic Ingredients	August 2001	Do.	N/A	*http://www.fda.gov/ora/inspect_ref/igs/iglist.html*
Computerized Systems Used in Clinical Trials	April 1999	Do.	N/A	*http://www.fda.gov/ora/compliance_ref/bimo/*
Compliance Program 7348.001: Bioresearch Monitoring, Human Drugs, In Vivo Bioequivalence	October 1, 1999	Do.	Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0420	Do.
Guide for Detecting Fraud in Bioresearch Monitoring Inspections	April 2003	Do.	Division of Freedom of Information (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857	N/A
Good Laboratory Practice Program 7348.808A (Nonclinical Laboratories); EPA Data Audit Inspections	October 1, 2000	Do.	Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0420	*http://www.fda.gov/ora/compliance_ref/bimo/*
Guideline for the Monitoring of Clinical Investigations	January 1988	FDA regulated industry	Do.	Do.
Small Business Guide to FDA	Revised March 31, 2004	Do.	Federal-State Relations (HFC–150), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2905	*http://www.fda.gov/ora/fed_state/small_business/sb_guide/default.htm*
Compliance Program 7348.808; Bioresearch Monitoring, Good Laboratory Practice (Nonclinical Laboratories)	Revised February 21, 2001	FDA staff	Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD. 20857, 301–827–0420	*http://www.fda.gov/ora/compliance_ref/bimo/*

GUIDANCE DOCUMENTS ISSUED BY ORA—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
			Mailing Address	Internet Address
Compliance Program 7348.809; Bioresearch Monitoring; Institutional Review Board	October 1, 1994	Do.	Do.	Do.
Compliance Program 7348.811; Bioresearch Monitoring, Clinical Investigators	October 1, 1997	Do.	Do.	Do.
Good Laboratory Practice Regulations; Management Briefings; Post Conference Report	August 1979	Do.	Do.	Do.
Good Laboratory Practices; Questions and Answers	June 1981	Do.	Do.	Do.
Guidance for FDA Staff on Sampling or Detention Without Physical Examination of Decorative Contact Lenses (Import Alert #86–10)	April 4, 2003	FDA staff	N/A	*http://www.fda.gov/ohrms/dockets/98fr/03-8315.pdf*
Compliance Policy Guide; Section 345.100: Male Condom Defects (CPG 7124.21); Draft	March 29, 2002	FDA staff and industry	Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0420	*http://www.fda.gov/ora/compliance_ref/cpg/*
PTC for Internal Reviews and Corrective Action Operating Plans	June 1991	Do.	N/A	*http://www.fda.gov/ora/compliance_ref/aip_points.html*
WITHDRAWALS				
Compliance Policy Guide—Section 305.100: Acupuncture Devices and Accessories (CPG 7124.11)	June 15, 1976	FDA staff and industry	N/A	
Compliance Policy Guide—Section 396.100: Applicability of the Sunlamp Performance Standard to UVA Tanning Products (CPG 7133.16)	October 1, 1980	Do.	Do.	
Compliance Policy Guide—Section 391.100: Advertisement Literature for High-Intensity Mercury Vapor Discharge Lamps (CPG 7133.13)	October 1, 1980	Do.	Do.	
Compliance Policy Guide—Section 315.200: Status of Dental Supplies Such As Denture Cleaners, Adhesives, Cushions, and Repair Materials as a Device or Cosmetic (CPG 7124.05)	April 26, 1976	Do.	Do.	
Compliance Policy Guide—Section 398.475: Minimum X-Ray Field Size for Spot-Film Operation of Fluoroscopic Systems With Fixed SID and Without Stepless Adjustment of the Field Size (CPG 7133.17)	October 1, 1980	Do.	Do.	
Medical Device Warning Letter Pilot Termination	March 8, 1999	Do.	Do.	
Compliance Policy Guide—Section 160.850: Enforcement Policy: 21 CFR Part 11; Electronic Records; Electronic Signatures (CPG 7153.17)	May 13, 1999	Do.	Do.	
Draft Guidance—21 CFR Part 11; Electronic Records; Electronic Signatures, Electronic Copies of Electronic Records	August 2002	Do.	Do.	

GUIDANCE DOCUMENTS ISSUED BY ORA—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
			Mailing Address	Internet Address
Draft Guidance—21 CFR Part 11; Electronic Records; Electronic Signatures Validation	August 2001	Do.	Do.	
Draft Guidance—21 CFR Part 11; Electronic Records; Electronic Signatures, Glossary of Terms	August 2001	Do.	Do.	
Draft Guidance—21 CFR Part 11; Electronic Records; Electronic Signatures, Time Stamps	February 2002	Do.	Do.	
Draft Guidance—21 CFR Part 11; Electronic Records; Electronic Signatures, Maintenance of Electronic Records	July 2002	Do.	Do.	
Compliance Policy Guide—Section 300.700: Direct Reference Authority for Class III Medical Devices Without a Premarket Notification (510(k)) or an Approved Premarket Approval Application (PMA) (CPG 7124.30)	February 26, 1991	Do.	Do.	
Compliance Policy Guide—Section 405.100: Prescriptions Prepared From Certified Antibiotics (CPG 7122.01)	October 1, 1980	Do.	Do.	
Compliance Policy Guide—Section 405.200: Export of Uncertified Antibiotics (CPG 7122.02)	October 1, 1980	Do.	Do.	
Compliance Policy Guide—Section 405.210: Returned Antibiotics Exported Under 801(d) of the Act (CPG 7122.03)	July 1, 1981	Do.	Do.	
Draft Compliance Policy Guide—Distributor Medical Device Reporting	August 28, 1997	Do.	Do.	

Dated: December 22, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–155 Filed 1–4–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0479]

Draft Risk Assessment of Streptogramin Resistance in Enterococcus faecium Attributable to the Use of Streptogramins in Animals; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to February 23, 2005, the comment period for the notice that appeared in the **Federal Register** of November 24, 2004 (69 FR 68384). In the notice, FDA requested comments on a draft risk assessment of the potential impact that food-animal use of streptogramin antimicrobials has on the resistance to chemically similar streptogramins used to treat human enterococcal infections. The agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: Submit written and electronic comments by February 23, 2005.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Barry Hooberman, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–8557, e-mail: *bhooberm@cvm.fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 24, 2004 (69 FR 68384), FDA published a notice with a 60-day comment period to request comments on a draft risk assessment of the potential impact that food-animal use of streptogramin antimicrobials has on the resistance to chemically similar streptogramins used to treat human enterococcal infections. The veterinary drug of interest in this risk assessment is the streptogramin, virginiamycin, a drug approved for use in chicken, turkey, swine, and cattle feed. FDA will consider information received during the comment period in its preparation of a final risk assessment.

The agency has received a request for a 60-day extension of the comment period for the notice. This request conveyed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the notice.

FDA has considered the request and is extending the comment period for the notice for an additional 30 days, until February 23, 2005. The agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying the preparation of the final risk assessment.

II. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 28, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 05–111 Filed 1–4–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Treatment; Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given that the 41st meeting of the Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Substance Abuse Treatment (CSAT) National Advisory Council will be held in January 2005.

A portion of the meeting will be open and include discussion of the Center's policy issues, current administrative, legislative, and program developments. The meeting will also include the review, discussion, and evaluation of individual grant applications. Therefore a portion of the meeting will be closed to the public as determined by the SAMHSA Administrator, in accordance with Title 5 U.S.C. 552b(c) and (6) and 5 U.S.C. App. 2, § 10(d).

SAMHSA/CSAT welcomes the attendance of the public at its advisory council meetings, and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please inform the contact person by January 19.

Substantive program information, a summary of the meeting, transcript of the open session, and a roster of Council members may be obtained by accessing the SAMHSA Advisory Committee Web site (*http://www.samhsa.gov*), or by communicating with the contact whose name and telephone number are listed below.

Committee Name: SAMHSA's Center for Substance Abuse Treatment National Advisory Council.

Meeting Dates: January 26–9 a.m.–4 p.m. January 27–9 a.m.–1 p.m.

Place: 1 Choke Cherry Road, Sugar Loaf Room, Rockville, Maryland 20857.

Type: Open: January 26–9 a.m.–4 p.m.; *Closed:* January 27–9 a.m.–10:15 a.m.; *Open:* January 27–10:30 a.m.–1 p.m.

Contact: Cynthia Graham, Executive Secretary, SAMHSA/CSAT National Advisory Council, 1 Choke Cherry Road, Room 5–1036, Rockville, MD 20857, telephone: (240) 276–1692, FAX: (240) 276–1690, e-mail: *Cynthia.graham@samhsa.hhs.gov.*

Dated: December 29, 2004.

Toian Vaughn, Committee Management Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 05–188 Filed 1–4–05; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

Reports, Forms, and Record Keeping Requirements: Agency Information Collection Activity Under OMB Review; Flight Crew Self-Defense Training—Registration and Evaluation

AGENCY: Transportation Security Administration (TSA), DHS.

ACTION: Notice of emergency clearance request.

SUMMARY: The U.S. Department of Homeland Security, Transportation Security Administration, has submitted a request for emergency processing of a new public information collection to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. 35). This notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to OMB for review and comment. The ICR describes the nature of the information collection and its expected burden.

DATES: Send your comments by February 4, 2005. A comment to OMB is most effective if OMB receives it within 30 days of publication.

ADDRESSES: Comments may be faxed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: DHS–TSA Desk Officer, at (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Lisa Dean, Privacy Officer, Office of Transportation Security Policy, TSA–9, Transportation Security Administration, 601 South 12th Street, Arlington, VA 22202–4220; telephone (571) 227–3947; facsimile (571) 227–2555.

SUPPLEMENTARY INFORMATION:

Transportation Security Administration (TSA)

Title: Flight Crew Self-Defense Training—Registration and Evaluation.

Type of Request: Emergency processing request of new collection.

OMB Control Number: Not yet assigned.

Form(s): "Level 1 End-of-Course Evaluation"; "Community College Sign-In Sheet."

Affected Public: Flight and cabin crew on commercial passenger and cargo flights.

Abstract: Section 603 of Vision 100—Century of Aviation Reauthorization Act (Pub. L. 108–176) requires TSA to develop and provide a voluntary advanced self-defense training program for flight and cabin crew members of air carriers providing scheduled passenger air transportation. This collection would allow TSA to collect identifying information from volunteer flight and cabin crew members who register for self-defense classes, and would permit TSA to solicit voluntary feedback on the quality of the training. Due to an impending statutory deadline, TSA is seeking an emergency three-month authorization, until April 2005, to collect this information.

Identifying information would be gathered from trainees who have registered for a self-defense program to confirm that they are eligible for that program (i.e., that they are an active flight or cabin crew member for a commercial or cargo air carrier), and to confirm their attendance at the self-defense classes. The information that would be collected consists of the trainee's identifying information (such as the trainee's name and employee number), the name of their employer, and contact information. TSA will use a sign-in sheet to collect this information at the beginning of the self-defense course.

After training is completed, TSA would solicit written feedback from trainees by using a standard TSA training evaluation form. Completion of this form would be voluntary and anonymous.

Number of Respondents: 3,000.

Estimated Annual Burden Hours: An estimated 750 hours annually.

Estimated Annual Cost Burden: $0.00.

TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Issued in Arlington, Virginia, on December 29, 2004.

Lisa S. Dean,

Privacy Officer.

[FR Doc. 05–198 Filed 1–4–05; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4907–N–34]

Notice of Proposed Information Collection: Comment Request; FHA Fee Inspector Panel Application Package

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Notice

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paper work Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* March 7, 2005.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent: Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, SW., L'Enfant Plaza Building, Room 8001, Washington, DC 20410 or *Wayne_Eddins@hud.gov.*

FOR FURTHER INFORMATION CONTACT: Joyce Johnson, Valuation Manager, Office of Single Family Program Development, Office of Housing, Room 9270, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410, telephone (202) 708–2121, (this is not a toll free number), for copies of the proposed forms and other available information.

SUPPLEMENTARY INFORMATION: The Department is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond; including the use of appropriate automated collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

This notice also lists the following information:

Title of Proposal: FHA Fee Inspector Panel Application Package.

OMB Control Number, if Applicable: 2502–0548.

Description of the Need for the Information and Proposed Use: The FHA Inspector Roster is a national listing of FHA approved inspectors who determine the quality of construction of houses before they can be accepted as security for FHA insured loans. The use of qualified inspectors is critical to minimizing the placement of FHA mortgage insurance on poorly constructed dwellings. FHA approved mortgages use the FHA Inspector Roster to select qualified inspectors.

Agency Form Numbers, if Applicable: Form HUD–92563.

Estimation of the Total Numbers of Hours Needed to Prepare the Information Collection Including Number of Respondents, Frequency of Response, and Hours of Response: The number of respondents is 1,000, the frequency of response is on occasion, and the burden hours are 3.5 hours per submission. The cost of providing the information is $30.00 per hour, for a total annual cost to respondents of $105,000 (1,000 x 3.5 x $30 = $105,000).

Status of the Proposed Information Collection: Request for extension of a currently approved collection. The form HUD–92563, is currently approved under OMB Control Number 2502–0538 with an expiration date of 06/30/2006.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C., Chapter 35, as amended.

Dated: December 20, 2004.

Sean G. Cassidy,

General Deputy Assistant Secretary for Housing-Deputy Federal Housing Commissioner.

[FR Doc. 05–213 Filed 1–4–05; 8:45 am]

BILLING CODE 7120–32–M

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Notice of Deadline for Submitting Completed Applications To Begin Participation in the Tribal Self-Governance Program in Fiscal Year 2006 or Calendar Year 2006

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of application deadline.

SUMMARY: In this notice, the Office of Self-Governance and Self-Determination (OSG) establishes a March 1, 2005, deadline for tribes/consortia to submit completed applications to begin participation in the tribal self-governance program in fiscal year 2006 or calendar year 2006.

DATES: Completed application packages must be received by the Director, Office of Self-Governance and Self-Determination on or before March 1, 2005.

ADDRESSES: Application packages for inclusion in the applicant pool should be sent to William A. Sinclair, Director, Office of Self-Governance and Self-Determination, Department of the Interior, 1849 C Street NW., Mail Stop 4618, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Dr. Kenneth D. Reinfeld, Office of Self-Governance and Self-Determination, Telephone 202–208–5734.

SUPPLEMENTARY INFORMATION: Under the Tribal Self-Governance Act of 1994 (Pub. L. 103–413), as amended by the Fiscal Year 1997 Omnibus Appropriations Bill (Pub. L. 104–208), the Director, Office of Self-Governance and Self-Determination may select up to 50 additional participating tribes/consortia per year for the tribal self-governance program, and negotiate and enter into a written funding agreement with each participating tribe. The Act mandates that the Secretary submit copies of the funding agreements at least 90 days before the proposed effective

date to the appropriate committees of the Congress and to each tribe that is served by the Bureau of Indian Affairs (BIA) agency that is serving the tribe that is a party to the funding agreement. Initial negotiations with a tribe/consortium located in a region and/or agency which has not previously been involved with self-governance negotiations, will take approximately 2 months from start to finish. Agreements for an October 1 to September 30 funding year need to be signed and submitted by July 1. Agreements for a January 1 to December 31 funding year need to be signed and submitted by October 1.

Purpose of Notice

25 CFR parts 1000.10 to 1000.31 will be used to govern the application and selection process for tribes/consortia to begin their participation in the tribal self-governance program in fiscal year 2006 and calendar year 2006. Applicants should be guided by the requirements in these subparts in preparing their applications. Copies of these subparts may be obtained from the information contact person identified in this notice.

Tribes/consortia wishing to be considered for participation in the tribal self-governance program in fiscal year 2006 or calendar year 2006 must respond to this notice, except for those which are (1) currently involved in negotiations with the Department; (2) one of the 88 tribal entities with signed agreements; or (3) one of the tribal entities already included in the applicant pool as of the date of this notice.

Dated: December 23, 2004.

David W. Anderson,

Assistant Secretary—Indian Affairs.

[FR Doc. 05–190 Filed 1–4–05; 8:45 am]

BILLING CODE 4310–W8–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Indian Gaming

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of approved Tribal-State compact.

SUMMARY: This notice publishes the approval of the Tribal-State Off-Track Wagering Compact between the Peoria Tribe of Indians and the State of Oklahoma.

EFFECTIVE DATE: January 5, 2005.

FOR FURTHER INFORMATION CONTACT: George T. Skibine, Director, Office of Indian Gaming Management, Office of the Deputy Assistant Secretary—Policy and Economic Development, Washington, DC 20240, (202) 219–4066.

SUPPLEMENTARY INFORMATION: Under Section 11 of the Indian Gaming Regulatory Act of 1988 (IGRA), Public Law 100–497, 25 U.S.C. 2710, the Secretary of the Interior shall publish in the **Federal Register** notice of approved Tribal-State compacts for the purpose of engaging in Class III gaming activities on Indian lands. This Compact allows for the Tribe to conduct Off-Track wagering.

Dated: December 21, 2004.

Michael D. Olsen,

Acting Principal Deputy Assistant Secretary—Indian Affairs.

[FR Doc. 05–189 Filed 1–4–05; 8:45 am]

BILLING CODE 4310–4N–P

INTERNATIONAL TRADE COMMISSION

[Investigations Nos. 731–TA–1082 and 1083 (Final)]

Chlorinated Isocyanurates From China and Spain

AGENCY: United States International Trade Commission.

ACTION: Scheduling of the final phase of antidumping investigations.

SUMMARY: The Commission hereby gives notice of the scheduling of the final phase of antidumping investigations Nos. 731–TA–1082 and 1083 (Final) under section 735(b) of the Tariff Act of 1930 (19 U.S.C. 1673d(b)) (the Act) to determine whether an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of less-than-fair-value imports from China and Spain of chlorinated isocyanurates, provided for in subheading 2933.69.60 of the Harmonized Tariff Schedule of the United States.[1]

For further information concerning the conduct of this phase of the investigations, hearing procedures, and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

EFFECTIVE DATE: December 16, 2004.

FOR FURTHER INFORMATION CONTACT: Joanna Lo (202–205–1888), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*.

SUPPLEMENTARY INFORMATION:

Background.—The final phase of these investigations is being scheduled as a result of affirmative preliminary determinations by the Department of Commerce that imports of chlorinated isocyanurates from China and Spain are being sold in the United States at less than fair value within the meaning of section 733 of the Act (19 U.S.C. 1673b). The investigations were requested in a petition filed on May 14, 2004 by Clearon Corporation, Fort Lee, New Jersey and Occidental Chemical Corporation, Dallas, Texas.

Participation in the investigations and public service list.—Persons, including industrial users of the subject merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the final phase of these investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11 of the Commission's rules, no later than 21 days prior to the hearing date specified in this notice. A party that filed a notice of appearance during the preliminary phase of the investigations need not file an additional notice of appearance during this final phase. The Secretary will maintain public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to

[1] For purposes of these investigations, the Department of Commerce has defined the subject imported merchandise as chlorinated isocyanurates. Chlorinated isocyanurates are derivatives of cyanuric acid, described as chlorinated s-triazine triones. There are three primary chemical compositions of chlorinated isocyanurates: (1) Trichloroisocyanuric acid ($Cl_3(NCO)_3$), (2) sodium dichloroisocyanurate (dihydrate) ($NaCl_2(NCO)_3 \cdot 2H_2O$), and (3) sodium dichloroisocyanurate (anhydrous) ($NaCl_2(NCO)_3$). Chlorinated isocyanurates are available in powder, granular, and tableted forms. The scope of these investigations covers all chlorinated isocyanurates, including Arch Chemicals, Inc.'s patented chlorinated isocyanurates tablet.

section 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in the final phase of these investigations available to authorized applicants under the APO issued in the investigations, provided that the application is made no later than 21 days prior to the hearing date specified in this notice. Authorized applicants must represent interested parties, as defined by 19 U.S.C. 1677(9), who are parties to the investigations. A party granted access to BPI in the preliminary phase of the investigations need not reapply for such access. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Staff report.—The prehearing staff report in the final phase of these investigations will be placed in the nonpublic record on April 20, 2005, and a public version will be issued thereafter, pursuant to section 207.22 of the Commission's rules.

Hearing.—The Commission will hold a hearing in connection with the final phase of these investigations beginning at 9:30 a.m. on May 5, 2005, at the U.S. International Trade Commission Building. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before April 25, 2005. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the hearing. All parties and nonparties desiring to appear at the hearing and make oral presentations should attend a prehearing conference to held at 9:30 a.m. on April 29, 2005, at the U.S. International Trade Commission Building. Oral testimony and written materials to be submitted at the public hearing are governed by sections 201.6(b)(2), 201.13(f), and 207.24 of the Commission's rules. Parties must submit any request to present a portion of their hearing testimony *in camera* no later than 7 days prior to the date of the hearing.

Written submissions.—Each party who is an interested party shall submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of section 207.23 of the Commission's rules; the headline for filing is April 27, 2005. Parties may also file written testimony in connection with their presentation at the hearing, as provided in section 207.24 of the Commission's rules, and posthearing briefs, which must conform with the provisions of section 207.25 of the Commission's rules. The deadline for filing posthearing briefs is May 12, 2005; witness testimony must be filed no later than three days before the hearing. In addition, any person who has not entered an appearance as a party to the investigations may submit a written statement of information pertinent to the subject of the investigations, including statements of support or opposition to the petition, on or before May 12, 2005. On May 26, 2005, the Commission will make available to parties all information on which they have not had an opportunity to comment. Parties may submit final comments on this information on or before May 31, 2005, but such final comments must not contain new factual information and must otherwise comply with section 207.30 of the Commission's rules. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's rules do not authorize filing of submissions with the Secretary by facsimile or electronic means, except to the extent permitted by section 201.8 of the Commission's rules, as amended, 67 FR 68036 (November 8, 2002).

Additional written submissions to the Commission, Including requests pursuant to section 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.21 of the Commission's rules.

Issued: December 29, 2004.
By order of the Commission.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. 05–152 Filed 1–4–05; 8:45 am]

BILLING CODE 7020–02–M

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Water Act

Under 28 CFR 50.7, notice is hereby given that on December 16, 2004, a proposed Consent Decree in *United States* v. *District of Columbia Water and Sewer Authority,* et al., Consolidated Civil Action 1:CV00183TFH, was lodged with the United States District Court for the District of Columbia.

In February 2000, Citizen Plaintiffs environmental groups sued the District of Columbia Water and Sewer Authority ("WASA") for violations of the Clean Water Act arising from its discharges from the combined sewer of wastewater containing untreated sewage and other pollutants into the Anacostia River, the Potomac River, and Rock Creek in the District of Columbia. The United States filed suit in December 2000, against both WASA and the District of Columbia. The United States alleged several claims, including that WASA's discharges from the combined sewer violated the terms of its National Pollutant Discharge Elimination System ("NPDES") permit and Section 301 of the Clean Water Act, 33 U.S.C. 1311. The two cases were consolidated.

Plaintiffs' other claims, claims for civil penalty and liability issues in the case were previously resolved through stipulations or a partial consent decree entered by the court in October 2003.

The consent decree lodged today resolves the remaining claim of the United States in the case. It requires WASA to construct and operate a system of pumps and tunnels to create additional storage in the combined sewer, which is expected to reduce the volume and frequency of the combined sewer discharges. The construction projects, which WASA estimates will cost more than $1.265 billion to plan, design, and construct, will be built over a twenty (20) year period.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, and should refer to *United States* v. *District of Columbia Water and Sewer Authority,* DOJ # 90–5–1–1–07137 and Consolidated Civil Action No. 1:CV00183TFH.

The Consent Decree may be examined at the Office of the United States Attorney, District of Columbia, c/o Brian

Sonfield, 501 Third Avenue, NW., Washington, DC 20001, and at U.S. EPA Region III, 1650 Arch Street, Philadelphia, PA 19103–2029. During the public comment period, the Consent Decree many also be examined on the following Department of Justice Web site, *http://www.usdoj.gov/enrd/open.html*. A copy of the Consent Decree may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611 or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov*), fax no. (202) 514–0097, phone confirmation number (202) 514–1547. In requesting a copy from the Consent Decree Library, please enclose a check in the amount of $162.00 (25 cents per page) payable to the U.S. Treasury.

Robert Brook,

Assistant Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 05–211 Filed 1–4–05; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decrees Pursuant to the Comprehensive Environmental Response Compensation and Liability Act

In accordance with Departmental policy, 28 CFR 50.7 and section 122(d)(2)(B) of CERCLA, 42 U.S.C. 9622(d)(2)(B), notice is hereby given that on December 22, 2004, two proposed consent decrees in *United States* v. *Johnson Controls, Inc.*, et al. Civil Action No. 04–74987, were lodged with the United States District Court for the Eastern District of Michigan.

The two consent decrees resolve certain claims of the United States against three companies under sections 106 and 107(a) of CERCLA, 42 U.S.C. 9606 and 9607(a), at the Shiawassee River Superfund Site ("the Site") in Howell, Livingston County Michigan. One of the consent decrees is with Johnson Controls, Inc. and Hoover Universal, Inc. That consent decree requires Johnson Controls and Hoover Universal to perform the remedial action EPA has selected for the Site. EPA's selected remedial action involves the removal of polychlorinated biphenyl ("PCB") contamination from specified areas of the flood plain and river sediment of the Shiawassee River. The second consent decree is with Multifastener Corporation. That consent decree requires that Multifastener pay the United States $1,700,000 for past response costs incurred by EPA in connection with the Site.

The Department of Justice will receive, for a period of thirty (30) days from the date of this publication, comments relating to the two proposed consent decrees. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, United States Department of Justice, P.O. Box 7611, Ben Franklin Station, Washington, DC 20044–7611, and should refer to *United States* v. *Johnson Controls, Inc.* et al., Civil Action No. 04–74987, and the Department of Justice Reference No. 90–11–3–07946.

The two proposed consent decrees may be examined at the Office of the United States Attorney for the Eastern District of Michigan, 211 W. Fort Street, Suite 2001, Detroit, Michigan 48226. During the public comment period, the two consent decrees may also be examined on the following Justice Department Web site, *http://www.usdoj.gov/enrd/open.html*. Copies of the consent decrees may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611 or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov*), fax no. (202) 514–0097, phone confirmation number (202) 514–1547. In requesting a copy from the Consent Decree Library, please enclose a check in the amount of $59.50 (25 cents per page reproduction cost) payable to the U.S. Treasury.

Benjamin Fisherow,

Deputy Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 05–212 Filed 1–4–05; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—ANSI Accredited Standards Committee "C136"

Notice is hereby given that, on September 17, 2004, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ("the Act"), ANSI Accredited Standards Committee "C136" ("C136 Committee"), by its Secretariat, National Electrical Manufacturers Association ("NEMA"), has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the name and principal place of business of the standards development organization and (2) the nature and scope of its standards development activities. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Pursuant to section 6(b) of the Act, the name and principal place of business of the standards development organization is: ANSI Accredited Standards Committee "C136", Rosslyn, VA. The nature and scope of C136 Committee's standards development activities are: To develop and maintain American National Standards related to roadway and area lighting equipment. C136 Committee currently maintains 38 standards relating to specifications, markings, testing and maintenance of roadway, and area lighting equipment, including components. The standards developed by C136 Committee are published by NEMA.

Dorothy B. Fountain,

Deputy Director of Operations, Antitrust Division.

[FR Doc. 05–139 Filed 1–4–05; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Association for the Advancement of Medical Instrumentation

Notice is hereby given that, on September 20, 2004, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ("the Act"), Association for the Advancement of Medical Instrumentation ("AAMI") has filed written notifications simultaneously with the Attorney General and the Federal Trade commission disclosing (1) the name and principal place of business of the standards development organization and (2) the nature and scope of its standards development activities. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Pursuant to section 6(b) of the Act, the name and principal place of business of the standards development organization is: Association for the Advancement of Medical Instrumentation, Arlington,

VA. The nature and scope of AAMI's standards development activities are: standards for medical devices and for healthcare products and services.

Dorothy B. Fountain,

Deputy Director of Operations, Antitrust Division.

[FR Doc. 05–147 Filed 1–4–05; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Central Station Alarm Association

Notice is hereby given that, on September 20, 2004, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ("the Act"), Central Station Alarm Association ("CSAA") has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the name and principal place of business of the standards development organization and (2) the nature and scope of its standards development activities. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Pursuant to section 6(b) of the Act, the name and principal place of business of the standards development organization is: Central Station Alarm Association, Vienna, VA. The nature and scope of CSAA's standards development activities are: The development of American National Standards specific to industry practice and conduct for the monitoring of electronic security systems. These standards shall apply to all operations of security system monitoring, and to the monitoring of all types of electronic systems which provide as their primary function the protection and safeguard of life, property, or information. These standards shall include standardization terms and definitions, specifications, requirements, procedures, and methods which apply to monitoring facilities, personnel, operators, and situation handling.

Dorothy B. Fountain,

Deputy Director of Operations, Antitrust Division.

[FR Doc. 05–142 Filed 1–4–05; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Institute of Inspection Cleaning and Restoration Certification

Notice is hereby given that, on September 15, 2004, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ("the Act"), Institute of Inspection Cleaning and Restoration Certification ("IICRC") has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the name and principal place of business of the standards development organization and (2) the nature and scope of its standards development activities. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Pursuant to section 6(b) of the Act, the name and principal place of business of the standards development organization is: Institute of Inspection Cleaning and Restoration Certification, Vancouver, WA. The nature and scope of IICRC's standards development activities are: IICRC is engaged in a segment of the cleaning, restoration and inspection industry, primarily involving floor coverings, upholstery, personal property, water and fire damage restoration of structures and contents, and mold remediation of structures and contents.

Dorothy B. Fountain,

Deputy Director of Operations, Antitrust Division.

[FR Doc. 05–141 Filed 1–4–05; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Interchangeable Virtual Instruments Foundation, Inc.

Notice is hereby given that, on November 26, 2004, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ("the Act"), the Interchangeable Virtual Instruments Foundation, Inc., has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Elgar Electronics Corporation, San Diego, CA; and Rockwell Collins, Cedar Rapids, IA have been added as parties to this venture. Also, Lucent Technologies, Murray Hill, NJ; and L–3 Communications, Vienna, VA have been withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and Interchangeable Virtual Instruments Foundation, Inc., intends to file additional written notification disclosing all changes in membership.

On May 29, 2001, Interchangeable Virtual Instruments Foundation, Inc., filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on July 30, 2001 (66 FR 39336).

The last notification was filed with the Department on June 2, 2004. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on June 22, 2004 (69 FR 34693).

Dorothy B. Fountain,

Deputy Director of Operations, Antitrust Division.

[FR Doc. 05–143 Filed 1–4–05; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—International Electrotechnical Commission Technical Committee Subcommittee 22G

Notice is hereby given that, on September 17, 2004, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ("the Act"), International Electrotechnical Commission Technical Committee Subcommittee 22G ("IEC TC SC 22G"), by its Secretariat, National Electrical Manufacturers Association ("NEMA"), has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the name and principal place of business of the standards development organization

and (2) the nature and scope of its standards development activities. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Pursuant to section 6(b) of the Act, the name and principal place of business of the standards development organization is: International Electrotechnical Commission Technical Committee Subcommittee 22G, Rosslyn, VA. The nature and scope of IEC TC SC 22G's standards development activities are: related to electronic power conversion equipment for adjustable speed drives. IEC TC SC 22G currently maintains a series of IEC 61800 standards dealing with general requirements for this equipment including ratings, electromagnetic compatibility, and safety. The standards developed by IEC TC SC 22G are published by NEMA.

Dorothy B. Fountain,

Deputy Director of Operations Antitrust Division.

[FR Doc. 05–137 Filed 1–4–05; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—International Electrotechnical Commission Technical Committee 98

Notice is hereby given that, on September 17, 2004, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ("the Act"), International Electrotechnical Commission Technical Committee 98 ("IEC TC 98"), by its Secretariat, National Electrical Manufacturers Association ("NEMA"), has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the name and principal place of business of the standards development organization and (2) the nature and scope of its standards development activities. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Pursuant to section 6(b) of the Act, the name and principal place of business of the standards development organization is: International Electrotechnical Commission Technical Committee 98, Rosslyn, VA. The nature and scope of IEC TC 98's standards development activities are: the development and maintenance of standards dealing with the performance and testing of electrical insulation systems. The standards developed by IEC TC 98 are published by NEMA.

Dorothy B. Fountain,

Deputy Director of Operations, Antitrust Division.

[FR Doc. 05–140 Filed 1–4–05; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—International Window Cleaning Association

Notice is hereby given that, on September 16, 2004, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ("the Act"), International Window Cleaning Association ("IWCA") has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the name and principal place of business of the standards development organization and (2) the nature and scope of its standards development activities. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Pursuant to section 6(b) of the Act, the name and principal place of business of the standards development organization is: International Window Cleaning Association, Alexandria, VA. The nature and scope of IWCA's standards development activities are: standards that focus on safety guidelines for the use of window cleaning access equipment and the manufacture, design and installation of window cleaning access equipment. The IWCA develops standards through the IWCA I–14 Committee, which includes three categories of groups for whom standards are relevant: "Users" or window cleaners; "Producers" or manufacturers of equipment; and those with "General Interest," or safety consultants, designers, regulatory officials, and associations of building and contracting officials.

Dorothy B. Fountain,

Deputy Director of Operations Antitrust Division.

[FR Doc. 05–138 Filed 1–4–05; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Petroleum Environmental Research Forum ("PERF")

Notice is hereby given that, on December 1, 2004, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ("the Act"), the Petroleum Environmental Research Forum ("PERF") has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Petrozyme Technologies, Inc., Guelph, Ontario, Canada has withdrawn as a party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and PERF intends to file additional written notification disclosing all changes in membership.

On February 10, 1986, PERF filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on March 14, 1986 (51 FR 8903).

The last notification was filed with the Department on August 4, 2004. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on August 30, 2004 (69 FR 52931).

Dorothy B. Fountain,

Deputy Director of Operations, Antitrust Division.

[FR Doc. 05–146 Filed 1–4–05; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—PXI Systems Alliance, Inc.

Notice is hereby given that, on November 26, 2004, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ("the Act"), the PXI Systems Alliance, Inc., has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Opensystems Publishing, St. Clair Shores, MI has been added as a party to this venture. Also, B&B Technologies, Albuquerque, NM; CMI Technology, Seoul, Republic of Korea; Datum, San Jose, CA; ERNI Components, Chester, VA; EXFO Electro-Optical Engineering, Inc., Canier, Quebec, Canada; Gespac, Geneva, Switzerland; Innovative Integration, Simi Valley, CA; International Test Technologies, Co Donegal, Ireland; IPTE, Genk, Belgium; Kinetic Systems, Lockport, IL; Mass Interface Connections GmbH (MIC), Woinzach, Germany; Measurement Computing, Middleboro, MA; Precision Photonics, Boulder, CO; and santec Corporation, Aichi, Japan have been withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and PXI Systems Alliance, Inc., intends to file additional written notification disclosing all changes in membership.

On November 22, 2000, PXI Systems Alliance, Inc., filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on March 8, 2001 (66 FR 13971).

The last notification was filed with the Department on August 31, 2004. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on October 4, 2004 (69 FR 59270).

Dorothy B. Fountain,

Deputy Director of Operations, Antitrust Division.

[FR Doc. 05–144 Filed 1–4–05; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Southwest Research Institute: Clean Diesel IV

Notice is hereby given that, on November 16, 2004, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ("the Act"), Southwest Research Institute: Clean Diesel IV ("SwRI: Clean Diesel IV") has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Engelhard, Iselin, NJ; Komatsu, Tokyo, Japan; and NGK Insulators, Ltd., Nagoya, Japan have been added as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and SwRI: Clean Diesel IV intends to file additional written notification disclosing all changes in membership.

On April 6, 2004, SwRI: Clean Diesel IV filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on May 10, 2004 (69 FR 25923).

The last notification was filed with the Department on October 6, 2004. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on November 10, 2004 (69 FR 65228).

Dorothy B. Fountain,

Deputy Director of Operations, Antitrust Division.

[FR Doc. 05–145 Filed 1–4–05; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review: Comment Request

December 20, 2004.

The Department of Labor (DOL) has submitted the following public information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Public Law 104–13, 44 U.S.C. chapter 35). A copy of this ICR, with applicable supporting documentation, may be obtained by contacting Darrin King on 202–693–4129 (this is not a toll-free number) or e-mail: *king.darrin@dol.gov.*

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Office of the Secretary, Office of Management and Budget, Room 10235, Washington, DC 20503, 202–395–7316 (this is not a toll-free number), within 30 days from the date of this publication in the **Federal Register**.

The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Agency: Office of the Assistant Secretary for Administration and Management, Civil Rights Center.

Type of Review: Extension of currently approved collection.

Title: Compliance Information Report—29 CFR Part 37 Nondiscrimination—Workforce Investment Act of 1998.

OMB Number: 1225–0077.

Form Number: DL–1–2014A.

Frequency: On occasion; Biennially; and Annually.

Type of Response: Reporting; Recordkeeping; and Third party disclosure.

Affected Public: State, local, or tribal government and Individuals or households.

Number of Respondents: 34,884,387.

Collection of information	Number of respondents	Average response time (hours)	Annual burden hours
Data and Information Collection and Maintenance	34,884,387	0.006	193,802
Compliant Log	1,200	0.050	60
Methods of Administration:			
Periodic Updates	26	6	156
Biennial Updates	39	3	117
Compliant Information and Privacy Act Form	900	0.25	225
Written Justifications	20	2.00	40
Total	34,886,572		194,400

Total Annualized Capital/Startup Costs: $0.

Total Annual Costs (Operating/Maintaining Systems or Purchasing Services): $125,200.

Description: The Compliance Information Report and the information collection requirements at 29 CFR part 37 are designed to ensure that programs or activities funded in whole or in part by the Department of Labor operate in a nondiscriminatory manner. The Report requires such programs and activities to collect, maintain and report upon request from the Department, race, ethnicity, sex, age and disability data for program applicants, eligible applicants, participants, terminees, applicants for employment and employees. The Form DL–1–2014A is used for filing a complaint of alleged discrimination.

Ira L. Mills,

Departmental Clearance Officer.

[FR Doc. 05–157 Filed 1–4–05; 8:45 am]

BILLING CODE 4510–23–P

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review: Comment Request

December 22, 2004.

The Department of Labor (DOL) has submitted the following public information collection requests (ICRs) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Public Law 104–13, 44 U.S.C. chapter 35). A copy of each ICR, with applicable supporting documentation, may be obtained by contacting Darrin King on 202–693–4129 (this is not a toll-free number) or e-mail: *king.darrin@dol.gov.*

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Occupational Safety and Health Administration (OSHA), Office of Management and Budget, Room 10235, Washington, DC 20503, 202–395–7316 (this is not a toll-free number), within 30 days from the date of this publication in the **Federal Register**.

The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Agency: Occupational Safety and Health Administration.

Type of Review: Extension of currently approved collection.

Title: Notice of Alledged Safety and Health Hazards, OSHA–7 Form.

OMB Number: 1218–0064.

Frequency: On occasion.

Type of Response: Reporting.

Affected Public: Individuals or households.

Number of Respondents: 50,955.

Number of Annual Responses: 50,955.

Estimated Time Per Response: 17 minutes for electronic submission; 15 minutes for oral complaints; and 25 minutes for written complaints.

Total Burden Hours: 13,611.

Total Annualized Capital/Startup Costs: $0.

Total Annual Costs (Operating/Maintaining Systems or Purchasing Services): $692.

Description: Under paragraphs (a) and (c) of 29 CFR 1903.11 ("Complaints by employers") employees and their representatives may notify the OSHA area director or an OSHA compliance officer of safety and health hazards regulated by the Agency that they believe exist in their workplaces at any time. These provisions state further that this notification must be in writing and "shall set forth with reasonable particularity the grounds for the notice, and shall be signed by the employee or representatives of the employee." Along with providing specific hazard information to the Agency, paragraph (a) permits employees/employee representatives to request an inspection of the workplace. Paragraph (c) also addresses situations in which employees/employee representatives may provide the information directly to the OSHA compliance officer during an inspection. An employer's former employees may also submit complaints to the Agency.

To address the requirements of paragraphs (a) and (c), especially the requirement that the information be in writing, the Agency developed the OSHA–7 Form; this form standardized and simplified the hazard-reporting process. For paragraph (a), they may complete an OSHA–7 Form obtained from the Agency's Web site and then send it to OSHA on-line, or deliver a hardcopy of the form to the OSHA area office by mail or facsimile, or by hand. They may also write a letter containing the information and hand-deliver it to the area office, or send it by mail or facsimile. In addition, they may provide the information orally to the OSHA area office or another party (e.g., a Federal safety and health committee for Federal employees), in which case the area office or other party completes the hardcopy version of the form. For the typical situation addressed by paragraph (c), an employee/employee representation informs an OSHA compliance officer orally of the alleged hazard during an inspection, and the compliance officer then completes the hardcopy version of the OSHA–7 Form; occasionally, the employee/employee representative provides the compliance

officer with the information on the hardcopy version of the OSHA–7 Form.

Agency: Occupational Safety and Health Administration.

Type of Review: Extension of currently approved collection.

Title: Respiratory Protection (29 CFR 1910.134).

OMB Number: 1218–0099.

Frequency: On occasion.

Type of Response: Recordkeeping; Reporting; and Third party disclosure.

Affected Public: Business or other for-profit; Not-for-profit institutions; Federal government; and State, local, or tribal government.

Number of Respondents: 619,430.

Number of Annual Responses: 19,136,624.

Estimated Time Per Response: Varies from 5 minutes to mark a storage compartment or protective cover to 8 hours for large employers to gather and prepare information to develop a written program.

Total Burden Hours: 6,334,648.

Total Annualized Capital/Startup Costs: $0.

Total Annual Costs (Operating/Maintaining Systems or Purchasing Services): $98,545,304.

Description: The Respiratory Protection Standard (Sec. 1910.134; hereafter, "Standard") information collection requirements require employers to: Develop a written respirator program; conduct employee medical evaluations and provide follow-up medical evaluations to determine the employee's ability to use a respirator; provide the physician or other licensed health care professional with information about the employee's respirator and the conditions under which the employee will use the respirator; and administrator fit tests for employees who will use negative- or positive-pressure, tight-fitting face-pieces. In addition, employers must ensure that employees store emergency-use respirators in compartments clearly marked as containing emergency-use respirators. For respirators maintained for emergency use, employers must label or tag the respirator with a certificate stating the date of inspection, the name of the individual who made the inspection, the findings of the inspection, required remedial action, and the identity of the respirator.

The Standard also requires employers to ensure that cylinders used to supply breathing air to respirators have a certificate of analysis from the supplier stating that the breathing air meets the requirements for Type 1—Grade D breathing air; such certification assures employers that the purchased breathing air is safe. Compressors used to supply breathing air to respirators must have a tag containing the most recent change date and the signature of the individual authorized by the employer to perform the change. Employers must maintain this tag at the compressor. These tags provide assurance that the compressors are functioning properly.

Ira L. Mills,

Departmental Clearance Officer.

[FR Doc. 05–158 Filed 1–4–05; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review; Comment Request

December 28, 2004.

The Department of Labor (DOL) has submitted the following public information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). A copy of each ICR, with applicable supporting documentation, may be obtained by contacting the Department of Labor (DOL). To obtain documentation, contact Ira Mills on (202) 693–4122 (this is not a toll-free number) or e-mail: *mills.ira@dol.gov.*

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL, Office of Management and Budget, Room 10235, Washington, DC 20503 (202) 395–7316 (this is not a toll-free number), within 30 days from the date of this publication in the **Federal Register**.

The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Agency: Employment and Training Administration.

Type of Review: Extension of a currently approved collection.

Title: Interstate Arrangement for Combining Employment and Wages.

OMB Number: 1205–0029.

Frequency: Quarterly.

Affected Public: State, local, or tribal government.

Number of Respondents: 53.

Number of Annual Responses: 212.

Total Burden Hours: 848.

Estimated Time Per Response: 4 hours.

Total Annualized Capital/Startup Costs: $0.

Total Annual Costs (Operating/Maintaining Systems or Purchasing Services): $0.

Description: This report provides data necessary to measure the scope and effect of the program for combining employment and wages covered under difference States' laws of a single State and to monitor States' payment and wage transfer performance.

Ira L. Mills,

Departmental Clearance Officer.

[FR Doc. 05–159 Filed 1–4–05; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

Announcement of Public Briefings on Using the New Permanent Foreign Labor Certification (PERM) System

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice.

SUMMARY: The regulation to implement the re-engineered permanent foreign labor certification program (PERM) was published in the **Federal Register** on December 27, 2004, with an effective date of March 28, 2005. The Employment and Training Administration (ETA) of the Department of Labor (Department or DOL) is issuing this notice to announce DOL will offer four public briefings to educate the public on using the new permanent foreign labor certification system. The four briefings will take place in early 2005 in Chicago, Atlanta, Costa Mesa (California) and Washington, DC. During the briefings, the Department will also provide an update on backlog reduction efforts. This notice provides the public with locations, dates, and registration information regarding these four briefings.

As of December 13, 2004, The Department opened two new National Processing Centers in Atlanta and Chicago. The National Processing Centers will handle permanent labor certification cases to be filed under the PERM system. For the sessions held in Atlanta and Chicago, the Department will offer an open house to allow the public to tour the two new facilities. Attendees of the briefings are not required to formally register for the open house, but instead are invited to visit the National Processing Centers during the hours listed below.

FOR FURTHER INFORMATION CONTACT: William Carlson, Chief, Division of Foreign Labor Certification, Employment and Training Administration, 200 Constitution Avenue, NW., Room C–4312, Washington, DC 20210; Telephone: (202) 693–3010 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: The following registration information should be used by any member of the public planning to attend a PERM briefing session.

Chicago

Date: Monday, January 10, 2005.
Event: Open house.
Time: 2 p.m. to 4 p.m.
Location: U.S. Department of Labor, Employment and Training Administration, Foreign Labor Certification National Processing Center, 844 North Rush Street, 12th Floor, Chicago, Illinois 60611.
Date: Tuesday, January 11, 2005.
Event: PERM briefing.
Time: 9 a.m. to 1 p.m.
Location: Drake Hotel, 140 E. Walton Place, Chicago, IL 60611.

Atlanta:

Date: Tuesday, January 11, 2005.
Event: Open house.
Time: 2 p.m. to 4 p.m.
Location: U.S. Department of Labor, Employment and Training Administration, Foreign Labor Certification National Processing Center, Harris Tower, 233 Peachtree Street, Suite 410, Atlanta, Georgia 30303.
Date: Wednesday, January 12, 2005.
Event: PERM briefing.
Time: 9 a.m. to 1 p.m.
Location: Wyndham Atlanta, 160 Spring St., NW., Atlanta, GA 30303.

Costa Mesa:

Date: Tuesday, January 25, 2005.
Event: PERM briefing.
Time: 9 a.m. to 1 p.m.
Location: Hilton Costa Mesa, 3050 Bristol Street, Costa Mesa, CA 92626.

Washington, DC:

Date: Thursday, February 3, 2005.
Event: PERM briefing.
Time: 9 a.m. to 1 p.m.
Location: Marriott Washington, 1221 22nd Street, NW., Washington, DC 20037.

To Register. To register for one of the PERM briefings listed above, please use the following information. To complete the registration process on-line, please visit *http://www.namsinc.org/DOLETA*. For questions regarding the registration process, please call 703–821–2226 extension 232.

Signed in Washington, DC, this 29th day of December, 2004.

Emily Stover DeRocco,

Assistant Secretary, Employment and Training Administration.

[FR Doc. 05–156 Filed 1–4–05; 8:45 am]

BILLING CODE 4510–30–M

NATIONAL COUNCIL ON DISABILITY

Youth Advisory Committee Meeting (Teleconference)

Time and Date: 12:30 p.m., EST, February 4, 2005.

Place: National Council on Disability, 1331 F Street, NW., Suite 850, Washington, DC.

Agency: National Council on Disability (NCD).

Status: All parts of this meeting will be open to the public. Those interested in participating should contact the appropriate staff member listed below.

Agenda: Roll call, announcements, reports, new business, adjournment.

Contact Person for More Information: Geraldine Drake Hawkins, Ph.D., Program Analyst, National Council on Disability, 1331 F Street, NW., Suite 850, Washington, DC 20004; (202) 272–2004 (voice), (202) 272–2074 (TTY), (202) 272–2022 (fax), *ghawkins@ncd.gov* (e-mail).

Youth Advisory Committee Mission: The purpose of NCD's Youth Advisory Committee is to provide input into NCD activities consistent with the values and goals of the Americans with Disabilities Act.

Dated: December 29, 2004.

Mark S. Quigley,

Director of Communications and Acting Executive Director.

[FR Doc. 05–153 Filed 1–4–05; 8:45 am]

BILLING CODE 6820–MA–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 72–1]

Notice of Issuance of Renewed Materials License SNM–2500, General Electric Company, Morris Operation, Independent Spent Fuel Storage Installation

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of issuance of license renewal.

FOR FURTHER INFORMATION CONTACT: Christopher M. Regan, Senior Project Manager, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Telephone: (301) 415–1179; fax number: (301) 415–8555; e-mail: *cmr1@nrc.gov*.

SUPPLEMENTARY INFORMATION:

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC or the Commission) has issued renewed Materials License No. SNM–2500 held by the General Electric Company (GE) for the possession, storage, and transfer of spent fuel at the Morris Operation Independent Spent Fuel Storage Installation (ISFSI), located in Grundy County, Illinois. The renewed license authorizes operation of the Morris Operation ISFSI in accordance with the provisions of the renewed license and its Technical Specifications.

II. Background

By application dated May 22, 2000, as supplemented August 13, 2001, August 6, 2003, and August 9, 2004, GE requested to renew the operating license for the Morris Operation ISFSI. The renewed operating license would permit operation for an additional 20 years beyond the initial licensed period.

III. Finding

The application for the renewed license complies with the standards and requirements of the Atomic Energy Act of 1954 (the Act), as amended, and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter 1, which are set forth in the license. Public notice of the proposed action and opportunity for a hearing regarding the proposed issuance of the renewed license was published in the **Federal Register** on October 19, 2000 (65 FR 62766).

Further Information: As of October 25, 2004, the NRC initiated an additional

security review of publicly available documents to ensure that potentially sensitive information is removed from the Agencywide Documents and Management System (ADAMS) database accessible through the NRC's Web site. Interested members of the public should check the NRC's Web pages for updates on the availability of documents through the ADAMS system. Copies of the referenced documents are available for review and/or copying at the NRC Public Document Room after resumption of public access to ADAMS. The NRC Public Document Room (PDR) Reference staff can be contacted at 1–800–397–4209, 301–415–4737 or by e-mail to *pdr@nrc.gov*.

Dated at Rockville, Maryland, this 21st day of December, 2004.

For the Nuclear Regulatory Commission.

Christopher M. Regan,

Senior Project Manager, Licensing Section, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 05–149 Filed 1–4–05; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 72–1]

Notice of Issuance of Amendment to Materials License SNM–2500, General Electric Morris Operation Docket No. 72–1

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of issuance of license amendment.

FOR FURTHER INFORMATION CONTACT: Christopher M. Regan, Senior Project Manager, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Telephone: (301) 415–1179; fax number: (301) 415–8555; e-mail: *cmr1@nrc.gov*.

SUPPLEMENTARY INFORMATION:

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC or the Commission) has issued Amendment 12 to Special Nuclear Materials License No. SNM–2500 held by the General Electric Company (GE) for the possession, storage, and transfer of spent fuel at the Morris Operation Independent Spent Fuel Storage Installation (ISFSI), located in Grundy County, Illinois. The amendment is effective as of the date of issuance.

II. Background

By application dated July 30, 2004, as supplemented August 9, 2004, GE requested an amendment to revise the license (SNM–2500) and the Technical Specifications (TS) of SNM–2500 for the Morris Operation ISFSI. The changes would be made to reflect the current condition of the fuel stored and only that equipment necessary for its safe storage. The major changes include revisions to information regarding the spent fuel inventory, deletion of the requirement for ventilation exhaust vacuum, deletion of the requirement to have certain instrumentation operative for equipment that is no longer in service, a change in the methods to verify pool water quality, revision to the description of the company organization, and removal of "receipt" from the license which effectively will not permit the Morris Operation ISFSI to accept shipment of any additional spent fuel.

III. Finding

This amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment. This amendment satisfied the criteria specified in 10 CFR 51.22(c)(11) for a categorical exclusion from the requirements to perform an environmental assessment or to prepare an environmental impact statement.

IV. Hearing

In accordance with 10 CFR 72.46(b)(2), a determination has been made that the amendment does not present a genuine issue as to whether public health and safety will be significantly affected. Therefore, the publication of a notice of proposed action and an opportunity for hearing or a notice of hearing is not warranted. Notice is hereby given of the right of interested persons to request a hearing on whether the action should be rescinded or modified.

Further Information: As of October 25, 2004, the NRC initiated an additional security review of publicly available documents to ensure that potentially sensitive information is removed from the Agencywide Documents Access and Management System (ADAMS) database accessible through the NRC's Web site. Interested members of the public should check the NRC's Web pages for updates on the availability of documents through the ADAMS system. Copies of the referenced documents are available for review and/or copying at the NRC Public Document Room after resumption of public access to ADAMS. The NRC Public Document Room (PDR) Reference staff can be contacted at 1–800–397–4209, 301–415–4737 or by e-mail to *pdr@nrc.gov*.

Dated at Rockville, Maryland, this 21st day of December 2004.

For the Nuclear Regulatory Commission.

Christopher M. Regan,

Senior Project Manager, Licensing Section, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 05–150 Filed 1–4–05; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Notice of Availability of Environmental Assessment and Finding of No Significant Impact for the Kiski Valley Water Pollution Control Authority (KVWPCA) Site in Leechburg, PA

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Environmental assessment and finding of no significant impact.

FOR FURTHER INFORMATION CONTACT: Kenneth Kalman, Project Manager, Decommissioning Directorate, Division of Waste Management and Environmental Protection, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville, MD 20852. Telephone: (301) 415–6664; fax number: (301) 415–5397; e-mail: *KLK@nrc.gov*.

SUPPLEMENTARY INFORMATION:

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) has decided to take no further action on the Kiski Valley Water Pollution Control Authority (KVWPCA) site in Leechburg, Pennsylvania. In accordance with the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) part 51, the NRC published a Draft Environmental Assessment (EA) in support of this action in the **Federal Register** (69 FR 56102) requesting comments on the proposed action and Draft EA. The NRC did not receive any comments. Based on the EA, the NRC has concluded that a Finding of No Significant Impact is appropriate.

II. Environmental Assessment

In 1994, KVWPCA made plans to remove the ash from the lagoon at the

KVWPCA site. Over the course of site closure, the Pennsylvania Department of Environmental Resources notified NRC that elevated uranium concentrations had been found in an ash sample from the KVWPCA site. Subsequent analyses revealed that subsurface uranium contamination was present at concentrations of up to 34 becquerels per gram (Bq/g) [923 picocuries per gram(pCi/g)] total uranium, and that the material was enriched to approximately 4% uranium-235. Further characterization revealed that the volume of the contaminated ash is approximately 9,000 cubic meters (320,000 cubic feet) and that the total uranium inventory is approximately 32–41 gigabecquerels (0.85–1.1 Ci), resulting in an average total uranium concentration of approximately 3.0 Bq/g (80 pCi/g). The contaminated ash is highly heterogeneous and the highest levels of contamination are found over a relatively small area, at a depth of 2 to 3 meters (m) [7 to 10 feet (ft)]. Radionuclides other than uranium are also present, but at much lower concentrations.

The contamination is believed to have resulted from the reconcentration of uranium-contaminated effluents released from the sanitary sewers and laundry drains of the Babcock & Wilcox (B&W) Apollo facility. During its operation, the B&W Apollo facility conducted fuel manufacturing and fabrication. Upon successful completion of its decommissioning activities, the NRC terminated the B&W Apollo site's license on April 14, 1997. There is no evidence suggesting that the discharges from the B&W Apollo facility exceeded permissible levels in effect during operation.

Since 1994, NRC, KVWPCA, and the Pennsylvania Department of Environmental Protection (PADEP) have engaged in numerous interactions on the decommissioning of the KVWPCA site. By letter dated November 7, 2003, NRC staff informed KVWPCA that it would conduct a dose assessment to determine what actions should be taken at the KVWPCA site. The NRC letter dated November 7, 2003, also noted that PADEP has taken the position that under Pennsylvania's Solid Waste Management Act, the ash in the lagoon should be removed and properly disposed of per the Commonwealth's jurisdiction over the material as solid waste. Therefore, the NRC staff's dose assessment included scenarios for leaving the ash on site as well as scenarios for removing the ash.

NRC staff conducted dose assessments for a range of potential scenarios. These scenarios include a removal scenario, in which the contaminated ash is excavated and removed to an offsite disposal facility, and an onsite no-action scenario, in which the lagoon is abandoned in place with no remedial actions performed. The onsite scenarios included a reasonably foreseeable future land use case and a pair of less likely cases used as assessment tools to bound the uncertainty associated with future land use. In all of the scenarios, doses from the groundwater pathway are expected to be significantly limited by the relatively non-leachable form of uranium in the ash as determined by leaching tests.

It is likely that the contaminated ash will be removed from the lagoon, and that the site will continue to be used as a waste water treatment plant. Thus, the critical group in the removal scenario is the workers who excavate the contaminated ash and are exposed through inhalation of resuspended fine contaminated ash particles and direct irradiation. In addition, to address the possibility that the ash may be removed to a RCRA-permitted landfill, potential impacts of more aggressive leachate chemistry (low or high pH conditions) on uranium mobility were considered and the range of doses to a hypothetical individual residing near the landfill was qualitatively evaluated.

The dose to workers who excavate and remove the ash is expected to be approximately 0.15 mSv (15 mrem). As any removal operation would take considerably less than one year, this constitutes the total annual dose in the year of removal. Doses to ash removal workers are dominated by the inhalation of uranium-234 and uranium-238 along with a small additional dose from external exposure. Doses to the ash removal workers are limited by the relatively low average concentration of these isotopes, the limited exposure time during excavation of the ash, and the limited respirability of the ash particles.

Three cases of the onsite no-action scenario, in which the ash is assumed to be left in place without any remedial action, were also evaluated. These include a recreational use case, in which the property is converted into a riverside park; an agricultural use case; and an intrusion case, in which it is assumed that a volume of ash is excavated for the construction of a basement and the excavated ash is spread on the land surface. These cases, while less likely, were evaluated because they are useful assessment tools. As they comprise a range of future land use and include all exposure pathways, they can be used to bound other scenarios and, therefore, provide an evaluation of the uncertainty associated with future land use.

In the event that the contaminated ash remains onsite with no remedial action taken, the assumption of a recreational exposure case results in a annual dose of approximately 0.01 mSv (1 mrem) over the next few centuries, eventually rising to approximately 0.02 mSv (2 mrem) at 1000 years. This result is approximately an order of magnitude lower than either the agricultural case or the intrusion case because no crop intake is assumed in the recreational case.

The results of analysis of the agricultural case indicate that the peak annual dose within the 1000-year compliance period is predicted to be less than 0.2 mSv (20 mrem) and to occur at 1000 years after the present time. Results of the analysis of the intrusion case indicate that the peak mean annual dose within the 1000-year compliance period is also expected to be less than 0.2 mSv (20 mrem) and to occur at 1000 years after the present time.

In the agricultural and intrusion cases, it was assumed that a person would install a well or cultivated field at a random location within the 4000 m^2 (1 acre) site. In the unrealistic case that a farmer were to occupy the site and place a home in the most contaminated 200 m^2 (0.05 acre) area on the site, the peak annual dose would be expected to be well below the public dose limit and thus this scenario is not given further consideration in the staff's evaluation.

Regardless of whether the ash is left in place or excavated and removed pursuant to Pennsylvania State law, the NRC staff concludes that the doses for all scenarios meet the NRC's criteria for unrestricted use. Therefore, no further remedial action under NRC authority is required. The staff's dose assessment is presented in greater detail in SECY–04–0102, "The Results of the Staff's Evaluation of Potential Doses to the Public from Materials at the KVWPCA site in Leechburg, Pennsylvania".

Proposed Action

NRC proposes to take no further regulatory action regarding the KVWPCA site.

Purpose and Need for the Proposed Action

The purpose of the proposed action is to allow the KVWPCA site in Leechburg, Pennsylvania, to be made available for unrestricted use. This can be justified by demonstrating that the site meets the NRC criteria for unrestricted use. Should the proposed action be approved, under Pennsylvania's Solid

Waste Management Act, PADEP could require that the ash in the lagoon be removed and disposed of as solid waste.

Alternative to the Proposed Action

Based on its dose assessment, the NRC staff found the KVWPCA site to be acceptable for release for unrestricted use. The only alternative to the proposed action would be to make no determination regarding the need for NRC action at the site. This would leave the KVWPCA site subject to potential unnecessary regulation by NRC. NRC has determined that the site meets the NRC's criteria for unrestricted use and that no further action by NRC is necessary. The no action alternative is not acceptable because KVWPCA does not plan to conduct any activities that would require NRC oversight.

The Affected Environment and Environmental Impacts

The site is located in the central portion of the Appalachian Plateau physiographic province. The Allegheny River and its tributaries such as the Kiskimenetas River drain the majority of the region. The KVWPCA site drains into the Kiskimenetas River.

The ash lagoon occupies approximately one acre of the 36-acre KVWPCA site. The bottom of the lagoon basin was excavated into the native silty clay of the bench terrace of the Kiskimenetas River. The lagoon is 2 to 3 meters deep. Land use within the vicinity of the site consists of medium-sized rural residences, small farms, and light industrial areas.

The NRC staff has reviewed the Closure Plan for the KVWPCA site and as discussed earlier, the NRC staff has conducted a dose assessment using site-specific data. Based on its review and analyses, the staff has determined that the affected environment and environmental impacts associated with the release for unrestricted use of the KVWPCA site are bounded by the impacts evaluated by the "Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License Termination of NRC-Licensed Nuclear Facilities" (NUREG–1496). The staff also finds that the proposed release for unrestricted use of the KVWPCA site is in compliance with 10 CFR 20.1402, "Radiological Criteria for Unrestricted Use." The proposed action will result in no physical change to the site. Therefore, NRC expects no significant impact of a non-radiological nature. However, by NRC taking no action, PADEP will have the ability to exercise its authority to require the material to be removed from the site, which will result in physical change to the site. The NRC staff has found no other activities in the area that could result in cumulative impacts.

Agencies and Persons Consulted

This EA was prepared by the NRC staff. The State Office of Historical Preservation, the State Fish and Wildlife Service, and the U.S. Fish and Wildlife Service were not contacted because release of the KVWPCA site for unrestricted use would not affect historical or cultural resources, nor would it affect threatened or endangered species. The NRC staff consulted with PADEP on an ongoing basis. No other sources were used beyond those referenced in this EA.

Conclusions

The NRC staff concludes that the proposed action meets the NRC's criteria for unrestricted use under the License Termination Rule, 10 CFR part 20, subpart E. NRC has prepared this EA in support of the proposal to take no further action in regard to the KVWPCA site. On the basis of the EA, NRC has concluded that the environmental impacts from the proposed action are expected to be insignificant and has determined that an environmental impact statement for the proposed action is not necessary.

List of Preparers

Kenneth Kalman, Project Manager, Division of Waste Management and Environmental Protection.

List of References

1. November 7, 2003 Letter from Kenneth Kalman to Robert Kossack, "Nuclear Regulatory Commission Staff Intent to Conduct Dose Assessment of the Kiski Valley Water Pollution Control Authority Site. (ADAMS ML032880386).

2. Kenneth Kalman (2004) *The Results of the Staff's Evaluation of Potential Doses to the Public from Materials at the Kiski Valley Water Pollution Control Authority site in Leechburg, Pennsylvania. (SECY–04–0102).* U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, June 22, 2004. (ADAMS ML041110312).

3. Chester Environmental (1994). *Closure Plan for Incinerator Ash Lagoon, Kiski Valley Water Pollution Control Authority, Westmoreland County, Pennsylvania.* Chester Environmental. Pittsburgh, PA, July 1994. (ADAMS ML003693188).

4. Chester Engineers (1997) *Ash Lagoon Closure: Kiski Valley Water Pollution Control Authority.* Chester Engineers, Pittsburgh, PA. February 1998. (ADAMS ML003683061).

5. *Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License Termination of NRC-Licensed Nuclear Facilities (NUREG–1496). Volumes 1–3* U.S. Nuclear Regulatory Commission, Office of Nuclear Regulatory Research, July 1997. (ADAMS ML042310492, ML042320379, and ML042330385).

III. Finding of No Significant Impact

The staff has prepared an EA in support of the proposed license amendment to terminate the license and release the site for unrestricted use. The staff has found that the radiological environmental impacts from the proposed amendment are bounded by the impacts evaluated by NUREG 1496, Volumes 1–3, "Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License termination of NRC-Licensed Facilities" (ML042310492, ML042320379, and ML042330385). The staff has also found that the non-radiological impacts are not significant. On the basis of the EA, NRC has concluded that there are no significant environmental impacts from the proposed amendment and has determined not to prepare an environmental impact statement.

IV. Further Information

Documents related to this action, are available electronically at the NRC's Electronic Reading Room at *http://www.nrc.gov/reading-rm/adams.html.* From this site, you can access the NRC's Agencywide Documents Access and Management System (ADAMS), which provides text and image files of NRC's public documents. The ADAMS accession numbers for the documents related to this notice are cited in the list of references, under EA Summary. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1–800–397–4209, 301–415–4737, or by e-mail to *pdr@nrc.gov.*

These documents may also be viewed electronically on the public computers located at the NRC's PDR, O–1–F21, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852. The PDR reproduction contractor will copy documents for a fee.

Please note that on October 25, 2004, the NRC suspended public access to ADAMS, and initiated an additional security review of publicly available documents to ensure that potentially sensitive information is removed from the ADAMS database accessible through

the NRC's Web site. Interested members of the public may obtain copies of the referenced documents for review and/or copying by contacting the Public Document Room pending resumption of public access to ADAMS.

Dated in Rockville, Maryland this 29th day of December, 2004. For the Nuclear Regulatory Commission.

Daniel Gillen,

Deputy Director, Decommissioning Directorate Division of Waste Management and Environmental Protection, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 05–151 Filed 1–4–05; 8:45 am]

BILLING CODE 7590–01–P

OVERSEAS PRIVATE INVESTMENT CORPORATION

January 19, 2005, Public Hearing

Time and Date: 1 p.m., Wednesday, January 19, 2005.

Place: Offices of the Corporation, Twelfth Floor Board Room, 1100 New York Avenue, NW., Washington, DC.

Status: Hearing Open to the public at 1 p.m.

Purpose: Public hearing in conjunction with each meeting of OPIC's Board of Directors, to afford an opportunity for any person to present views regarding the activities of the Corporation.

Procedures: Individuals wishing to address the hearing orally must provide advance notice to OPIC's Corporate Secretary no later than 5 p.m., Thursday, January 13, 2005. The notice must include the individual's name, title, organization, address, and telephone number, and a concise summary of the subject matter to be presented.

Oral presentations may not exceed ten (10) minutes. The time for individual presentations may be reduced proportionately, if necessary, to afford all participants who have submitted a timely request to participate, an opportunity to be heard.

Participants wishing to submit a written statement for the record must submit a copy of such statement to OPIC's Corporate Secretary no later than 5 p.m. Thursday, January 13, 2005. Such statements must be typewritten, double-spaced, and may not exceed twenty-five (25) pages.

Upon receipt of the required notice, OPIC will prepare an agenda for the hearing identifying speakers, setting forth the subject on which each participant will speak, and the time allotted for each presentation. The agenda will be available at the hearing.

A written summary of the hearing will be compiled, and such summary will be made available, upon written request to OPIC's Corporate Secretary, at the cost of reproduction.

Contact Person for Information: Information on the hearing may be obtained from Connie M. Downs at (202) 336–8438, via facsimile at (202) 218–0136, or via e-mail at *cdown@opic.gov.*

Dated: January 3, 2005.

Connie M. Downs,

OPIC Corporate Secretary.

[FR Doc. 05–256 Filed 1–3–05; 12:10 pm]

BILLING CODE 3210–01–M

OVERSEAS PRIVATE INVESTMENT CORPORATION

January 19, 2005, Annual Public Hearing

Time and Date: 2 p.m., Wednesday, January 19, 2005.

Place: Offices of the Corporation. Twelfth Floor Board Room, 1100 New York Avenue, NW., Washington, DC.

Status: Hearing open to the public at 2 p.m.

Purpose: Annual public hearing to afford an opportunity for any person to present views regarding the activities of the Corporation.

Procedures: Individuals wishing to address the hearing orally must provide advance notice to OPIC's Corporate Secretary no later than 5 p.m., Thursday, January 13, 2005. The notice must include the individual's name, organization, address, and telephone number, and a concise summary of the subject matter to be presented.

Oral presentations may not exceed ten (10) minutes. The time for individual presentations may be reduced proportionately, if necessary, to afford all participants who have submitted a timely request to participate, an opportunity to be heard.

Participants wishing to submit a written statement for the record must submit a copy of such statement to OPIC's Corporate Secretary no later than 5 p.m., Thursday, January 13, 2005. Such statements must be typewritten, double-spaced and may not exceed twenty-five (25) pages.

Upon receipt of the required notice, OPIC will prepare an agenda for the hearing identifying speakers, setting forth the subject on which each participant will speak, and the time allotted for each presentation. The agenda will be available at the hearing.

A written summary of the hearing will be compiled, and such summary will be made available, upon written request to OPIC's Corporate Secretary, at the cost of reproduction.

Contact Person for Information: Information on the hearing may be obtained from Connie M. Downs at (202) 336–8438, via facsimile at (202) 218–0136, or via e-mail at *cdown@opic.gov.*

Supplementary Information: OPIC is a U.S. Government agency which provides, on a commercial basis, political risk insurance and financing in friendly developing countries and emerging democracies for environmentally sound projects which confer positive developmental benefits upon the project country while creating employment in the U.S. OPIC is required by section 231A(c) of the Foreign Assistance Act of 1961, as amended ("The Act") to hold at least one public hearing each year.

Dated: January 3, 2005.

Connie M. Downs,

OPIC Corporate Secretary.

[FR Doc. 05–257 Filed 1–3–05; 12:10 pm]

BILLING CODE 3210–01–M

POSTAL SERVICE

Board of Governors; Sunshine Act Meeting

DATE AND TIMES: Tuesday, January 11, 2005; 8:30 a.m. and 9:30 a.m.

PLACE: Washington, DC, at U.S. Postal Service Headquarters, 475 L'Enfant Plaza, SW., in the Benjamin Franklin Room.

STATUS: January 11—8:30 a.m. (Open); 9:30 a.m. (Closed).

MATTERS TO BE CONSIDERED:

Tuesday, January 11—8:30 a.m. (Open)

1. Minutes of the Previous Meeting, December 7, 2004.
2. Remarks of the Postmaster General and CEO.
3. Committee Reports.
4. Consideration of Board Resolution on Capital Funding.
5. Annual Report on Government in the Sunshine Act Compliance.
6. Fiscal Year 2004 Comprehensive Statement on Postal Operations, including the Preliminary Fiscal Year 2006 Annual Performance Plan—GPRA.
7. Capital Investment.
   a. Southern Maine Processing and Distribution Center.
8. Election of Chairman and Vice Chairman of the Board of Governors
9. Tentative Agenda for the February 16–17, 2005, meeting in Sarasota, Florida.

Tuesday, January 11—9:30 a.m. (Closed)

1. Financial Update.

2. Postal Rate Commission Opinion and Recommended Decision in Repositionable Notes Provisional Service Change, Docket No. MC2004–5.
3. Rate Case Planning.
4. Strategic Planning.
5. Personnel Matters and Compensation Issues.

FOR FURTHER INFORMATION CONTACT: William T. Johnstone, Secretary of the Board, U.S. Postal Service, 475 L'Enfant Plaza, SW., Washington, DC 20260–1000. Telephone (202) 268–4800.

William T. Johnstone,
Secretary.
[FR Doc. 05–278 Filed 1–3–04; 1:46 pm]
BILLING CODE 7710–12–M

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon written request, copies available from: Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20594.

Extension: Rule 11Aa3–2, SEC File No. 270–439, OMB Control No. 3235–0500.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission ("Commission") is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for a revision of the existing collection of information discussed below.

Rule 11Aa3–2 provides that self-regulatory organizations (SROs) may, acting jointly, file a National Market System Plan ("NMS Plan") or may propose an amendment to an effective NMS Plan by submitting the text of the plan or amendment to the Secretary of the Commission, together with a statement of the purpose of such plan or amendment and, to the extent applicable, the documents and information required by paragraphs (b)(4) and (5) of Rule 11Aa3–2.

The collection of information is designed to permit the Commission to achieve its statutory directive to facilitate the development of a national market system. The information is used to determine if a NMS Plan, or an amendment thereto, should be approved and implemented.

The respondents to the collection of information are self-regulatory organizations (as defined by the Act), including national securities exchanges, national securities associations, registered clearing agencies and the Municipal Securities Rulemaking Board.

The respondents to the collection of information are self-regulatory organizations (as defined by the Act), including national securities exchanges and national securities associations.

Ten respondents file an average total of twelve responses per year, which corresponds to an estimated annual response burden of 553 hours.

Written comments are invited on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Direct your written comments to R. Corey Booth, Director/Chief Information Officer, Office of Information Technology, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549.

Dated: December 22, 2004.
Margaret H. McFarland,
Deputy Secretary.
[FR Doc. 05–127 Filed 1–4–05; 8:45 am]
BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon written request, copies available from: Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549.

Extension: Regulation D and Form D; OMB Control No. 3235–0076; SEC File No. 270–72.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission ("Commission") is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Regulation D sets forth rules governing the limited offer and sale of securities without Securities Act registration. The purpose of Form D notice is to collect empirical data, which provides a continuing basis for action by the Commission either in terms of amending existing rules and regulations or proposing new ones. In addition, the Form D allows the Commission to elicit information necessary in assessing the effectiveness of Regulation D and Section 4(6) as capital-raising devices for all businesses. Approximately 17,500 issuers file Form D and it takes an estimated 4 hours to prepare for a total annual burden of 70,000 hours. It is estimated that 25% of the total burden hours (17.500 reporting burden hours) is prepared by the company.

Written comments are invited on: (a) Whether this collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to R. Corey Booth, Director/Chief Information Officer, Office of Information Technology, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549.

Dated: December 28, 2004.
Margaret H. McFarland,
Deputy Secretary.
[FR Doc. 05–174 Filed 1–4–05; 8:45 am]
BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon written request, Copies available from: Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549.

Extensions:
Rule 701, OMB Control No. 3235–0522, SEC File No. 270–306
Regulations 14D and 14E, OMB Control No. 3235–0102, SEC File No. 270–114
Schedule 14D–9

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) the Securities and Exchange Commission ("Commission") is soliciting comments on the collections of information summarized below. The Commission plans to submit these existing collections of information to the Office of Management and Budget for extension and approval.

Securities Act Rule 701 requires when offerings in excess of $5 million are made under the employee benefit plan exemptive rule, the issuers must provide the employees with risk and financial statement disclosures among other things. The purpose of the Rule 701 to ensure that a basic level of information is available to employees and others when substantial amounts of securities are issued in compensatory arrangements. Approximately 300 companies annually rely on Rule 701 exemption and it takes an estimated .5 hours to prepare for a total annual burden of 600 hours. It is estimated that 25% of the 600 total annual burden hours (150 reporting burden hours) is prepared by the company.

Regulations 14D and 14E and related Schedule 14D–9 require information important to security holders in deciding how to respond to tender offers. Approximately 360 companies annually file Schedule 14D–9 and it takes 258 hours to prepare for a total annual burden of 92,880. It is estimated that 25% of the 92,880 total burden hours (23,220 reporting burden hours) is prepared by the company.

Written comments are invited on: (a) Whether these collections of information are necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collections of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to R. Corey Booth, Director/Chief Information Officer, Office of Information Technology, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549.

Dated: December 28, 2004.

Margaret H. McFarland,

Deputy Security.

[FR Doc. 05–175 Filed 1–4–05; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. IC–26715]

Notice of Applications for Deregistration Under Section 8(f) of the Investment Company Act of 1940

December 29, 2004.

The following is a notice of applications for deregistration under section 8(f) of the Investment Company Act of 1940 for the month of December, 2004. A copy of each application may be obtained for a fee at the SEC's Public Reference Branch, 450 Fifth St., NW., Washington, DC 20549–0102 (tel. 202–942–8090). An order granting each application will be issued unless the SEC orders a hearing. Interested persons may request a hearing on any application by writing to the SEC's Secretary at the address below and serving the relevant applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on January 24, 2005, and should be accompanied by proof of service on the applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Secretary, SEC, 450 Fifth Street, NW., Washington, DC 20549–0609.

For Further Information Contact: Diane L. Titus at (202) 942–0564, SEC, Division of Investment Management, Office of Investment Company Regulation, 450 Fifth Street, NW., Washington, DC 20549–0504.

General Securities, Incorporated [File No. 811–594]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On September 30, 2004, applicant transferred its assets to Kopp Total Quality Management Fund, a series of Kopp Funds, Inc., based on net asset value. Expenses of $40,700 incurred in connection with the reorganization were paid by Robinson Capital Management, Inc., applicant's former investment adviser.

Filing Date: The application was filed on November 17, 2004.

Applicant's Address: 7701 France Ave. S, Suite 500, Edina, MN 55435.

Lake Shore Family of Funds [File No. 811–8431]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On December 29, 2003, applicant made a liquidating distribution to its shareholders, based on net asset value. Expenses of $6,235 incurred in connection with the liquidation were paid by Lake Shore Fund Group, LLC, applicant's investment adviser.

Filing Date: The application was filed on November 23, 2004.

Applicant's Address: 8280 Montgomery Rd., Suite 302, Cincinnati, OH 45236–6101.

Albemarle Investment Trust [File No. 811–5098]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On February 6, 2004, applicant made a liquidating distribution to its shareholders, based on net asset value. Expenses of $16,856 incurred in connection with the liquidation were paid by Boys, Arnold & Company, Inc., applicant's investment adviser.

Filing Date: The application was filed on November 23, 2004.

Applicant's Address: Boys, Arnold & Company, Inc., 1272 Hendersonville Rd., Asheville, NC 28813.

Fiduciary Capital Pension Partners Liquidating Trust [File No. 811–6305], Fiduciary Capital Partners Liquidating Trust [File No. 811–6306]

Summary: Each applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. On December 31, 2003, each applicant made a final liquidating distribution to its shareholders, based on net asset value. Expenses of $101,393 and $102,217, respectively, incurred in connection with the liquidations were paid by each applicant.

Filing Date: The applications were filed on November 19, 2004.

Applicants' Address: 1530 16th St., Suite 200, Denver, CO 80202–1468.

Pitcairn Funds [File No. 811–9943]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On July 30, 2004, applicant transferred its assets to Constellation Funds, based on net asset

value. Expenses of $109,239 incurred in connection with the reorganization were paid by Pitcairn Investment Management, applicant's investment adviser, and Constellation Investment Management Company, L.P., investment adviser to the surviving fund.

Filing Date: The application was filed on November 24, 2004.

Applicant's Address: One Pitcairn Place, Suite 3000, 165 Township Line Rd., Jenkintown, PA 19046–3593.

CommonFund Institutional Funds [File No. 811–9555]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On July 31, 2004, applicant made a liquidating distribution to its shareholders based on net asset value. Two of applicant's series have outstanding receivables for certain foreign tax reclaims. Upon receipt of any foreign tax reclaims, the series will distribute the amount pro rata to the shareholders of record as of the liquidation date. Expenses of $9,879 incurred in connection with the liquidation were paid by Commonfund Asset Management Company, Inc., applicant's investment adviser, and its affiliates.

Filing Dates: The application was filed on October 4, 2004, and amended on December 3, 2004.

Applicant's Address: 1209 Orange St., Wilmington, DE 19801.

The France Growth Fund, Inc. [File No. 811–5994]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. On June 28, 2004, applicant made a liquidating distribution to its shareholders, based on net asset value. Expenses of $1,110,000 incurred in connection with the liquidation were paid by applicant. Applicant has retained $197,870 in cash, which is being held in a bank account maintained by PFPC Inc., to fund distributions to 41 stockholders who have not yet submitted their share certificates. Applicant also has retained $355,000 in cash, which is being held by applicant's custodian, Brown Brothers Harriman & Co., to pay for outstanding liabilities and estimated expenses.

Filing Dates: The application was filed on September 30, 2004, and amended on November 22, 2004.

Applicant's Address: 245 Park Ave., Suite 3906, New York, NY 10167.

Saffron Fund, Inc. [File No. 811–8284]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. On November 24, 2004, applicant made a final liquidating distribution to its shareholders, based on net asset value. Expenses of $241,600 incurred in connection with the liquidation were paid by applicant.

Filing Dates: The application was filed on August 30, 2004, and amended on November 30, 2004.

Applicant's Address: c/o UBS Global Asset Management (U.S.), 51 West 52nd St., New York, NY 10019.

The Southern Africa Fund, Inc. [File No. 811–7596]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. On November 23, 2004, applicant made a liquidating distribution to its shareholders, based on net asset value. Expenses of $328,630 incurred in connection with the liquidation were paid by applicant. The Bank of New York, applicant's liquidating agent, is holding $317,844 in cash for certificated shareholders who have not surrendered their shares. The unclaimed assets will be held for a period of three years, after which time any unclaimed assets will escheat to the State of Maryland. Applicant's custodian, Brown Brothers Harriman & Co., also is holding $213,258 in cash to cover certain unpaid expenses and liabilities.

Filing Date: The application was filed on November 30, 2004.

Applicant's Address: Investec Asset Management U.S. Limited, 1055 Washington Blvd., 3rd Floor, Stamford, CT 06901.

Orchard Series Fund [Filed No. 811–7735]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On June 25, 2004, applicant transferred its assets to Maxim Series Fund, Inc., based on net asset value. Expenses of $53,867 incurred in connection with the reorganization were paid by GW Capital Management, LLC, applicant's investment adviser.

Filing Dates: The application was filed on October 20, 2004, and amended on November 29, 2004.

Applicant's Address: 8515 East Orchard Rd., Greenwood Village, CO 80111.

Target Income Fund, Inc. [File No. 811–6542]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On March 13, 1997, applicant completed a liquidation and sale of all of its investment assets to Concord Growth Corporation, a commercial finance services firm unaffiliated with applicant. On April 3, 1997, applicant completed a tender offer were each shareholder received its pro rata share of the aggregate net asset value of applicant. Applicant paid approximately $25,000 in expenses related to the liquidation. A notice of the filing of the application was previously issued on November 26, 1997 (Investment Company Act Release No. 22913).

Filing Dates: The application was filed on July 24, 1997, and amended on October 23, 1997.

Applicant's Address: 26691 Plaza Drive, Suite 222, Mission Viejo, CA 92691.

Thornburg Limited Term Municipal Fund, Inc. [File No. 811–4302]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On June 21, 2004, applicant transferred its assets to Thornburg Investment Trust, based on net asset value. Expenses of $304,047 incurred in connection with the reorganization were paid by applicant.

Filing Date: The application was filed on December 15, 2004.

Applicant's Address: 119 East Marcy St., Santa Fe, NM 87501.

GE Life & Annuity Separate Account III [File No. 811–5054]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On July 14, 2004, applicant transferred its assets to GE Life & Annuity Separate Account II, based on net asset value. Expenses of $83,359 incurred in connection with the merger were paid by GE Life and Annuity Assurance Company.

Filing Dates: The application was filed on August 7, 2004 and amended and restated on November 10, 2004.

Applicant's Address: 6610 West Broad Street, Richmond, VA 23230.

GE Life & Annuity Separate Account I [File No. 811–4016]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On July 14, 2004, applicant transferred its assets to GE Life & Annuity Separate Account II, based on net asset value. Expenses of $41,370 incurred in connection with the merger were paid by GE Life and Annuity Assurance Company.

Filing Dates: The application was filed on August 4, 2004 and amended and restated on November 10, 2004.

Applicant's Address: 6610 West Broad Street, Richmond, VA 23230.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 05–129 Filed 1–4–05; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–50940; File No. SR–Amex–2004–102]

Self-Regulatory Organizations; American Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change and Amendment No. 1 Thereto Relating to Transaction Fees in Connection With the iShares® FTSE/Xinhua China 25 Index Fund

December 28, 2004.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 13, 2004, the American Stock Exchange LLC ("Amex" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in items I, II, and III below, which items have been prepared by the Exchange. On December 23, 2004, the Exchange filed Amendment No. 1 to the proposed rule change.[3] The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons.

1. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to revise transaction fees for specialists and registered options traders ("ROTs") in connection with transactions in the iShares® FTSE/Xinhua China 25 Index Fund ("FTSE/Xinhua Fund"). The text of the proposed rule change is available at the office of the Secretary, Amex, and at the Commission.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] In Amendment No. 1, the Exchange: (1) Specified that the trading of the iShares® FTSE/Xinhua China 25 Index Fund commended on the Exchane on December 20, 2004; (2) clarified that the proposed transaction fee with respect to the iShares® FTSE/Xinhua China 25 Index Fund is not changing; (3) made clarifying changes to the statement of the purpose of the proposed license fee; and (4) made technical changes to the proposed rule text. The Commission notes that Exhibit 4 of Amendment No. 1 included marked additions to the Amex Exchange Traded Funds and Trust Issued Receipts Fee Schedule that had already been indicated in the original proposal.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The proposed rule change sets forth the manner in which the Exchange will charge transaction fees for the FTSE/ Xinhua Fund. The Amex launched the trading of the FTSE/Xinhua Fund on December 20, 2004.[4] Transaction charges for specialists, ROTs, broker-dealers and customers in connection with the FTSE/Xinhua Fund would be billed at current rates existing for exchange traded funds ("ETFs") without unreimbursed fees to a third party as set forth in Item #7 to the Exchange's Equity Fee Schedule and Section 1 of the Amex Exchange Traded Funds and Trust Issued Receipts Fee Schedule. Accordingly, specialists would be charged a transaction fee of $.0033 per share ($0.33 per 100 shares), capped at $300 per trade (90,909 shares) while ROTs would be charged a transaction fee of $.0036 per share ($0.36 per 100 shares), capped at $300 per trade (83,333 shares). Transaction charges for specialists would be capped at $400,000 per month per specialist unit. Off-floor orders (*i.e.*, customer and broker-dealer) would be charged a transaction fee of $.006 per share ($.60 per 100 shares), capped at $100 per trade (16,667 shares). These fees are not changing.

In addition to the transaction charges set forth above, the Exchange would charge specialists and ROTs a license fee of $0.06 per 100 shares in connection with transactions in shares of the FTSE/Xinhua Fund. Thus, the total proposed fee for transactions in shares of the FTSE/Xinhua Fund is: (1) For specialists, $.0039 per share ($0.39 per 100 shares), capped at $300 per trade (76,923 shares); (2) for ROTs, $.0042 per share ($0.42 per 100 shares), capped at $300 per trade (71,428 shares); and (3) for customers and brokers-dealers, $.006 per share ($0.60 per 100 shares), capped at $100 per trade (16,667 shares).

The purpose of the proposed license fee is for the Exchange to recoup its costs in connection with the index license fee for the trading of shares of the FTSE/Xinhua Fund. The proposed licensing fee will be collected on every transaction of the FTSE/Xinhua Fund in which the specialist or ROT is a party. The Exchange believes that requiring the payment of a per contract licensing fee by those specialists units and ROTs that are the beneficiaries of the Exchange's index license agreements is justified and consistent with the rules of the Exchange. In addition, passing along the license fee (on a per contract basis) to the specialist allocated to the FTSE/Xinhua Fund and those ROTs trading such product is efficient and consistent with the intent of the Exchange to pass on its non-reimbursed costs to those market participants that are the beneficiaries.

The Exchange notes that in recent years it has increased a number of member fees to better align Exchange fees with the actual cost of delivering services and reduce Exchange subsidies of such services.[5] Implementation of this proposal is consistent with the reduction and/or elimination of theses subsidies.

The Exchange submits that the proposed license fee is intended to recoup the costs associated with the trading of the FTSE/Xinhua Fund. The Exchange will monitor the revenue generated in connection with the FTSE/Xinhua Fund license fee. In the event the revenue generated is greater than the Exchange's cost to the index provider, the Exchange will seek to rebate the difference back to the affected specialists and ROTs. The Amex believes that this fee will help to allocate to those specialists and ROTs transacting in FTSE/Xinhua Fund shares a fair share of the related costs of offering such ETFs. Accordingly, the Exchange believes that the proposed fee is reasonable.

2. Statutory Basis

The proposed fee change is consistent with section 6(b)(4) of the Act[6] regarding the equitable allocation of reasonable dues, fees, and other charges

[4] *See* Securities Exchange Act Release No. 50800 (December 6, 2004), 69 FR 72228 (December 13, 2004) (SR–Amex–2004–85).

[5] *See* Securities Exchange Act Release Nos. 45360 (January 29, 2002), 67 FR 5626 (February 6, 2002) (SR–Amex–2001–102) and 44286 (May 9, 2001), 66 FR 27187 (May 16, 2001) (SR–Amex–2001–22).

[6] 15 U.S.C. 78f(b)(4).

among Exchange members and other persons using Exchange facilities.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change will impose no burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to section 19(b)(3)(A) of the Act[7] and subparagraph (f)(2) of Rule 19b–4 thereunder[8] because it establishes or changes a due, fee, or other charge imposed by the Exchange. At any time within 60 days of December 23, 2004, the Commission may summarily abrogate such proposed rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in the furtherance of the purposes of the Act.[9]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–Amex–2004–102 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number SR–Amex–2004–102. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Amex–2004–102 and should be submitted on or before January 26, 2005.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[10]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 05–128 Filed 1–4–05; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–50930; File No. SR–NASD–2004–182]

Self-Regulatory Organizations, National Association of Securities Dealers, Inc.; Notice of Filing of Proposed Rule Change Regarding Minor Modifications to the Nasdaq Opening Process for Nasdaq-Listed Stocks

December 27, 2004.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 13, 2004, the National Association of Securities Dealers, Inc. ("NASD"), through its subsidiary, The Nasdaq Stock Market, Inc. ("Nasdaq"), filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in items I and II below, which items have been prepared by Nasdaq. Nasdaq has designated the proposed rule change as "non-controversial" under section 19(b)(3)(A)[3] of the Act and Rule 19b–4(f)(6) thereunder,[4] which renders the proposed rule change effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Nasdaq is filing a proposed rule change to modify the process for calculating the Nasdaq Official Opening Price ("NOOP"). There is no new proposed rule language for this proposal.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Nasdaq included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in item IV below. Nasdaq has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Nasdaq previously proposed to create two new voluntary opening processes—the Modified Opening Process and the Nasdaq Opening Cross—that together constitute the beginning of the trading day for all Nasdaq-listed securities. The Commission approved that proposal on September 16, 2004.[5] Nasdaq has

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[7] 15 U.S.C. 78s(b)(3)(A).

[8] 17 CFR 240.19b–4(f)(2).

[9] For purposes of calculating the 60-day period within which the Commission may summarily abrogate the proposed rule change under Section 19(b)(3)(C) of the Act, 15 U.S.C. 78s(b)(3)(C), the Commission considers that period to have commenced on December 23, 2004, the date the Exchange filed Amendment No. 1 to the proposed rule change.

[10] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6).

[5] Securities Exchange Act Release No. 50405 (September 16, 2004) 69 FR 57118 (September 23, 2004) (approving SR–NASD–2004–071). The Commission notes that Nasdaq made minor amendments to the Modified Opening Process and the Nasdaq Opening Cross as of October 12, 2004, which were not reflected in this filing. The Commission has made changes to the filing to correct this oversight. *See* Securities Exchange Act

Continued

identified a minor modification to the operation of the Nasdaq Opening Cross and Modified Opening Process that will improve the fair and orderly opening of the market in Nasdaq listed securities.

Specifically, Nasdaq proposes to modify the process for calculating the NOOP. Currently, the NOOP is equal to the reported price of the first trade executed by the execution functionality of the Nasdaq Market Center based upon orders that are in queue when Nasdaq begins trading at 9:30 a.m. ("Opening Match").[6] If there is no Opening Match within fifteen seconds after the system opens at 9:30, the NOOP is based upon the first, last sale eligible trade that is submitted to the trade reporting functionality of the Nasdaq Market Center.

Nasdaq proposes to change from fifteen to sixty seconds the length of time Nasdaq will wait for an Opening Match within Nasdaq's execution functionality before looking for a last sale eligible trade submitted to Nasdaq's trade reporting functionality. If the system executes a trade sooner than sixty seconds, the NOOP will be calculated at that time rather than waiting the full sixty seconds. By waiting up to sixty seconds, Nasdaq increases the likelihood that, in non-cross eligible stocks, a Nasdaq market center execution as opposed to an internalized trade will serve as the NOOP. Nasdaq believes that this outcome is consistent with the Act, more consistently fulfills the purpose of adopting the NOOP, and better serves investors.

2. Statutory Basis

Nasdaq believes that the proposed rule change is consistent with the provisions of section 15A of the Act,[7] in general, and with section 15A(b)(6) of the Act,[8] in particular, in that section 15A(b)(6) requires the NASD's rules to be designed, among other things, to protect investors and the public interest. Nasdaq's current proposal is consistent with the NASD's obligations under these provisions of the Act because it will result in a more orderly opening for all Nasdaq stocks. The proposed rule change will create a fair, orderly, and unified opening for Nasdaq stocks, prevent the occurrence of locked and crossed markets in halted securities, and preserve price discovery and transparency that is vital to an effective opening of trading.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Nasdaq neither solicited nor received written comments with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not:

(i) Significantly affect the protection of investors or the public interest;

(ii) Impose any significant burden on competition; and

(iii) Become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, it has become effective pursuant to Section 19(b)(3)(A) of the Act[9] and Rule 19b–4(f)(6), thereunder.[10] At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

Nasdaq has requested that the Commission waive the 30-day operative delay. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because it will allow Nasdaq to implement the proposed rule change which should help Nasdaq to maintain a fair and orderly market at the critical period of opening of trading. For this reason, the Commission designates the proposal to be effective and operative upon filing with the Commission.[11]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comments form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–NASD–2004–182 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number SR–NASD–2004–182. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Intenet Web site (*http://www.sec.gov/rules/sro.html*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of the filing also will be available for inspection and copying at the principal office of the NASD. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASD–2004–182 and should be submitted on or before January 26, 2005.

Release No. 50602 (October 28, 2004), 69 FR 64350 (November 4, 2004) (SR–NASD–2004–152).

[6] Securities Exchange Act Release No. 48997 (December 29, 2003), 69 FR 716 (January 6, 2004) (approving SR–NASD–2003–161).

[7] 15 U.S.C. 78*o*–3.

[8] 15 U.S.C. 78*o*–3(b)(6).

[9] 15 U.S.C. 78*o*–3.

[10] 15 U.S.C. 78*o*–3(b)(6). Nasdaq provided written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change at least five business days before the date of filing of the proposed rule change.

[11] For purposes only of waiving the 30-day operative delay of the proposed rule change, the Commission considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[12]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 05–126 Filed 1–4–05; 8:45 am]

BILLING CODE 8010–01–M

DEPARTMENT OF STATE

[Public Notice 4947]

30-Day Notice of Proposed Information Collection: DS–10, Birth Affidavit, OMB Control Number 1405–0132

ACTION: Notice of request for public comment and submission to OMB of proposed collection of information.

SUMMARY: The Department of State has submitted the following information collection request to the Office of Management and Budget (OMB) for approval in accordance with the Paperwork Reduction Act of 1995.

- *Title of Information Collection:* Birth Affidavit.
- *OMB Control Number:* 1405–0132.
- *Type of Request:* Revision of a currently approved collection.
- *Originating Office:* Bureau of Consular Affairs, CA/PPT/FO/FC.
- *Form Number:* DS–10.
- *Respondents:* U.S. citizens.
- *Estimated Number of Respondents:* 81,500 per year.
- *Estimated Number of Responses:* 81,500 per year.
- *Average Hours Per Response:* .25 (15 minutes).
- *Total Estimated Burden:* 20,375.
- *Frequency:* On Occasion.
- *Obligation to Respond:* Required To Obtain or Retain a Benefit.

DATES: Submit comments to the Office of Management and Budget (OMB) for up to 30 days from January 5, 2005.

ADDRESSES: Direct comments and questions to Alex Hunt, the Department of State Desk Officer in the Office of Information and Regulatory Affairs at the Office of Management and Budget (OMB), who may be reached on 202–395–7860. You may submit comments by any of the following methods:

- *E-mail:* *Alexander_T._Hunt@omb.eop.gov*. You must include the DS form number (if applicable), information collection title, and OMB control number in the subject line of your message.
- *Hand Delivery or Courier:* OIRA, Department of State Desk Officer, Office of Management and Budget, 725 17th Street, NW., Washington DC 20503.
- *Fax:* 202–395–6974.

FOR FURTHER INFORMATION CONTACT: You may obtain copies of the proposed information collection and supporting documents from Margaret A. Dickson, U.S. Department of State, CA/PPT/FO/FC, 2100 Pennsylvania Avenue, NW., 3rd Floor, Washington, DC 20037, who may be reached on 202–663–2460 and at *dicksonma@state.gov*.

SUPPLEMENTARY INFORMATION: We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary to properly perform our functions.
- Evaluate the accuracy of our estimate of the burden of the proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of technology.

Abstract of proposed collection: The Birth Affidavit is submitted in conjunction with an application for a U.S. passport and used by Passport Services to collect information for the purpose of establishing the citizenship of a passport applicant who has not submitted an acceptable United States birth certificate with his/her passport application.

Methodology: When needed, a Birth Affidavit is completed at the time a U.S. citizen applies for a U.S. passport.

Dated: November 19, 2004.

Frank Moss,

Deputy Assistant Secretary for Passport Services, Bureau of Consular Affairs, Department of State.

[FR Doc. 05–191 Filed 1–4–05; 8:45 am]

BILLING CODE 4710–06–P

DEPARTMENT OF STATE

[Public Notice: 4948]

30-Day Notice of Proposed Information Collection: DS–60, Affidavit Regarding a Change of Name, OMB Control Number 1405–0133

ACTION: Notice of request for public comment and submission to OMB of proposed collection of information.

SUMMARY: The Department of State has submitted the following information collection request to the Office of Management and Budget (OMB) for approval in accordance with the Paperwork Reduction Act of 1995.

- *Title of Information Collection:* Affidavit Regarding A Change of Name.
- *OMB Control Number:* 1405–0133.
- *Type of Request:* Revision of a Currently Approved Collection.
- *Originating Office:* Bureau of Consular Affairs, CA/PPT/FO/FC.
- *Form Number:* DS–60.
- *Respondents:* U.S. citizens.
- *Estimated Number of Respondents:* 106,800 per year.
- *Estimated Number of Responses:* 106,800 per year.
- *Average Hours Per Response:* .25 (15 minutes).
- *Total Estimated Burden:* 26,700 hours per year.
- *Frequency:* On Occasion.
- *Obligation to Respond:* Required to Obtain or Retain a Benefit.

DATES: Submit comments to the Office of Management and Budget (OMB) for up to 30 days from January 5, 2005.

ADDRESSES: Direct comments and questions to Alex Hunt, the Department of State Desk Officer in the Office of Information and Regulatory Affairs at the Office of Management and Budget (OMB), who may be reached on 202–395–7860. You may submit comments by any of the following methods:

- E-mail: *Alexander_T._Hunt@omb.eop.gov*. You must include the DS form number (if applicable), information collection title, and OMB control number in the subject line of your message.
- Hand Delivery or Courier: OIRA, Department of State Desk Officer, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503
- Fax: 202–395–6974

FOR FURTHER INFORMATION CONTACT: You may obtain copies of the proposed information collection and supporting documents from Margaret A. Dickson, U.S. Department of State, CA/PPT/FO/FC, 2100 Pennsylvania Avenue, NW., 3rd Floor, Washington, DC 20037, who may be reached on 202–663–2460 or at *dicksonma@state.gov*.

SUPPLEMENTARY INFORMATION: We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary to properly perform our functions.
- Evaluate the accuracy of our estimate of the burden of the proposed collection, including the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of technology.

Abstract of proposed collection: The Affidavit Regarding a Change of Name is submitted in conjunction with an application for a U.S. passport. It is used

[12] 17 CFR 200.30–3(a)(12).

by Passport Services to collect information for the purpose of establishing that a passport applicant who has adopted a new name without formal court proceedings or by marriage has publicly and exclusively used the adopted name over a period of time (at least five years).

Methodology: When needed, The Affidavit Regarding a Change of Name is completed at the time a U.S. citizen applies for a U.S. passport.

Dated: November 19, 2004.

Frank Moss,

Deputy Assistant Secretary for Passport, Services, Bureau of Consular Affairs, Department of State.

[FR Doc. 05–192 Filed 1–4–05; 8:45 am]

BILLING CODE 4710–06–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Rule on Application (04–05–C–00–SUN) To Impose and Use, the Revenue From a Passenger Facility Charge (PFC) at Friedman Memorial Airport, Submitted by the Friedman Memorial Airport Authority, Friedman Memorial Airport, Hailey, ID

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of intent to rule on application.

SUMMARY: The FAA proposes to rule and invites public comment on the application to impose and use, PFC revenue at Friedman Memorial Airport under the provisions of 49 U.S.C. 40117 and part 158 of the Federal Aviation Regulations (14 CFR part 158).

DATES: Comments must be received on or before February 4, 2005.

ADDRESSES: Comments on this application may be mailed or delivered in triplicate to the FAA at the following address: Mr. J. Wade Bryant, Manager, Seattle Airports District Office, SEA–ADO; Federal Aviation Administration; 1601 Lind Avenue, SW., Suite 250, Renton, Washington 98055–4056.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Mr. Richard Baird, Airport Manager, at the following address: PO Box 929, Hailey, ID 83333.

Air Carriers and foreign air carriers may submit copies of written comments previously provided to Friedman Memorial Airport, under section 158.23 of part 158.

FOR FURTHER INFORMATION CONTACT: Ms. Suzanne Lee-Pang, (425) 227–2654, Seattle Airports District Office, SEA–ADO; Federal Aviation Administration; 1601 Lind Avenue, SW., Suite 250, Renton, Washington 98055–4056. The application may be reviewed in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA proposes to rule and invites public comment on the application 04–05–C–00–SUN to impose and use, PFC revenue at Friedman Memorial Airport, under the provisions of 49 U.S.C. 40117 and part 158 of the Federal Aviation Regulations (14 CFR part 158).

On December 23, 2004, the FAA determined that the application to impose and use the revenue from a PFC submitted by Friedman Memorial Airport Authority, Friedman Memorial Airport, Hailey, Idaho, was substantially complete within the requirements of section 158.25 of part 158. The FAA will approve or disapprove the application, in whole or in part, no later than April 2, 2005.

The following is a brief overview of the application.

Level of the proposed PFC: $4.50.

Proposed charge effective date: June 1, 2005.

Proposed charge expiration date: December 1, 2008.

Total requested for use approval: $1,158,554.

Brief description of proposed projects: Property Acquisition; Passenger Terminal Building Addition/Renovation; Airport Traffic Control Voice Communication Control System; Snow Removal Equipment (SRE) Acquisition; Aircraft Rescue and Firefighting (ARFF) Truck; Aircraft Rescue and Fire Fighting (ARFF) Building Expansion; Master Plan Update; Airport Site Selection and Feasibility Study; Air Traffic Control Tower (ATCT) Improvements, Phase 1; Terminal Building Improvements; Acquire Trailer Mounted De-icing Equipment; Automated Weather Observation System (AWOS); Terminal Access Road, Phase 1; Safety Area Grading and Runway Shift; Install Engineered Material Arresting System (EMAS) on Runway 13; Snow Removal Equipment (SRE)/Maintenance Vehicle Building; Airport Master Plan, Preferred Airport Alternative; Environmental Assessment (Pre-Environmental Impact Statement) for the Preferred Airport Alternative; Snow Removal Equipment (SRE) Acquisition; Replace Runway 13–31 Porous Friction Course.

Class or classes of air carriers which the public agency has requested not be required to collect PFCs: Operations by Air/Taxi/Commercial Operators utilizing aircraft having a maximum seating capacity of less than twenty passengers when enplaning revenue passengers in a limited, irregular/non-scheduled, or special service manner. Also exempted are Operations by Air Taxi/Commercial Operators, without regard to seating capacity, for revenue passengers transported for student instruction, non-stop sightseeing flights that begin and end at Friedman Memorial Airport and are conducted within a 25 mile radius of the same airport, fire fighting charters, ferry or training flights, air ambulance/medivac flights and aerial photography or survey flights.

Any person may inspect the application in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT** and at the FAA Regional Airports Office located at: Federal Aviation Administration, Northwest Mountain Region, Airports Division, ANM–600, 1601 Lind Avenue, SW., Suite 315, Renton, WA 98055–4056.

In addition, any person may, upon request, inspect the application, notice and other documents germane to the application in person at the Friedman Memorial Airport.

Issued in Renton, Washington on December 23, 2004.

David A. Field,

Manager, Planning, Programming and Capacity Branch, Northwest Mountain Region.

[FR Doc. 05–124 Filed 1–4–05; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Rule on Application 05–04–C–00–SAT To Impose and Use the Revenue From a Passenger Facility Charge (PFC) at San Antonio International Airport, San Antonio, TX

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of intent to rule on application.

SUMMARY: The FAA proposes to rule and invites public comment on the application to impose and use the revenue from a PFC at San Antonio International Airport under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (Title IX of the Omnibus Budget Reconciliation Act of 1990) (Pub. L. 101–508) and part 158 of the Federal Aviation Regulations (14 CFR part 158).

DATES: Comments must be received on or before January 4, 2005.

ADDRESSES: Comments on this application may be mailed or delivered in triplicate copies to the FAA at the following address: Mr. G. Thomas Wade, Federal Aviation Administration, Southwest Region, Airports Division, Planning and Programming Branch, ASW–611, Fort Worth, Texas 76193–0610.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Mr. Kevin Dolliole, Director of Aviation, San Antonio International Airport at the following address: Mr. Kevin Dolliole, Director of Aviation, 9800 Airport Blvd., San Antonio, Texas 78216–9990.

Air carriers and foreign air carriers may submit copies of the written comments previously provided to the Airport under section 158.23 of part 158.

FOR FURTHER INFORMATION CONTACT: Mr. G. Thomas Wade, Federal Aviation Administration, Southwest Region, Airports Division, Planning and Programming Branch, ASW–611, Fort Worth, Texas 76193–0610, (817) 222–5613.

The application may be reviewed in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA proposes to rule and invites public comment on the application to impose and use the revenue from a PFC at San Antonio International Airport under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (Title IX of the Omnibus Budget Reconciliation Act of 1990) (Pub. L. 101–508) and part 158 of the Federal Aviation Regulations (14 CFR part 158).

On December 22, 2004, the FAA determined that the application to impose and use the revenue from a PFC submitted by the Airport was substantially complete within the requirements of section 158.25 of part 158. The FAA will approve or disapprove the application, in whole or in part, no later than April 19, 2005.

The following is a brief overview of the application.

Level of the proposed PFC: $3.00.

Proposed charge effective date: November 1, 2009.

Proposed charge expiration date: April 1, 2016.

Total estimated PFC revenue: $50,682,244.

PFC application number: 05–04–C–00–SAT.

Brief description of proposed project(s):

Projects To Impose and Use PFC's

1. Construct Elevated Terminal Roadways.
2. Upgrade Central Utilities Plant.
3. New Utilities—Terminal Expansion.
4. Replace Apron.
5. Replace Two ARFF Vehicles.
6. Conduct Environmental Impact Statement.
7. Reconstruct Terminal Area Roadways.
8. Acquire Noise Monitoring System.

Proposed class or classes of air carriers to be exempted from collecting PFC's: Air Taxi/Commercial Operators Filing FAA Form 1800–31.

Any person may inspect the application in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT** and at the FAA regional Airports office located at: Federal Aviation Administration, Southwest Region, Airports Division, Planning and Programming Branch, ASW–610, 2601 Meacham Blvd., Fort Worth, Texas 76137–4298.

In addition, any person may, upon request, inspect the application, notice and other documents germane to the application in person at San Antonio International Airport.

Issued in Fort Worth, Texas on December 22, 2004.

Edward N. Agnew,

Acting Manager, Airports Division.

[FR Doc. 05–123 Filed 1–4–05; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Petition for Waiver of Compliance

In accordance with Part 238.21 of Title 49 Code of Federal Regulations (CFR), notice is hereby given that the Federal Railroad Administration (FRA) received a request for a waiver of compliance with certain requirements of its safety standards. The individual petition is described below, including the party seeking relief, the regulatory provisions involved, the nature of the relief being requested, and the petitioner's arguments in favor of relief.

Northeast Illinois Regional Commuter Railroad Corporation Waiver Petition Docket Number FRA–2004–19396

The Northeast Illinois Regional Commuter Railroad Corporation (Metra) further identified herein as the railroad, seeks approval for a waiver of compliance with the requirements of the Passenger Equipment Safety Standards contained in 49 CFR 238.105(d)(1), *train electronic hardware and software safety.* Section 49 CFR 238.105(d)(1) states that: Hardware and software that controls or monitors a train's primary braking system shall either: (i) Fail safely by initiating a full service brake application in the event of a hardware or software failure that could impair the ability of the engineer to apply or release the brakes; or (ii) Access to direct manual control of the primary braking system (both service and emergency braking) shall be provided to the engineer.

The railroad is purchasing 26 new bi-level electric passenger MU's and the braking software being provided by the manufacturer only partly meets the above requirements. The railroad requests that an application of only emergency brakes in the event of a loss of power, or failure (hardware and software), of the friction brake control unit be allowed in lieu of either the requirement for a full service brake application or restoration of direct manual control of the primary braking system to the operator.

The twenty-six new electric MU locomotives are being built by Sumitomo Corporation of America/Nippon Sharyo and the air brake system is provided by Knorr Brake Corporation, Westminster, Maryland. The railroad explains in their petition that the full service brake application is transmitted electronically to each MU's Friction Brake Control Unit (FBCU). The FBCU then provides the requested brake application without drawing down brake pipe pressure. An Emergency Magnetic Valve (EMV) is provided on each MU for an electronic emergency brake application. During normal operations, the EMVs are energized in the closed position and any loss of power of software malfunction causes the EMVs to open and vent to atmosphere causing the brakes over the entire consist to apply at an emergency rate.

Interested parties are invited to participate in these proceedings by submitting written views, data or comments. Each comment shall set forth specifically the basis upon which it is made, and contain a concise statement of the interest of the commenter in the proceeding. The FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify the FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number (FRA–2004–19396) and must be submitted to the Docket Clerk, DOT Docket Management Facility, Room PL–401 (Plaza Level),

400 7th Street, SW., Washington, DC 20590. Communications received within 30 days of the date of this notice will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.–5 p.m.) at the above facility. All documents in the public docket are also available for inspection and copying on the Internet at the docket facility's Web site at *http://dms.dot.gov.*

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78). The Statement may also be found at *http://dms.dot.gov.*

Issued in Washington, DC on December 27, 2004.

Grady C. Cothen, Jr.,

Acting Associate Administrator for Safety.

[FR Doc. 05–121 Filed 1–4–05; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Docket No. AB–33 (Sub–No. 227X)]

Union Pacific Railroad Company—Abandonment Exemption—in Caribou County, ID

On December 16, 2004, Union Pacific Railroad Company (UP) filed with the Surface Transportation Board a petition under 49 U.S.C. 10502 for exemption from the provisions of 49 U.S.C. 10903 to abandon and discontinue service over UP's Dry Valley Subdivision from milepost 23.90 to milepost 24.11, a distance of 0.21 miles, in Caribou County, ID. The line traverses U.S. Postal Service Zip Code 83230 and it includes no stations.

The line does not contain federally granted rights-of-way. Any documentation in UP's possession will be made available promptly to those requesting it.

The interest of railroad employees will be protected by the conditions set forth in *Oregon Short Line R. Co.—Abandonment—Goshen,* 360 I.C.C. 91 (1979).

By issuing this notice, the Board is instituting an exemption proceeding pursuant to 49 U.S.C. 10502(b). A final decision will be issued by April 5, 2005.

Any offer of financial assistance (OFA) under 49 CFR 1152.27(b)(2) will be due no later than 10 days after service of a decision granting the petition for exemption. Each OFA must be accompanied by a $1,200 filing fee. *See* 49 CFR 1002.2(f)(25).

All interested persons should be aware that, following abandonment of rail service and salvage of the line, the line may be suitable for other public use, including interim trail use. Any request for a public use condition under 49 CFR 1152.28 or for trail use/rail banking under 49 CFR 1152.29 will be due no later than January 25, 2005. Each trail use request must be accompanied by a $200 filing fee. *See* 49 CFR 1002.2(f)(27).

All filings in response to this notice must refer to STB Docket No. AB–33 (Sub-No. 227X) and must be sent to: (1) Surface Transportation Board, 1925 K Street, NW., Washington, DC 20423–0001; and (2) Mack H. Shumate, Jr., Senior General Attorney, 101 North Wacker Drive, Room 1920, Chicago, IL 60606. Replies to the petition are due on or before January 25, 2005.

Persons seeking further information concerning abandonment procedures may contact the Board's Office of Public Services at (202) 565–1592 or refer to the full abandonment or discontinuance regulations at 49 CFR part 1152. Questions concerning environmental issues may be directed to the Board's Section of Environmental Analysis (SEA) at (202) 565–1539. (Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1–800–877–8339.)

An environmental assessment (EA) (or environmental impact statement (EIS), if necessary) prepared by SEA will be served upon all parties of record and upon any agencies or other persons who commented during its preparation. Other interested persons may contact SEA to obtain a copy of the EA (or EIS). EAs in these abandonment proceedings normally will be made available within 60 days of the filing of the petition. The deadline for submission of comments on the EA will generally be within 30 days of its service.

Board decisions and notices are available on our Web site at *http://www.stb.dot.gov.*

Decided: December 28, 2004.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 05–179 Filed 1–4–05; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

December 28, 2004.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 11000, 1750 Pennsylvania Avenue, NW., Washington, DC 20220.

DATES: Written comments should be received on or before February 4, 2005, to be assured of consideration.

Internal Revenue Service (IRS)

OMB Number: 1545–1628.

Regulation Project Number: REG–118620–97 Final.

Type of Review: Extension.

Title: Communications Excise Tax; Prepaid Telephone Cards.

Description: Carriers must keep certain information documenting their sales of prepaid telephone cards to other carriers to avoid responsibility for collecting tax. The regulations provide rules for the application of the communications excise tax to prepaid telephone cards.

Respondents: Business or other for-profit.

Estimated Number of Respondents/Recordkeepers: 104.

Estimated Burden Hours Respondent/Recordkeeper: 20 minutes.

Frequency of Response: On occasion.

Estimated Total Reporting/Recordkeeping Burden: 34 hours.

Clearance Officer: Paul H. Finger, (202) 622–3634, Internal Revenue Service, Room 6516, 1111 Constitution Avenue, NW., Washington, DC 20224.

OMB Reviewer: Joseph F. Lackey, Jr., (202) 395–7316, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Treasury PRA Clearance Officer.

[FR Doc. 05–172 Filed 1–4–05; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Fiscal Service

Surety Companies Acceptable on Federal Bonds: Platinum Underwriters Reinsurance, Inc.

AGENCY: Financial Management Service, Fiscal Service, Department of the Treasury.

ACTION: Notice

SUMMARY: This is Supplement No. 6 to the Treasury Department Circular 570; 2004 Revision, published July 1, 2004, at 69 FR 40224.

FOR FURTHER INFORMATION CONTACT: Surety Bond Branch at (202) 874–7102.

SUPPLEMENTARY INFORMATION: A Certificate of Authority as an acceptable reinsurer on Federal bonds is hereby issued to the following company under 31 U.S.C. 9304 to 9308. Federal bond-approving officers should annotate their reference copies of the Treasury Circular 570, 2004 Revision, on page 40264 to reflect this addition:

Platinum Underwriters Reinsurance, Inc.

Business Address: 225 Liberty Street, Suite 2300, New York, NY 10281.

Phone: (212) 238–9600. *Underwriting Limitation b/:* $37,292,000.

Certificates of Authority expire on June 30 each year, unless revoked prior to that date. The Certificates are subject to subsequent annual renewal as long as the companies remain qualified (31 CFR part 223). A list of qualified companies is published annually as of July 1 in Treasury Department Circular 570, with details as to underwriting limitations, areas in which licensed to transact surety business and other information.

The Circular may be viewed and downloaded through the Internet at *http://www.fms.treas.gov/c570.* A hard copy may be purchased from the Government Printing Office (GPO) Subscription Service, Washington, DC, telephone (202) 512–1800. When ordering the Circular from GPO, use the following stock number: 769–004–04926–1.

Questions concerning this Notice may be directed to the U.S. Department of the Treasury, Financial Management Service, Financial Accounting and Services Division, Surety Bond Branch, 3700 East-West Highway, Room 6F07, Hyattsville, MD 20782.

Dated: December 22, 2004.

Vivian L. Cooper,

Director, Financial Accounting and Services Division, Financial Management Service.

[FR Doc. 05–120 Filed 1–4–05; 8:45 am]

BILLING CODE 4810–35–M

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0623]

Proposed Information Collection Activity: Proposed Collection; Comment Request

AGENCY: Office of Management, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Office of Management (OM), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each extension of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments on the information needed to evaluate bidder's qualification and to support claims for price adjustment due to delay in construction caused by severe weather.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before March 7, 2005.

ADDRESSES: Submit written comments on the collection of information to Donald E. Kaliher, Office of Acquisition Resources Service (049A5), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail *donald.kaliher@mail.va.gov.* Please refer to "OMB Control No. 2900–0623" in any correspondence.

FOR FURTHER INFORMATION CONTACT: Donald E. Kaliher at (202) 273–8819.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Public Law 104–13; 44 U.S.C. 3501–3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, OM invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of OM's functions, including whether the information will have practical utility; (2) the accuracy of OM's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Department of Veterans Affairs Acquisition Regulation (VAAR) Clause 852.236.91.

OMB Control Number: 2900–0623.

Type of Review: Extension of a currently approved collection.

Abstract: VAAR Clause 852.236.91 requires bidders to furnish information on previous experience, technical qualifications, financial resources, and facilities available to perform the work. The clause also requires contractors submitting a claim for price adjustment due to severe weather delay to provide climatologically data covering the period of the claim and covering the same period for the ten preceding years. VA uses the data collected to evaluate the bidder's qualification and responsibility, and to evaluate the contractor's claims for contract price adjustment due to weather-related delays.

Affected Public: Business or other for-profit; individuals and households; and not-for-profit institutions.

Estimated Annual Burden: 778 hours.

a. Qualifications Data: 758 hours

b. Weather Data: 20 hours.

Estimated Average Burden Per Respondent:

a. Qualifications Data: 30 min.

b. Weather Data: 1 hour.

Frequency of Response: On occasion.

Estimated Number of Respondents: 1,536.

a. Qualifications Data: 1516.

b. Weather Data: 20.

Dated: December 20, 2004.

By direction of the Secretary:

Loise Russell,

Director, Records Management Service.

[FR Doc. 05–203 Filed 1–4–05; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0629]

Proposed Information Collection Activity: Proposed Collection; Comment Request

AGENCY: Veterans Health Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Health Administration (VHA) is announcing an opportunity for public comment on the proposed collection of certain

information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments on information needed to determine eligibility for extended care benefits.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before March 7, 2005.

ADDRESSES: Submit written comments on the collection of information to Ann Bickoff, Veterans Health Administration (193E1), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail *ann.bickoff@mail.va.gov*. Please refer to "OMB Control No. 2900–0629" in any correspondence.

FOR FURTHER INFORMATION CONTACT: Ann Bickoff at (202) 273–8310.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Public Law 104–13; 44 U.S.C. 3501–3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VHA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VHA's functions, including whether the information will have practical utility; (2) the accuracy of VHA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Application for Extended Care Services, VA Form 10–10EC.

OMB Control Number: 2900–0629.

Type of Review: Extension of a currently approved collection.

Abstract: VA Form 10–10EC is used to gather current income and financial information from nonservice-connected veterans and their spouse applying for extended care services. VA uses the data collected to establish veteran's eligibility for extended care services, financial liability, if any, to pay if accepted for placement or treatment in extended care services, and the applicable co-payment.

Affected Public: Individuals or Households.

Estimated Total Annual Burden: 9,000 hours.

Estimated Average Burden Per Respondent: 90 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 6,000.

Dated: December 22, 2004.

By direction of the Secretary:

Jacqueline Parks,

IT Specialist, Records Management Service.

[FR Doc. 05–204 Filed 1–4–05; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0469]

Proposed Information Collection Activity: Proposed Collection; Comment Request

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments on information needed to establish entitlement to Government Life insurance proceeds.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before March 7, 2005.

ADDRESSES: Submit written comments on the collection of information to Nancy J. Kessinger, Veterans Benefits Administration (20M35), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail: *irmnkess@vba.va.gov*. Please refer to "OMB Control No. 2900–0469" in any correspondence.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 273–7079 or FAX (202) 275–5947.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Certificate Showing Residence and Heirs of Deceased Veteran or Beneficiary, VA Form 29–541.

OMB Control Number: 2900–0469.

Type of Review: Extension of a currently approved collection.

Abstract: VA uses the information collected on VA Form 29–541 to establish entitlement to Government Life Insurance proceeds in estate cases when formal administration of the estate is not required.

Affected Public: Individuals or households.

Estimated Annual Burden: 1,039 hours.

Estimated Average Burden Per Respondent: 30 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 2,078.

Dated: December 20, 2004.

By direction of the Secretary.

Loise Russell,

Director, Records Management Service.

[FR Doc. 05–205 Filed 1–4–05; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0120]

Proposed Information Collection Activity: Proposed Collection; Comment Request

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of

Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments on information needed to determine claimants' eligibility for disability insurance benefits.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before March 7, 2005.

ADDRESSES: Submit written comments on the collection of information to Nancy J. Kessinger, Veterans Benefits Administration (20M35), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail: *irmnkess@vba.va.gov*. Please refer to "OMB Control No. 2900–0120" in any correspondence.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 273–7079 or Fax (202) 275–5947.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Report of Treatment by Attending Physician, VA Form 29–551a.

OMB Control Number: 2900–0120.

Type of Review: Extension of a currently approved collection.

Abstract: VA Form 29–551a is used to collect information from the attending physician to determine the insured's eligibility disability insurance.

Affected Public: Individuals or households.

Estimated Annual Burden: 5,069 hours.

Estimated Average Burden Per Respondent: 15 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 20,277.

Dated: December 20, 2004.

By direction of the Secretary.

Loise Russell,

Director, Records Management Service.

[FR Doc. 05–206 Filed 1–4–05; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0622]

Proposed Information Collection Activity: Proposed Collection; Comment Request

AGENCY: Office of Management, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Office of Management (OM), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each extension of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments on the information needed to consider the use of domestic foreign construction material.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before March 7, 2005.

ADDRESSES: Submit written comments on the collection of information to Donald E. Kaliher, Office of Acquisition Resources Service (049A5), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail *donald.kaliher@mail.va.gov*. Please refer to "OMB Control No. 2900–0622" in any correspondence.

FOR FURTHER INFORMATION CONTACT: Donald E. Kaliher at (202) 273–8819.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, OM invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of OM's functions, including whether the information will have practical utility; (2) the accuracy of OM's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Department of Veterans Affairs Acquisition Regulation (VAAR) Clause 852.236–89, Buy American Act.

OMB Control Number: 2900–0622.

Type of Review: Extension of a currently approved collection.

Abstract: The Buy American Act requires that only domestic construction material shall be used to perform domestic Federal contracts for construction, with certain exceptions. Despite the allowable exceptions, it is VA policy not to accept foreign construction material. VAAR clause 852.236–89 advises bidders of these provisions and requires bidders who choose to submit a bid that includes foreign construction material to identify and list the price of such material. VA uses the information to determine whether to accept or not accept a bid that includes foreign construction material.

Affected Public: Business or other for-profit; individuals and households; and not-for-profit institutions.

Estimated Annual Burden: 20 hours.

Estimated Average Burden Per Respondent: 30 min.

Frequency of Response: On occasion.

Estimated Number of Respondents: 40.

Dated: December 20, 2004.

By direction of the Secretary.

Loise Russell,

Director, Records Management Service.

[FR Doc. 05–207 Filed 1–4–05; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0047]

Proposed Information Collection Activity: Proposed Collection; Comment Request

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments for information needed to determine veteran-obligors' and prospective assumers' creditworthiness.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before March 7, 2005.

ADDRESSES: Submit written comments on the collection of information to Nancy J. Kessinger, Veterans Benefits Administration (20M35), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail *irmnkess@vba.va.gov*. Please refer to "OMB Control No. 2900–0047" in any correspondence.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 273–7079 or Fax (202) 275–5947.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Financial Statement, VA Form 26–6807.

OMB Control Number: 2900–0047.

Type of Review: Extension of a currently approved collection.

Abstract: The data collected on VA Form 26–6807 is used to determine release of liability and substitution of entitlement cases. VA may release original veteran obligors from personal liability arising from the original guaranty of their home loan, or the making of a direct loan, provided the purchasers/assumers meet the creditworthiness requirements. It is also used to determine a borrower's financial condition in connection with efforts to reinstate a seriously defaulted guaranteed, insured, or portfolio loan, and to determine homeowners eligibility for aid under the Homeowners Assistance Program which provides assistance by reducing losses incident to the disposal of homes when military installations at which the homeowners were employed or serving are ordered closed.

Affected Public: Individuals or households.

Estimated Annual Burden: 7,500 hours.

Estimated Average Burden Per Respondent: 45 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 10,000.

Dated: December 20, 2004.

By direction of the Secretary.

Loise Russell,

Director, Records Management Service.

[FR Doc. 05–208 Filed 1–4–05; 8:45 am]

BILLING CODE 8320–01–P

Federal Register

Wednesday,
January 5, 2005

Part II

Environmental Protection Agency

40 CFR Part 81

Air Quality Designations and Classifications for the Fine Particles (PM2.5) National Ambient Air Quality Standards; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 81

[OAR–2003–0061; FRL–7856–1]

RIN–2060–AM04

Air Quality Designations and Classifications for the Fine Particles (PM2.5) National Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule sets forth the initial air quality designations and classifications for all areas in the United States, including Indian country, for the fine particles (PM2.5) National Ambient Air Quality Standards (NAAQS). The EPA is issuing this rule so that citizens will know whether the air quality where they live and work is healthful or unhealthful. Health studies have shown significant associations between exposure to PM2.5 and premature death from heart or lung disease. Fine particles can also aggravate heart and lung diseases and have been linked to effects such as cardiovascular symptoms, cardiac arrhythmias, heart attacks, respiratory symptoms, asthma attacks, and bronchitis. These effects can result in increased hospital emissions, emergency room visits, absences from school or work, and restricted activity days.

Individuals that may be particularly sensitive to PM2.5 exposure include people with heart or lung disease, older adults, and children. This rule establishes the boundaries for areas designated as nonattainment, unclassifiable, or attainment/unclassifiable. This rule does not establish or address State and Tribal obligations for planning and control requirements that apply to nonattainment areas for the PM2.5 standards. The EPA will publish a separate rule which will set forth the planning and control requirements that apply to nonattainment areas for the PM2.5 standards.

DATES: The effective date of this rule is April 5, 2005.

ADDRESSES: The EPA has established a docket for this action under Docket ID NO. OAR–2003–0061. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available *i.e.*, Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in the EDOCKET or in hard copy at the Docket, EPA/DC, EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m. Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Office of Air and Radiation Docket and Information Center is (202) 566–1742. In addition, we have placed a copy of the rule and a variety of materials regarding designations on EPA's designation Web site at: *http://www.epa.gov/oar/oaqps/particles/designations/index.htm* and on the Tribal Web site at: *http://www/epa.gov/air/tribal.*

FOR FURTHER INFORMATION CONTACT: Designations: Mr. Rich Damberg, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Mail Code C504–02, Research Triangle Park, NC 27711, phone number (919) 541–5592 or by e-mail at: *damberg.rich@epa.gov.*

Designations and Part 81 Code of Federal Regulations: Dr. Larry D. Wallace, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Mail Code C504–02, Research Triangle Park, NC 27711, phone number (919) 541–0906 or by e-mail at: *wallace.larry@epa.gov.* Technical Issues Related to Designations: Mr. Thomas Rosendahl, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Mail Code C504–02, Research Triangle Park, NC 27711, phone number (919) 541–5314 or by e-mail at: *rosendahl.tom@epa.gov.*

PM2.5 Air Quality Data Issues: Mr. Mark Schmidt, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Mail Code C304–01, Research Triangle Park, NC 27711, phone number (919) 541–5314 or by e-mail at: *schmidt.mark@epa.gov.*

Regional Office Contacts:

Region I—Alison Simcox (617) 918–1684,

Region II—Kenneth Fradkin (212) 637–3702,

Region III—Denny Lohman (215) 814–2191,

Region IV—Steve Scofield (404) 562–9034,

Region V—John Summerhays (312) 886–6067,

Region VI—Joe Kordzi (214) 665–7186,

Region VII—Amy Algoe-Eakin (913) 551–7942,

Region VIII—Libby Faulk (303) 312–6083,

Region IX—Eleanor Kaplan (415) 744–1286,

Region X—Keith Rose (206) 553–1949.

SUPPLEMENTARY INFORMATION: The public may inspect the rule and the technical support information at the following locations:

Regional offices	States
Dave Conroy, Acting Branch Chief, Air Programs Branch, EPA New England, I Congress Street, Suite 1100, Boston, MA 02114–2023, (617) 918–1661.	Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont.
Raymond Werner, Chief, Air Programs Branch, EPA Region II, 290 Broadway, 25th Floor, New York, NY 10007–1866, (212) 637–4249.	New Jersey, New York, Puerto Rico, and Virgin Islands.
Makeba Morris, Branch Chief, Air Quality Planning Branch, EPA Region III, 1650 Arch Street, Philadelphia, PA 19103–2187, (215) 814–2187.	Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, and West Virginia.
Richard A. Schutt, Chief, Regulatory Development Section, EPA Region IV, Sam Nun Atlanta Federal Center, 61 Forsyth, Street, SW, 12th Floor, Atlanta, GA 30303, (404) 562–9033.	Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee.
Jay Bortzer, Chief, Air Programs Branch, EPA Region V, 77 West Jackson Street, Chicago, IL 60604, (312) 886–4447.	Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin.
Donna Ascenzi, Acting Associate Director, Air Programs, EPA Region VI, 1445 Ross Avenue, Dallas, TX 75202, (214) 665–2725.	Arkansas, Louisiana, New Mexico, Oklahoma, and Texas.
Joshua A. Tapp, Chief, Air Programs Branch, EPA Region VII, 901 North 5th Street, Kansas City, Kansas 66101–2907, (913) 551–7606.	Iowa, Kansas, Missouri, and Nebraska.

Regional offices	States
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Table of Contents

The following is an outline of the Preamble.

I. Preamble Glossary of Terms and Acronyms

The following are abbreviations of terms used in the preamble.

CAA Clean Air Act
CFR Code of Federal Regulations
CMAQ Congestion Mitigation Air Quality
CMSA Consolidated Metropolitan Statistical Area
D.C. District of Columbia
EPA Environmental Protection Agency
FR Federal Register
MPO Metropolitan Planning Organizations
MSA Metropolitan Statistical Area
NAAQS National Ambient Air Quality Standard
NO_X Nitrogen Oxides
NOA Notice of Availability
NPR Notice of Proposed Rulemaking
NSR New Source Review
OMB Office of Management and Budget
RTC Response to Comment
SIP State Implementation Plan
TAR Tribal Authority Rule
TEA–21 Transportation Equity Act for the 21st Century
TPY Tons Per Year
TSD Technical Support Document
U.S. United States
VOC Volatile Organic Compounds

II. What Is the Purpose of This Document?

The purpose of this document is to announce and promulgate designations and boundaries for areas of the country with respect to the PM2.5 NAAQS in accordance with the requirements of the CAA. The list of areas in each State, the boundaries of each area, and the designation of each area, appear in the table at the end of this final rule. This rule was signed by the EPA Administrator, Mike Leavitt, on December 17, 2004. Several steps were taken to announce that this rule is available. We posted the notice on several EPA Web sites and provided a copy of the rule to States and Tribes.

III. What Are Fine Particles?

Fine particles in the atmosphere are made up of a complex mixture of components. Common constituents include: sulfate (SO_4); nitrate (NO_3); ammonium (NH4); elemental carbon; a great variety of organic compounds; water; and inorganic material (including metals, dust, sea salt, and other trace elements), which often is categorized as "crustal" material. Airborne particles with a nominal aerodynamic diameter of 2.5 micrometers or less (a micrometer is one-millionth of a meter; 2.5 micrometers is less than about one-thirtieth the thickness of a human hair) are considered to be "fine particles," and are also known as PM2.5. "Primary" particles are emitted directly into the air as a solid or liquid particle (*e.g.*, elemental carbon and organic particles from diesel engines or burning activities). "Secondary" particles (*e.g.*, sulfate and nitrate) form in the atmosphere as a result of various chemical transformations of gaseous precursors such as sulfur dioxide (SO_2) and oxides of nitrogen (NO_X).

IV. What Are the Health Concerns Addressed by the PM2.5 Standard?

Epidemiological studies have shown a significant association between elevated PM2.5 levels and a number of serious health effects, including premature mortality, aggravation of respiratory and cardiovascular disease (as indicated by increased hospital admissions, emergency room visits, absences from school or work, and restricted activity days), lung disease, decreased lung function, asthma attacks, and certain cardiovascular problems such as heart attacks and cardiac arrhythmia. Individuals particularly sensitive to PM2.5 exposure include older adults, people with heart and lung disease, and children.

More information on the health effects of PM2.5 can be found at the following Web site: *http://www.epa.gov/ttn/naaqs/pm/pm25_index.html.*

V. What Is the Chronology of Events Leading Up to This Rule?

This section summarizes the relevant activities leading up to today's action, including promulgation of the PM2.5 NAAQS and litigation challenging that standard. The CAA establishes a process for air quality management through the establishment and implementation of the NAAQS. After the promulgation of a new or revised NAAQS, EPA is required to designate areas, pursuant to section 107(d)(1) of the CAA, as attainment, nonattainment, or unclassifiable.

On July 18, 1997, EPA revised the NAAQS for particulate matter to add new standards for PM2.5, using PM2.5 as the indicator for the pollutant. The EPA established health-based (primary) annual and 24-hour standards for PM2.5 (62 FR 38652). The annual standard is a level of 15 micrograms per cubic meter, based on a 3-year average of annual mean PM2.5 concentrations. The

24-hour standard is a level 65 micrograms per cubic meter, based on a 3-year average of the 98th percentile of 24-hour concentrations. The EPA established the standards based on significant evidence and numerous health studies demonstrating that serious health effects are associated with exposures to particulate matter.

The PM2.5 NAAQS were challenged by numerous litigants and in May 1999, the U.S. Court of Appeals for the D.C. Circuit issued a decision remanding, but not vacating, the standards. *American Trucking Assoc.* v. *EPA*, 175 F.3d 1027, 1047–48, *on rehearing* 195 F.3d 4 (D.C. Cir., 1999). The EPA sought review of two aspects of that decision in the U.S. Supreme Court. The Supreme Court upheld the PM2.5 standards. *EPA* v. *American Trucking Assoc.*, 531 U.S. 457 (2001). In March 2002, the D.C. Circuit rejected all remaining challenges to the PM2.5 standards, *American Trucking Assoc.* v. *EPA*, 283 F.3d 355 (D.C. Cir., 2002). Since final resolution of the litigation over the PM2.5 NAAQS, EPA has been acting to implement the standards.

The process for designating areas following promulgation of a new or revised NAAQS is contained in section 107(d)(1) of the CAA. In June 1998, Congress adopted the Transportation Equity Act for the 21st Century (TEA–21). Section 6102(c)(1)(d) of TEA–21 amended section 107 of the CAA by extending the time period for EPA to initiate the designations process for the PM2.5 NAAQS until 3 calendar years of air quality data, measured at Federal Reference Method monitors, were gathered. The EPA and State air quality agencies initiated the monitoring process for the PM2.5 NAAQS in 1999, and deployed all air quality monitors by January 2001. The EPA is designating areas across the country for the PM2.5 NAAQS based upon air quality monitoring data from these monitors for calendar years 2001–2003.

VI. What Are the Clean Air Act (CAA) Requirements for Air Quality Designations and What Action has EPA Taken to Meet These Requirements?

This section summarizes the provisions of section 107(d)(1) of the CAA which governs the process that States and EPA must follow in order to recommend and promulgate designations. Following the promulgation of a new or revised standard, each State Governor or Tribal leader has an opportunity to recommend air quality designations, including the appropriate boundaries for areas, to EPA. By no later than 120 days prior to promulgating designations, EPA is required to notify States or Tribes of any intended modifications to their boundaries that EPA deems necessary. States and Tribes then have an opportunity to provide a demonstration as to why the proposed modification indicated by EPA is inappropriate. Whether or not a State or Tribe provides a recommendation, EPA must promulgate the designation that it deems appropriate.

In April 2003, EPA requested that States and Tribes submit their designation recommendations and supporting documentation to EPA by February 15, 2004. After receiving recommendations from the States and Tribes and carefully reviewing and evaluating each recommendation, EPA on June 28 and 29, 2004, provided a response to each State and Tribe indicating whether or not EPA intended to make modifications to the initial recommendations, and explaining EPA's reasons for making any such modifications. The EPA provided an opportunity for States and Tribes to respond to any proposed modifications to their initial boundary recommendations until September 1, 2004. In response to our June 28 and 29, 2004 letters, EPA received letters from many States and Tribes suggesting changes to EPA's modifications and providing additional information. The EPA evaluated each supplemental letter, and all of the timely technical support information provided, before arriving at the final designation decisions reflected in today's action. Some of the designations reflect our modifications to the State and Tribal recommendations. We have placed these State and Tribal letters, and our responses to the issues contained in them, in the EPA docket for this action.

Tribal designation activities are covered under the authority of section 301(d) of the CAA. This provision of the CAA authorizes EPA to treat eligible Indian Tribes in the same manner as States. Pursuant to section 301(d)(2), we promulgated regulations, known as the Tribal Authority Rule (TAR), on February 12, 1999. 63 FR 7254, codified at 40 CFR 49 (1999). This rule specifies those provisions of the CAA for which it is appropriate to treat Tribes as States. Under the TAR, Tribes may choose to develop and implement their own CAA programs, but are not required to do so. The TAR also establishes procedures and criteria by which Tribes may request from EPA a determination of eligibility for such treatment. The designations process contained in section 107(d) of the CAA is included among those provisions determined to be appropriate by EPA for treatment of Tribes in the same manner as States. As authorized by the TAR, Tribes may request an opportunity to submit designation recommendations to us. In cases where Tribes do not make their own recommendations, EPA, in consultation with the Tribes, will promulgate the designation that EPA deems appropriate on their behalf. All Tribes were invited to submit recommendations concerning designations for PM2.5.

The EPA worked with the Tribes that requested an opportunity to submit designation recommendations. Eligible Tribes were provided an opportunity to submit their own recommendations and supporting documentation. The EPA reviewed the recommendations made by Tribes and, in consultation with the Tribes, made modifications as deemed necessary and appropriate. Under the TAR, Tribes generally are not subject to the same submission schedules imposed by the CAA on States.

VII. What Guidance Did EPA Issue and How Did EPA Apply the Statutory Requirements and Applicable Guidance To Determine Boundaries for the PM2.5 NAAQS?

Section 107(d)(1)(A)(I) of the CAA defines a nonattainment area as an area that is violating an ambient standard or is contributing to air quality in a nearby area that is violating the standard. If an area meets either prong of this definition, then EPA is obligated to designate the area as nonattainment. Section 107(d)(1)(A)(iii) provides that any area which EPA cannot designate on the basis of available information as meeting or not meeting the standards should be designated unclassifiable.

In April 2003, EPA issued designation guidance concerning how to determine the boundaries for PM2.5 nonattainment areas.[1] The guidance provided that EPA would use the 3 most recent calendar years of monitoring data for PM2.5 to determine each county's designation. For today's PM2.5 designations, we are basing our decision on air quality monitoring data from calendar years 2001–2003. When evaluating individual areas, we started with the premise that data recorded by a PM2.5 monitor in most cases represents air quality throughout the area in which it is located. In addition, we considered the county boundary as the basic jurisdictional boundary for determining the extent of the area reflected by the PM2.5 monitor. As a result, if a PM2.5

[1] *See* "Designations for the Fine Particle National Ambient Air Quality Standards." memorandum to Regional Administrators, Regions I–X, from Jeffrey R. Holmstead, Assistant Administrator, OAR, dated April 1, 2003.

monitor was violating the standard based on the 2001–2003 data, at a minimum we designated the entire county where that monitor is located as nonattainment. We made exceptions to this approach in a few very large western counties where a significant geographic feature such as a mountain range divided a county, resulting in different air quality in different parts of the county. In such cases, we considered designations of partial counties to be appropriate. After identifying the counties with violating monitors, we then proceeded to identify nearby counties that were potentially contributing to the violation(s) at the monitors.

In assessing whether nearby areas contributed to a violation, EPA started with the Consolidated Metropolitan Statistical Area (CMSA) and the Metropolitan Statistical Area (MSA) as the presumptive boundaries for PM2.5 nonattainment areas. A metropolitan area, as defined by the Office of Management and Budget (OMB) in 1999, consisted of a single MSA in some cases, or a CMSA in other cases. These metropolitan areas provide boundaries for the geographic extent of urban areas, We suggested the use of metropolitan area boundaries as the presumptive boundaries for urban nonattainment areas for air quality purposes, based upon evidence that violations of the PM2.5 air quality standards generally include a significant urban-scale contribution as well as a regional contribution. The actual size of each nonattainment area may be larger or smaller than the presumptive boundaries, depending upon the application of the nine factors contained in the April 2003 designations guidance for PM2.5.

In June 2003, OMB released a new list of metropolitan area descriptions. Because we had already issued the April 2003 designations guidance which recommended use of the 1999 OMB metropolitan definitions as a starting point, and because States and Tribes were already actively using this guidance in their planning efforts, we decided that it would be disruptive to recommend the use of the 2003 OMB definitions as the presumptive boundaries. Instead, we issued a second guidance memorandum in February 2004, which indicated that we would continue to consider the 1999 MSA boundaries as the presumptive boundaries, but that States should nevertheless take into consideration the 2003 OMB revised MSA boundaries. We particularly urged consideration of the 2003 MSA boundaries for those counties that OMB added to an existing metropolitan area due to growth, or because of a high degree of social and economic integration with the primary urban area.[2]

The April 2003 guidance memorandum described nine factors that EPA would take into consideration in determining appropriate nonattainment area boundaries, whether larger or smaller than the presumptive boundaries: (1) Emissions and air quality in adjacent areas (including adjacent CMSAs and MSAs), (2) air quality in potentially included versus excluded areas, (3) population density and degree of urbanization including commercial development in included versus excluded areas, (4) traffic and commuting patterns, (5) expected growth (including extent, pattern and rate of growth), (6) meteorology (weather/transport patterns), (7) geography/topography (*e.g.*, mountain ranges or other air basin boundaries), (8) jurisdictional boundaries (*e.g.*, counties, air districts, Reservations, etc.), and (9) level of existing controls on emission sources.

In assessing emissions under the first factor, we developed a "weighted emissions score" that valued the effect of direct emissions of PM2.5 and its precursors that contribute to "urban excess" PM2.5 concentrations at monitor sites. The "urban excess" concentrations for each PM2.5 component (direct or precursor emissions) are calculated from two PM2.5 speciation monitors by subtracting the regional concentration from the urban concentration for each component. The methodology we used to calculate urban excess concentration and the weighted emission score is explained in more detail in the technical support document (TSD).

We used this metric to compare the relative emissions contribution of different counties in and around each metropolitan area. Using this approach, we were able to take into consideration, in a single metric, the county-level emissions of carbonaceous particles, inorganic particles, SO_2, and NO_X (all of which contribute to PM2.5 formation) in the vicinity of each violating monitor. By comparing weighted emissions scores across counties in a metropolitan area, EPA was able to identify those counties having the highest estimated emissions contribution to the local nonattainment problem. In addition, by examining the data from the urban speciation monitors, we could draw some conclusions concerning the likely sources of emissions contributing to the violation. Knowing the likely sources of the emissions, we could better evaluate which of the nearby counties had emissions likely to be contributing to the ambient concentrations at the violating monitor.

Evaluation of the weighted emissions score and speciation data was an important element in our nine factor analysis, and we believe that it provided a reasonable tool for evaluating the relative contribution of nearby areas to violations at a monitor, given the variety of precursors and sources that participate in the formation of PM2.5. Further discussion of the weighted emissions score, and area-specific explanations of its application, appear in the TSD.

In some cases, considering the factors and additional information provided by the State, we determined that only part of a nearby county (*e.g.*, the part of the county that contained the significant sources of contributing emissions) should be considered as contributing to the violation at the monitor, and therefore included only a portion of that adjacent county in the nonattainment area. In other cases, we determined that the emissions from an identifiable large power plant in a county were contributing to the violations in a nearby area. In these cases, we concluded that it was appropriate to designate only the portion of the county where the source is located, even if that portion is not contiguous with the remainder of the nonattainment area. We adopted this approach where we determined, following the nine factor analysis, that it would be inappropriate to include other portions of a county, merely because those portions lay between the large stationary source and the remainder of the designated nonattainment area. We selected the boundaries for these noncontiguous portions of nonattainment areas by relying on legally recognized governmental boundaries (*e.g.*, townships, tax districts, or census blocks) in which the source is located.

We believe that the individual facts and circumstances of each area must be considered in determining whether to include a county as contributing to a particular nonattainment problem. Thus, our guidance does not establish bright lines or cut-points for how a particular factor is applied. For example, the guidance does not identify a set amount of a pollutant, or a specific level of commuting between counties, that would automatically require a county to be included in a nonattainment area as a contributing

[2] See "Additional Guidance on Defining Area Boundaries for PM–2.5 Designations," memorandum to Air Division Directors, Regions I–X, from Lydia N. Wegman, Director, AQSSD, dated February 13, 2004.

county. We analyzed the information provided by each State or Tribe in its recommendation letter, subsequently submitted information, and any other pertinent information available to EPA, in order to determine whether a county should be designated nonattainment. We evaluated each State's or Tribe's designation recommendation in light of the nine factors, bringing to bear our best technical and policy judgement. If the result of the evaluation showed that a county, whether inside or outside of the CMSA or MSA contributes to the violation in a nearby area with a violating monitor, we designated the area as nonattainment.

In a small number of areas, EPA concluded that there was insufficient information to designate a given area as either nonattainment or attainment/unclassifiable. In these instances, we have designated the area as unclassifiable. In each instance, these areas had violating monitors for the years 2000–2002, but incomplete data or other data issues for the years 2001–2003. Further explanation of the unclassifiable designations may be found in the TSD for this action.

The EPA did not rely on planned or potential regional PM2.5 reduction strategies in making decisions regarding nonattainment designations, even if those strategies predict that an area may attain the standard in the future. We recognize that some areas with a violating monitor may be projected to come into attainment in the future without additional local emission controls because of State and/or national programs that will reduce transported emissions. However, the CAA requires EPA to make nonattainment designations based on current data. While we cannot consider projected future attainment in determining current designations, we intend to expedite the redesignation of areas to attainment once they monitor clean air quality. We also intend to apply our policy which streamlines the planning process for nonattainment areas that are meeting the NAAQS but are not yet redesignated to attainment.[3]

Today's designation action is a final rule which establishes designations for all areas of the country for the PM2.5 NAAQS. In this action, we have added regulatory text to provide for the amendment of 40 CFR part 81 to identify the designation of areas across the country for the PM2.5 standard.

[3] *See* "Clean Data Policy for the Fine Particle National Ambient Air Quality Standards" memorandum to Air Division Directors, Regions I–X from Steve Page, Director, Office of Air Quality Planning and Standards, December 14, 2004.

VIII. Has EPA Used 2004 Air Quality Data?

The final PM2.5 designations announced in today's action are based upon air quality data for calendar years 2001 through 2003. Over the course of the designations process, a number of States have provided comments to EPA suggesting that the agency should delay designations in order to permit consideration of additional air quality data from 2004 as a part of the designation decision. As discussed above, EPA must by law make the designations by December 31, 2004. This statutory deadline and the practical difficulties of obtaining complete,[4] quality assured, certified data for calendar year 2004 by December 31, 2004, have precluded EPA from using 2004 data for today's action. Under normal circumstances, we would not expect such data to be available for some time following the end of the calendar year, and under the applicable regulations States would not be required to have submitted such data until April 1, 2005, and would not be required to have certified such data until July 1, 2005. However, because we are promulgating the designations so near the end of calendar year 2004, and because complete, quality assured, certified 2004 data may become available for some areas quickly, we are interested in providing a process by which we could utilize 2004 data where possible in the designation process.

We have provided that the final PM2.5 designations announced in today's action will be effective on the date 90 days following the date of publication. If any State submits complete, quality assured, certified 2004 data to EPA by February 22, 2005, that suggest that a change of designation status is appropriate for any area within that State, and we agree that a change of designation status is appropriate, then we will withdraw the designation announced in today's action for such area and issue another designation that reflects the inclusion of 2004 data. We emphasize that we will conduct this process only for those States that submit the necessary complete, quality assured, certified data by the deadline and in those instances where we can complete the analysis and effect the change of designation status before the original effective date established by today's final action.

[4] Fine particle monitoring data is to be determined as "complete" according to data handling regulations for the PM2.5 standards in 40 CFR Part 50, Appendix N (62 FR 138, July 18, 1997).

If inclusion of 2004 data causes an area to change from nonattainment to attainment, EPA will change the designation if every county in the area is neither monitoring a violation of the standards nor contributing to a violation of the standards in another nearby area. If inclusion of 2004 data results in nonattainment in an area that was designated attainment, we will evaluate the reasons for the violation in the area and determine the appropriate course of action, which could include redesignation of the area to nonattainment. Also, EPA commits to evaluate 2004 data for unclassifiable areas when it receives complete, quality assured, certified data from the State, which is due no later than July 2005. At that time, EPA will determine whether a change of designation for an unclassifiable area is appropriate.

IX. How Do Designations Affect Indian Country?

All counties, partial counties or Air Quality Control Regions listed in the table at the end of this document are designated as indicated, and include Indian Country geographically located within such areas, except as otherwise indicated in the table.

As mentioned earlier in this document, EPA's guidance for determining nonattainment area boundaries presumes that the CMSA or MSA monitor forms the presumptive boundary of the nonattainment areas but that the size of the area can be larger or smaller depending on contribution to the violation from nearby areas and other air quality-related technical factors. In general, and consistent with relevant air quality information, EPA intends to include Indian country encompassed within the presumptive CMSA or MSA boundaries as within the boundaries of the area for designation purposes, in order to protect public health and welfare. The EPA anticipates that in most cases, relevant air quality information will indicate that areas of Indian country located within CMSAs or MSAs should have the same designation as the surrounding area. However, based on the nine factors outlined in our guidance, there may be instances where a different designation is appropriate.

A State recommendation for a designation of an area that surrounds Indian country does not indicate the designation for Indian country. However, the conditions that support a State's designation recommendation, such as air quality data at the location of the sources, may indicate the likelihood that similar conditions exists for the Indian country located in that

area. States generally have neither the responsibility nor the authority for planning and regulatory activities under the CAA in Indian country.

X. Where Can I Find Information Forming the Basis for This Rule and Exchanges Between EPA, States, and Tribes Related to This Rule?

Information providing the basis for today's action and related decisions are provided in the TSD. The TSD, applicable EPA guidance memoranda, copies of correspondence regarding this process between EPA and the States, Tribes, and other parties, and EPA's responses to comments, are available for review at the EPA Docket Center listed above in the addresses section of this document and on our designation Web site at *http://www.epa.gov/oar/oaqps/particles/designations/index.htm.* State specific information is available at the EPA Regional Offices.

XI. Statutory and Executive Order Reviews

Upon promulgation of a new or revised NAAQS, the CAA requires EPA to designate areas as attaining or not attaining the NAAQS. The CAA then specifies requirements for areas based on whether such areas are attaining or not attaining the NAAQS. In this final rule, EPA assigns designations to areas as required.

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), EPA must determine whether the regulatory action is "significant" and, therefore, subject to OMB review and the requirements of the Executive Order. The order defines "significant regulatory action" as one that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, it has been determined that this rule is not a "significant regulatory action" because none of the above factors apply. As such, this final rule was not formally submitted to OMB for review.

B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* This rule responds to the requirement to promulgate air quality designations after promulgation of a NAAQS. This requirement is prescribed in the CAA section 107 of title 1. The present final rule does not establish any new information collection apart from that required by law. Burden means that total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in the CFR are listed in 40 CFR part 9.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedures Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For the purpose of assessing the impacts of today's final rule on small entities, small entity is defined as: (1) A small business that is a small industry entity as defined in the United States Small Business Administration (SBA) size standards (*See* 13 CFR part 121); (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominate in its field.

The rule designating nonattainment areas for the PM2.5 NAAQS is not subject to RFA because it was not subject to notice and comment rulemaking requirements. *See* CAA section 107(d)(2)(B).

After considering the economic impacts of today's final rule on small entities, I certify that this rule will not have a significant economic impact on a substantial number of small entities.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal Agencies to assess the effects of their regulatory actions on State, local and Tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandate" that may result in expenditures to State, local, and Tribal governments, in the aggregate, or to the private sector, of $100 million or more in any 1 year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation of why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including Tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small government on compliance with regulatory requirements.

Today's final action does not include a Federal mandate within the meaning of UMRA that may result in expenditures of $100 million or more in any 1 year by either State, local, or

Tribal governments in the aggregate or to the private sector, and therefore, is not subject to the requirements of sections 202 and 205 of the UMRA. It does not create any additional requirements beyond those of the PM2.5 NAAQS (62 FR 38652; July 18, 1997), therefore, no UMRA analysis is needed. This rule establishes the application of the PM2.5 standard and the designation for each area of the country for the PM2.5 NAAQS. The CAA requires States to develop plans, including control measures, based on their designations and classifications.

One mandate that may apply as a consequence of this action to all designated nonattainment areas is the requirement under CAA section 176(c) and associated regulations to demonstrate conformity of Federal actions to State Implementation Plans (SIPs). These rules apply to Federal agencies and Metropolitan Planning Organizations (MPOs) making conformity determinations. The EPA concludes that such conformity determinations will not cost $100 million or more in the aggregate.

The EPA believes that any new controls imposed as a result of this action will not cost in the aggregate $100 million or more annually. Thus, this Federal action will not impose mandates that will require expenditures of $100 million or more in the aggregate in any 1 year.

Nonetheless, EPA carried out consultation with government entities affected by this rule, including States, Tribal governments, and local air pollution control agencies.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, or the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

This final rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. The CAA establishes the scheme whereby States take the lead in developing plans to meet the NAAQS. This rule will not modify the relationship of the States and EPA for purposes of developing programs to implement the NAAQS. Thus, Executive Order 13132 does not apply to this rule.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure "meaningful and timely input by Tribal officials in the development of regulatory policies that have Tribal implications." This final rule does not have "Tribal implications" as specified in Executive Order 13175. This rule concerns the designation and classification of areas as attainment and nonattainment for the PM2.5 air quality standard. The CAA provides for States to develop plans to regulate emissions of air pollutants within their jurisdictions. The TAR provides Tribes the opportunity to develop and implement CAA programs such as programs to attain and maintain the PM2.5 NAAQS, but it leaves to the discretion of the Tribe the decision of whether to develop these programs and which programs, or appropriate elements of a program, the Tribe will adopt.

This final rule does not have Tribal implications as defined by Executive Order 13175. It does not have a substantial direct effect on one or more Indian Tribes, since no Tribe has implemented a CAA program to attain the PM2.5 NAAQS at this time. Furthermore, this rule does not affect the relationship or distribution of power and responsibilities between the Federal government and Indian Tribes. The CAA and the TAR establish the relationship of the Federal government and Tribes in developing plans to attain the NAAQS, and this rule does nothing to modify that relationship. Because this rule does not have Tribal implications, Executive Order 13175 does not apply.

Although Executive Order 13175 does not apply to this rule, EPA did outreach to Tribal leaders and environmental staff regarding the designations process. The EPA supports a national "Tribal Designations and Implementation Work Group" which provides an open forum for all Tribes to voice concerns to EPA about the designations and implementation process for the NAAQS, including the PM2.5 NAAQS. These discussions informed EPA about key Tribal concerns regarding designations as the rule was under development and gave Tribes the opportunity to express concerns about designations to EPA. Furthermore, EPA sent individualized letters to all federally recognized Tribes about EPA's intention to designate areas for the PM2.5 standard and gave Tribal leaders the opportunity for consultation.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

Executive Order 13045: "Protection of Children From Environmental Health and Safety Risks" (62 FR 19885, April 23, 1997) applies to any rule that (1) is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health and safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, EPA must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the EPA.

The final rule is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because EPA does not have reason to believe that the environmental health risks or safety risks addressed by this rule present a disproportionate risk or safety risk to children. Nonetheless, we have evaluated the environmental health or safety effects of the PM2.5 NAAQS on children. The results of this risk assessment are contained in the NAAQS for PM2.5, Final Rule (July 18, 1997, 62 FR 38652).

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This rule is not subject to Executive Order 13211, "Actions That Significantly Affect Energy Supply, Distribution, or Use," (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

Information on the methodology and data regarding the assessment of potential energy impacts is found in Chapter 6 of U.S. EPA 2002, Cost, Emission Reduction, Energy, and the Implementation Framework for the PM2.5 NAAQS, prepared by the Innovative Strategies and Economics Group, Office of Air Quality Planning and Standards, Research Triangle Park, NC, April 24, 2003.

I. National Technology Transfer Advancement Act (NTTAA)

Section 12(d) of the NTTAA of 1995, Public Law No. 104–113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards (VCS) in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impracticable. Voluntary consensus standards are technical standards (*e.g.*, materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by VCS bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable VCS.

This action does not involve technical standards. Therefore, EPA did not consider the use of any VCS.

J. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2). This rule will be effective April 5, 2005.

K. Judicial Review

Section 307 (b) (1) of the CAA indicates which Federal Courts of Appeal have venue for petitions of review of final actions by EPA. This section provides, in part, that petitions for review must be filed in the Court of Appeals for the District of Columbia Circuit (i) when the agency action consists of "nationally applicable regulations promulgated, or final actions taken, by the Administrator," or (ii) when such action is locally or regionally applicable, if "such action is based on a determination of nationwide scope or effect and if in taking such action the Administrator finds and publishes that such action is based on such a determination."

This rule designating areas for the PM2.5 NAAQS is "nationally applicable" within the meaning of section 307(b)(1). This rule establishes designations for all areas of the United States for the PM2.5 NAAQS. At the core of this rulemaking is EPA's interpretation of the definition of nonattainment under section 107(d)(1) of the CAA. In determining which areas should be designated nonattainment (or conversely, should be designated attainment/unclassifiable), EPA used a set of nine technical factors that it applied consistently across the United States.

For the same reasons, the Administrator also is determining that the final designations are of nationwide scope and effect for the purposes of section 307(b)(1). This is particularly appropriate because in the report on the 1977 Amendments that revised section 307(b)(1) of the CAA, Congress noted that the Administrator's determination that an action is of "nationwide scope or effect" would be appropriate for any action that has "scope or effect beyond a single judicial circuit." H.R. Rep. No. 95–294 at 323, 324, *reprinted* in 1977 U.S.C.C.A.N. 1402–03. Here, the scope and effect of this rulemaking extends to numerous judicial circuits since the designations apply to all areas of the country. In these circumstances, section 307(b)(1) and its legislative history calls for the Administrator to find the rule to be of "nationwide scope or effect" and for venue to be in the D.C. Circuit.

Thus, any petitions for review of final designations must be filed in the Court of Appeals for the District of Columbia Circuit within 60 days from the date final action is published in the **Federal Register**.

List of Subjects in 40 CFR Part 81

Environmental protection, Air pollution control, National parks, Wilderness areas.

Dated: December 17, 2004.

Michael O. Leavitt,

EPA Administrator.

■ For the reasons set forth in the preamble, 40 CFR Part 81, Subpart C is amended as follows:

PART 81—DESIGNATIONS OF AREAS FOR AIR QUALITY PLANNING PURPOSES

■ 1. The authority citation for part 81 continues to read as follows:

Authority: 42 U.S.C. 7401, *et seq.*

Subpart C—Section 107 Attainment Status Designations

■ 2. Section 81.300 is amended by revising paragraph (a) to read as follows:

§ 81.300 Scope.

(a) Attainment status designations as approved or designated by the Environmental Protection Agency (EPA) pursuant to section 107 of the CAA are listed in this subpart. Area designations are subject to revision whenever sufficient data becomes available to warrant a redesignation. Both the State and EPA can initiate changes to these designations, but any State redesignation must be submitted to EPA for concurrence. The EPA has replaced the national ambient air quality standards for particulate matter measured as total suspended particulate with standards measured as particulate matter with an aerodynamic diameter less than or equal to a nominal 10 micrometers (PM–10). Accordingly, area designations for PM–10 are included in the lists in subpart C of this part. However, the TSP area designations will also remain in effect until the Administrator determines that the designations are no longer necessary for implementing the maximum allowable increases in concentrations of particulate matter pursuant to section 163(b) of the CAA, as explained in paragraph (b) of this section. The EPA has also added national ambient air quality standards for fine particulate matter measured as particulate matter with an aerodynamic diameter less than or equal to a nominal 2.5 micrometers (PM2.5). Accordingly, area designations for PM2.5 are included in the lists in subpart C of this part.

* * * * *

■ 2a. In § 81.301, the table entitled "Alabama—PM2.5" is added to the end of the section to read as follows:

§ 81.301 Alabama.

* * * * *

ALABAMA.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
Birmingham, AL:		
Jefferson County		Nonattainment.
Shelby County		Nonattainment.
Walker County (part)		Nonattainment.
The area described by U.S. Census 2000 block group identifiers 01–127–0214–5, 01–127–0215–4, and 01–127–0216–2		
Chattanooga, TN-GA:		
Jackson County (part)		Nonattainment.
The area described by U.S. Census 2000 block block group identifier 01–071–9503–1		
Columbus, GA-AL:		
Russell County		Nonattainment.
DeKalb County, AL:		
DeKalb County		Unclassifiable
Gadsden, AL:		
Etowah County		Unclassifiable
Rest of State:		
Autauga County		Unclassifiable/Attainment.
Baldwin County		Unclassifiable/Attainment.
Barbour County		Unclassifiable/Attainment.
Bibb County		Unclassifiable/Attainment.
Blount County		Unclassifiable/Attainment.
Bullock County		Unclassifiable/Attainment.
Butler County		Unclassifiable/Attainment.
Calhoun County		Unclassifiable/Attainment.
Chambers County		Unclassifiable/Attainment.
Cherokee County		Unclassifiable/Attainment.
Chilton County		Unclassifiable/Attainment.
Choctaw County		Unclassifiable/Attainment.
Clarke County		Unclassifiable/Attainment.
Clay County		Unclassifiable/Attainment.
Cleburne County		Unclassifiable/Attainment.
Coffee County		Unclassifiable/Attainment.
Colbert County		Unclassifiable/Attainment.
Conecuh County		Unclassifiable/Attainment.
Coosa County		Unclassifiable/Attainment.
Covington County		Unclassifiable/Attainment.
Crenshaw County		Unclassifiable/Attainment.
Cullman County		Unclassifiable/Attainment.
Dale County		Unclassifiable/Attainment.
Dallas County		Unclassifiable/Attainment.
Elmore County		Unclassifiable/Attainment.
Escambia County		Unclassifiable/Attainment.
Fayette County		Unclassifiable/Attainment.
Franklin County		Unclassifiable/Attainment.
Geneva County		Unclassifiable/Attainment.
Greene County		Unclassifiable/Attainment.
Hale County		Unclassifiable/Attainment.
Henry County		Unclassifiable/Attainment.
Houston County		Unclassifiable/Attainment.
Jackson County (remainder)		Unclassifiable/Attainment.
Lamar County		Unclassifiable/Attainment.
Lauderdale County		Unclassifiable/Attainment.
Lawrence County		Unclassifiable/Attainment.
Lee County		Unclassifiable/Attainment.
Limestone County		Unclassifiable/Attainment.
Lowndes County		Unclassifiable/Attainment.
Macon County		Unclassifiable/Attainment.
Madison County		Unclassifiable/Attainment.
Marengo County		Unclassifiable/Attainment.
Marion County		Unclassifiable/Attainment.
Marshall County		Unclassifiable/Attainment.
Mobile County		Unclassifiable/Attainment.
Monroe County		Unclassifiable/Attainment.
Montgomery County		Unclassifiable/Attainment.
Morgan County		Unclassifiable/Attainment.
Perry County		Unclassifiable/Attainment.
Pickens County		Unclassifiable/Attainment.
Pike County		Unclassifiable/Attainment.
Randolph County		Unclassifiable/Attainment.
St. Clair County		Unclassifiable/Attainment.

ALABAMA.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Sumter County	.....	Unclassifiable/Attainment.
Talladega County	.....	Unclassifiable/Attainment.
Tallapoosa County	.....	Unclassifiable/Attainment.
Tuscaloosa County	.....	Unclassifiable/Attainment.
Walker County (remainder)	.....	Unclassifiable/Attainment.
Washington County	.....	Unclassifiable/Attainment.
Wilcox County	.....	Unclassifiable/Attainment.
Winston County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 3. In § 81.302, the table entitled "Alaska—PM2.5" is added to the end of the section to read as follows:

§ 81.302 Alaska.

* * * * *

ALASKA.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
AQCR 08 Cook Inlet Intrastate:		
Anchorage Borough	.....	Unclassifiable/Attainment.
Kenai Peninsula Borough	.....	Unclassifiable/Attainment.
Matanuska-Susitna Borough	.....	Unclassifiable/Attainment.
AQCR 09 Northern Alaska Intrastate:		
Denali Borough	.....	Unclassifiable/Attainment.
Fairbanks North Star Borough	.....	Unclassifiable/Attainment.
Nome Census Area	.....	Unclassifiable/Attainment.
North Slope Borough	.....	Unclassifiable/Attainment.
Northwest Arctic Borough	.....	Unclassifiable/Attainment.
Southeast Fairbanks Census Area	.....	Unclassifiable/Attainment.
Yukon-Koyukuk Census Area	.....	Unclassifiable/Attainment.
AQCR 10 South Central Alaska Intrastate:		
Aleutians East Borough	.....	Unclassifiable/Attainment.
Aleutians West Census Area	.....	Unclassifiable/Attainment.
Bethel Census Area	.....	Unclassifiable/Attainment.
Bristol Bay Borough	.....	Unclassifiable/Attainment.
Dillingham Census Area	.....	Unclassifiable/Attainment.
Kodiak Island Borough	.....	Unclassifiable/Attainment.
Lake and Peninsula Borough	.....	Unclassifiable/Attainment.
Valdez-Cordova Census Area	.....	Unclassifiable/Attainment.
Wade Hampton Census Area	.....	Unclassifiable/Attainment.
AQCR 11 Southeastern Alaska Intrastate:		
Haines Borough	.....	Unclassifiable/Attainment.
Juneau Borough	.....	Unclassifiable/Attainment.
Ketchikan Gateway Borough	.....	Unclassifiable/Attainment.
Prince of Wales-Outer Ketchikan Census	.....	Unclassifiable/Attainment.
Sitka Borough	.....	Unclassifiable/Attainment.
Skagway-Hoonah-Angoon Census Area	.....	Unclassifiable/Attainment.
Wrangell-Petersburg Census Area	.....	Unclassifiable/Attainment.
Yakutat Borough	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 4. In § 81.303, the table entitled "Arizona—PM2.5" is added to the end of the section to read as follows:

§ 81.303 Arizona.

* * * * *

ARIZONA.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
Statewide:		

ARIZONA.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Apache County	.....	Unclassifiable/Attainment.
Cochise County	.....	Unclassifiable/Attainment.
Coconino County	.....	Unclassifiable/Attainment.
Gila County	.....	Unclassifiable/Attainment.
Graham County	.....	Unclassifiable/Attainment.
Greenlee County	.....	Unclassifiable/Attainment.
La Paz County	.....	Unclassifiable/Attainment.
Maricopa County	.....	Unclassifiable/Attainment.
Mohave County	.....	Unclassifiable/Attainment.
Navajo County	.....	Unclassifiable/Attainment.
Pima County	.....	Unclassifiable/Attainment.
Pinal County	.....	Unclassifiable/Attainment.
Santa Cruz County	.....	Unclassifiable/Attainment.
Yavapai County	.....	Unclassifiable/Attainment.
Yuma County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 5. In § 81.304, the table entitled "Arizona.—PM2.5" is added to the end of the section to read as follows:

§ 81.304 Arkansas.

* * * * *

ARKANSAS.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
AQCR 016 Central Arkansas Intrastate:		
Chicot County	.....	Unclassifiable/Attainment.
Clark County	.....	Unclassifiable/Attainment.
Cleveland County	.....	Unclassifiable/Attainment.
Conway County	.....	Unclassifiable/Attainment.
Dallas County	.....	Unclassifiable/Attainment.
Desha County	.....	Unclassifiable/Attainment.
Drew County	.....	Unclassifiable/Attainment.
Faulkner County	.....	Unclassifiable/Attainment.
Garland County	.....	Unclassifiable/Attainment.
Grant County	.....	Unclassifiable/Attainment.
Hot Spring County	.....	Unclassifiable/Attainment.
Jefferson County	.....	Unclassifiable/Attainment.
Lincoln County	.....	Unclassifiable/Attainment.
Lonoke County	.....	Unclassifiable/Attainment.
Perry County	.....	Unclassifiable/Attainment.
Pope County	.....	Unclassifiable/Attainment.
Pulaski County	.....	Unclassifiable/Attainment.
Saline County	.....	Unclassifiable/Attainment.
Yell County	.....	Unclassifiable/Attainment.
AQCR 017 Metropolitan Fort Smith Interstate:		
Benton County	.....	Unclassifiable/Attainment.
Crawford County	.....	Unclassifiable/Attainment.
Sebastian County	.....	Unclassifiable/Attainment.
Washington County	.....	Unclassifiable/Attainment.
AQCR 019 Monroe-El Dorado Interstate:		
Ashley County	.....	Unclassifiable/Attainment.
Bradley County	.....	Unclassifiable/Attainment.
Calhoun County	.....	Unclassifiable/Attainment.
Nevada County	.....	Unclassifiable/Attainment.
Ouachita County	.....	Unclassifiable/Attainment.
Union County	.....	Unclassifiable/Attainment.
AQCR 020 Northeast Arkansas Intrastate:		
Arkansas County	.....	Unclassifiable/Attainment.
Clay County	.....	Unclassifiable/Attainment.
Craighead County	.....	Unclassifiable/Attainment.
Cross County	.....	Unclassifiable/Attainment.
Greene County	.....	Unclassifiable/Attainment.
Independence County	.....	Unclassifiable/Attainment.
Jackson County	.....	Unclassifiable/Attainment.
Lawrence County	.....	Unclassifiable/Attainment.

ARKANSAS.—PM2.5—Continued

Designated area	Designation[a]	
	Date[1]	Type
Lee County	.....	Unclassifiable/Attainment.
Mississippi County	.....	Unclassifiable/Attainment.
Monroe County	.....	Unclassifiable/Attainment.
Phillips County	.....	Unclassifiable/Attainment.
Poinsett County	.....	Unclassifiable/Attainment.
Prairie County	.....	Unclassifiable/Attainment.
Randolph County	.....	Unclassifiable/Attainment.
St. Francis County	.....	Unclassifiable/Attainment.
Sharp County	.....	Unclassifiable/Attainment.
White County	.....	Unclassifiable/Attainment.
Woodruff County	.....	Unclassifiable/Attainment.
AQCR 021 Northwest Arkansas Intrastate:		
Baxter County	.....	Unclassifiable/Attainment.
Boone County	.....	Unclassifiable/Attainment.
Carroll County	.....	Unclassifiable/Attainment.
Cleburne County	.....	Unclassifiable/Attainment.
Franklin County	.....	Unclassifiable/Attainment.
Fulton County	.....	Unclassifiable/Attainment.
Izard County	.....	Unclassifiable/Attainment.
Johnson County	.....	Unclassifiable/Attainment.
Logan County	.....	Unclassifiable/Attainment.
Madison County	.....	Unclassifiable/Attainment.
Marion County	.....	Unclassifiable/Attainment.
Montgomery County	.....	Unclassifiable/Attainment.
Newton County	.....	Unclassifiable/Attainment.
Pike County	.....	Unclassifiable/Attainment.
Polk County	.....	Unclassifiable/Attainment.
Scott County	.....	Unclassifiable/Attainment.
Searcy County	.....	Unclassifiable/Attainment.
Stone County	.....	Unclassifiable/Attainment.
Van Buren County	.....	Unclassifiable/Attainment.
AQCR 022 Shreveport-Texarkana-Tyler Interstate:		
Columbia County	.....	Unclassifiable/Attainment.
Hempstead County	.....	Unclassifiable/Attainment.
Howard County	.....	Unclassifiable/Attainment.
Lafayette County	.....	Unclassifiable/Attainment.
Little River County	.....	Unclassifiable/Attainment.
Miller County	.....	Unclassifiable/Attainment.
Sevier County	.....	Unclassifiable/Attainment.
Memphis, TN–AR:		
(AQCR 018 Metropolitan Memphis Interstate):		
Crittenden County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 6. In § 81.305, the table entitled "California.—PM2.5" is added to the end of the section to read as follows:

CALIFORNIA.—PM2.5

Designated area	Designation[a]	
	Date[1]	Type
Los Angeles-South Coast Air Basin, CA:		
Los Angeles County (part)	.....	Nonattainment.

CALIFORNIA.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
That portion of Los Angeles County which lies south and west of a line described as follows: Beginning at the Los Angeles-San Bernardino County boundary and running west along the Township line common to Township 3 North and Township 2 North, San Bernardino Base and Meridian; then north along the range line common to Range 8 West and Range 9 West; then west along the Township line common to Township 4 North and Township 3 North; then north along the range line common to Range 12 West and Range 13 West to the southeast corner of Section 12, Township 5 North and Range 13 West; then west along the south boundaries of Sections 12, 11, 10, 9, 8, and 7, Township 5 North and Range 13 West to the boundary of the Angeles National Forest which is collinear with the range line common to Range 13 West and Range 14 West; then north and west along the Angeles National Forest boundary to the point of intersection with the Township line common to Township 7 North and Township 6 North (point is at the northwest corner of Section 4 in Township 6 North and Range 14 West); then west along the Township line common to Township 7 North and Township 6 North; then north along the range line common to Range 15 West and Range 16 West to the southeast corner of Section 13, Township 7 North and Range 16 West; then along the south boundaries of Sections 13, 14, 15, 16, 17, and 18, Township 7 North and Range 16 West; then north along the range line common to Range 16 West and Range 17 West to the north boundary of the Angeles National Forest (collinear with the Township line common to Township 8 North and Township 7 North); then west and north along the Angeles National Forest boundary to the point of intersection with the south boundary of the Rancho La Liebre Land Grant; then west and north along this land grant boundary to the Los Angeles-Kern County boundary.		
Orange County	.....	Nonattainment.
Riverside County (part)	.....	Nonattainment.
That portion of Riverside County which lies to the west of a line described as follows: Beginning at the Riverside-San Diego County boundary and running north along the range line common to Range 4 East and Range 3 East, San Bernardino Base and Meridian; then east along the Township line common to Township 8 South and Township 7 South; then north along the range line common to Range 5 East and Range 4 East; then west along the Township line common to Township 6 South and Township 7 South to the southwest corner of Section 34, Township 6 South, Range 4 East; then north along the west boundaries of Sections 34, 27, 22, 15, 10, and 3, Township 6 South, Range 4 East; then west along the Township line common to Township 5 South and Township 6 South; then north along the range line common to Range 4 East and Range 3 East; then west along the south boundaries of Sections 13, 14, 15, 16, 17, and 18, Township 5 South, Range 3 East; then north along the range line common to Range 2 East and Range 3 East; to the Riverside-San Bernardino County line.		
San Bernardino County (part)	.....	Nonattainment.
That portion of San Bernardino County which lies south and west of a line described as follows: Beginning at the San Bernardino-Riverside County boundary and running north along the range line common to Range 3 East and Range 2 East, San Bernardino Base and Meridian; then west along the Township line common to Township 3 North and Township 2 North to the San Bernardino-Los Angeles County boundary.		
San Diego, CA:		
San Diego County (part)	.....	Nonattainment.
That portion of San Diego County that excludes the areas listed below: La Posta Areas #1 and #2, Cuyapaipe Area, Manzanita Area, Campo Areas #1 and #2[b].		
San Joaquin Valley, CA:		
Fresno County	.....	Nonattainment.
Kern County (part)	.....	Nonattainment.
That portion of Kern County which lies west and north of a line described as follows: Beginning at the Kern-Los Angeles County boundary and running north and east along the northwest boundary of the Rancho La Libre Land Grant to the point of intersection with the range line common to R. 16 W. and R. 17 W., San Bernardino Base and Meridian; north along the range line to the point of intersection with the Rancho El Tejon Land Grant boundary; then southeast, northeast, and northwest along the boundary of the Rancho El Tejon Land Grant to the northwest corner of S. 3, T. 11 N., R. 17 W.; then west 1.2 miles; then north to the Rancho El Tejon Land Grant boundary; then northwest along the Rancho El Tejon line to the southeast corner of S. 34, T. 32 S., R. 30 E., Mount Diablo Base and Meridian; then north to the northwest corner of S. 35, T. 31 S., R. 30 E.; then northeast along the boundary of the Rancho El Tejon Land Grant to the southwest corner of S. 18, T. 31 S., R. 31 E.; then east to the southeast corner of S. 13, T. 31 S., R. 31 E.; then north along the range line common to R. 31 E. and R. 32 E., Mount Diablo Base and Meridian, to the northwest corner of S. 6, T. 29 S., R. 32 E.; then east to the southwest corner of S. 31, T. 28 S., R. 32 E.; then north along the range line common to R. 31 E. and R. 32 E. to the northwest corner of S. 6, T. 28 S., R. 32 E., then west to the southeast corner of S. 36, T. 27 S., R. 31 E., then north along the range line common to R. 31 E. and R. 32 E. to the Kern-Tulare County boundary.		
Kings County	.....	Nonattainment.

CALIFORNIA.—PM2.5—Continued

Designated area	Designation[a]	
	Date[1]	Type
Madera County	.....	Nonattainment.
Merced County	.....	Nonattainment.
San Joaquin County	.....	Nonattainment.
Stanislaus County	.....	Nonattainment.
Tulare County	.....	Nonattainment.
North Coast Air Basin:		
Del Norte County	.....	Unclassifiable/Attainment.
Humboldt County	.....	Unclassifiable/Attainment.
Mendocino County	.....	Unclassifiable/Attainment.
Sonoma County (part)	.....	Unclassifiable/Attainment.
That portion of Sonoma county which lies north and west of a line described as follows: Beginning at the south-easterly corner of the Rancho Estero Americano, being on the boundary line between Marin and Sonoma Counties, California; thence running northerly along the easterly boundary line of said Rancho Estero Americano to the northeasterly corner thereof, being an angle corner in the westerly boundary line of Rancho Canada de Jonive, thence running along said boundary of Rancho Canada de Jonive westerly; northerly and easterly to its intersection with the easterly line of Graton Road; thence running along the easterly and southerly line of Graton Road northerly and easterly to its intersection with the easterly line of Sullivan Road; thence running northerly along said easterly line of Sullivan Road to the southerly line of Green Valley Road; thence running easterly along the said southerly line of Green Valley Road and easterly along the southerly line of State Highway 116, to the westerly and northerly line of Vine Hill Road; thence running along the westerly and northerly line of Vine Hill Road, northerly and easterly to its intersection with the westerly line of Laguna Road; thence running northerly along the westerly line of Laguna Road and the northerly projection thereof to the northerly line of Trenton Road; thence running westerly along the northerly line of said Trenton Road to the easterly line of Trenton-Healdsburg Road to the easterly line of Eastside Road: thence running northerly along said easterly line of Eastside Road to its intersection with the southerly line of Rancho Sotoyome; thence running easterly along said southerly line of Rancho Sotoyome to its intersection with the Township line common to Townships 8 and 9 north, Mt. Diablo Base and Meridian; thence running easterly along said Township line to its intersection with the boundary line between Sonoma and Napa Counties, State of California.		
Trinity County	.....	Unclassifiable/Attainment.
Northeast Plateau Air Basin:		
Lassen County	.....	Unclassifiable/Attainment.
Modoc County	.....	Unclassifiable/Attainment.
Siskiyou County	.....	Unclassifiable/Attainment.
Lake County Air Basin:		
Lake County	.....	Unclassifiable/Attainment.
Upper Sacramento Valley Region:		
Butte County	.....	Unclassifiable/Attainment.
Colusa County	.....	Unclassifiable/Attainment.
Glenn County	.....	Unclassifiable/Attainment.
Shasta County	.....	Unclassifiable/Attainment.
Sutter County (part)	.....	Unclassifiable/Attainment.
All portions of the county except that portion south of a line connecting the northern border of Yolo County to the southwest tip of Yuba County and continuing along the southern Yuba County border to Placer County.		
Tehama County	.....	Unclassifiable/Attainment.
Yuba County	.....	Unclassifiable/Attainment.
Sacramento Metropolitan Region:		
El Dorado County (part)	.....	Unclassifiable/Attainment.
All portions of the county except that portion of El Dorado County within the drainage area naturally tributary to Lake Tahoe including said Lake.		
Placer County (part)	.....	Unclassifiable/Attainment.
All portions of the county except that portion of Placer County within the drainage area naturally tributary to Lake Tahoe including said Lake, plus that area in the vicinity of the head of the Truckee River described as follows: Commencing at the point common to the aforementioned drainage area crestline and the line common to Townships 15 North and 16 North, Mount Diablo Base and Meridian, and following that line in a westerly direction to the northwest corner of Section 3, Township 15 North, Range 16 East, Mount Diablo Base and Meridian, thence south along the west line of Sections 3 and 10, Township 15 North, Range 16 East, Mount Diablo Base and Meridian, to the intersection with the said drainage area crestline, thence following the said drainage area boundary in a southeasterly, then northeasterly direction to and along the Lake Tahoe Dam, thence following the said drainage area crestline in a northeasterly, then northwesterly direction to the point of beginning.		
Sacramento County	.....	Unclassifiable/Attainment.
Solano County (part)	.....	Unclassifiable/Attainment.

CALIFORNIA.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
That portion of Solano County which lies north and east of a line described as follows: Beginning at the intersection of the westerly boundary of Solano County and the 1/4 section line running east and west through the center of Section 34; Township 6 North, Range 2 West, Mount Diablo Base and Meridian, thence east along said 1/4 section line to the east boundary of Section 36, Township 6 North, Range 2 West, thence south 1/2 mile and east 2.0 miles, more or less, along the west and south boundary of Los Putos Rancho to the northwest corner of Section 4, Township 5 North, Range 1 West, thence east along a line common to Township 5 North and Township 6 North to the northeast corner of Section 3, Township 5 North, Range 1 East, thence south along section lines to the southeast corner of Section 10, Township 3 North, Range 1 East, thence east along section lines to the south 1/4 corner of Section 8, Township 3 North, Range 2 East, thence east to the boundary between Solano and Sacramento Counties.		
Sutter County (part)	.....	Unclassifiable/Attainmant
That portion south of a line connecting the northern border of Yolo County to the southwest tip of Yuba County and continuing along the southern Yuba County border to Placer County.		
Yolo County	.....	Unclassifiable/Attainment.
Northern Mountain Counties:		
Nevada County	.....	Unclassifiable/Attainment.
Plumas County	.....	Unclassifiable/Attainment.
Sierra County	.....	Unclassifiable/Attainment.
Central Mountain Counties:		
Amador County	.....	Unclassifiable/Attainment.
Calaveras County	.....	Unclassifiable/Attainment.
Southern Mountain Counties:		
Mariposa County	.....	Unclassifiable/Attainment.
Tuolumne County	.....	Unclassifiable/Attainment.
Lake Tahoe Air Basin:		
El Dorado County (part)	.....	Unclassifiable/Attainmant
That portion of El Dorado County within the drainage area naturally tributary to Lake Tahoe including said Lake.		
Placer County (part)	.....	Unclassifiable/Attainment.
That portion of Placer County within the Attainment. drainage area naturally tributary to Lake Tahoe including said Lake, plus that area in the vicinity of the head of the Truckee River described as follows: Commencing at the point common to the aforementioned drainage area crestline and the line common to Townships 15 North and 16 North, Mount Diablo Base and Meridian, and following that line in a westerly direction to the northwest corner of Section 3, Township 15 North, Range 16 East, Mount Diablo Base and Meridian, thence south along the west line of Sections 3 and 10, Township 15 North, Range 16 East, Mount Diablo Base and Meridian, to the intersection with the said drainage area crestline, thence following the said drainage area boundary in a southeasterly, then northeasterly direction to and along the Lake Tahoe Dam, thence following the said drainage area crestline in a northeasterly, then northwesterly direction to the point of beginning.	.....	Attainment.
San Francisco Bay Area Air Basin:		
Alameda County	.....	Unclassifiable/Attainment.
Contra Costa County	.....	Unclassifiable/Attainment.
Marin County	.....	Unclassifiable/Attainment.
Napa County	.....	Unclassifiable/Attainment.
San Francisco County	.....	Unclassifiable/Attainment.
San Mateo County	.....	Unclassifiable/Attainment.
Santa Clara County	.....	Unclassifiable/Attainment.
Solano County (part)	.....	Unclassifiable/Attainment.
Portion of Solano County which lies south and west of a line described as follows: Beginning at the intersection of the westerly boundary of Solano County and the ¼ section line running east and west through the center of Section 34, T6N, R2W, M.D.B. & M., thence east along said ¼ section line to the east boundary of Section 36, T6N, R2W, thence south ½ mile and east 2.0 miles, more or less, along the west and south boundary of Los Putos Rancho to the northwest corner of Section 4, T5N, R1W, thence east along a line common to T5N and T6N to the northeast corner of Section 3, T5N, R1E, thence south along section lines to the southeast corner of Section 10, T3N, R1E, thence east along section lines to the south ¼ corner of Section 8, T3N, R2E, thence east to the boundary between Solano and Sacramento Counties.		
Sonoma County (part)	.....	Unclassifiable/Attainment.

CALIFORNIA.—PM2.5—Continued

Designated area	Designation[a]	
	Date[1]	Type
That portion of Sonoma County which lies south and east of a line described as follows: Beginning at the southeasterly corner of the Rancho Estero Americano, being on the boundary line between Marin and Sonoma Counties, California; thence running northerly along the easterly boundary line of said Rancho Estero Americano to the northeasterly corner thereof, being an angle corner in the westerly boundary line of Rancho Canada de Jonive; thence running along said boundary of Rancho Canada de Jonive westerly, northerly and easterly to its intersection with the easterly line of Graton Road; thence running along the easterly and southerly line of Graton Road, northerly and easterly to its intersection with the easterly line of Sullivan Road; thence running northerly along said easterly line of Sullivan Road to the southerly line of Green Valley Road; thence running easterly along the said southerly line of Green Valley Road and easterly along the southerly line of State Highway 116, to the westerly line of Vine Hill Road; thence running along the westerly and northerly line of Vine Hill Road, northerly and easterly to its intersection with the westerly line of Laguna Road; thence running northerly along the westerly line of Laguna Road and the northerly projection thereof to the northerly line of Trenton Road; thence running westerly along the northerly line of said Trenton Road to the easterly line of Trenton-Healdsburg Road; thence running northerly along said easterly line of Trenton-Healdsburg Road to the easterly line of Eastside Road; thence running northerly along said easterly line of Eastside Road to its intersection with the southerly line of Rancho Sotoyome; thence running easterly along said southerly line of Rancho Sotoyome to its intersection with the Township line common to Townships 8 and 9 North, M.D.M.; thence running easterly along said township line to its intersection with the boundary line between Sonoma and Napa Counties.		
North Central Coast Air Basin:		
Monterey County	.....	Unclassifiable/Attainment.
San Benito County	.....	Unclassifiable/Attainment.
Santa Cruz County	.....	Unclassifiable/Attainment.
San Luis Obispo County:		
San Luis Obispo County	.....	Unclassifiable/Attainment.
Santa Barbara County:		
Santa Barbara County (part)	.....	Unclassifiable/Attainment.
Excluding Channel Islands		
Ventura County:		
Ventura County (part)	.....	Unclassifiable/Attainment.
Excluding Anacapa and San Nicolas Islands.		
Northern Channel Islands:		
Santa Barbara County (part)	.....	Unclassifiable/Attainment.
The islands located in the South Central Coast Air Basin, including San Miguel, Santa Rosa, Santa Cruz, and San Nicolas.		
Ventura County (part)	.....	Unclassifiable/Attainment.
Anacapa and San Nicolas Islands.		
Great Basin Valleys Air Basin:		
Alpine County	.....	Unclassifiable/Attainment.
Inyo County (part)	.....	Unclassifiable/Attainment.
That portion of Inyo County that lies outside Hydrologic Unit Number 18090205.		
Mono County	.....	Unclassifiable/Attainment.
Coso Junction:		
Inyo County (part)	.....	Unclassifiable/Attainment.
That portion of Inyo County that lies inside Hydrologic Unit Number 18090205.		
Eastern Kern County:		
Kern County (part)	.....	Unclassifiable/Attainment.

CALIFORNIA.—PM2.5—Continued

Designated area	Designation[a]	
	Date[1]	Type
That portion of Kern County (with the exception of that portion in Hydrologic Unit Number 18090205 —the Indian Wells Valley) east and south of a line described as follows: Beginning at the Kern—Los Angeles County boundary and running north and east along the northwest boundary of the Rancho La Liebre Land Grant to the point of intersection with the range line common to Range 16 West and Range 17 West, San Bernardino Base and Meridian; north along the range line to the point of intersection with the Rancho El Tejon Land Grant boundary; then southeast, northeast, and northwest along the boundary of the Rancho El Tejon Grant to the northwest corner of Section 3, Township 11 North, Range 17 West; then west 1.2 miles; then north to the Rancho El Tejon Land Grant boundary; then northwest along the Rancho El Tejon line to the southeast corner of Section 34, Township 32 South, Range 30 East, Mount Diablo Base and Meridian; then north to the northwest corner of Section 35, Township 31 South, Range 30 East; then northeast along the boundary of the Rancho El Tejon Land Grant to the southwest corner of Section 18, Township 31 South, Range 31 East; then east to the southeast corner of Section 13, Township 31 South, Range 31 East; then north along the range line common to Range 31 East and Range 32 East, Mount Diablo Base and Meridian, to the northwest corner of Section 6, Township 29 South, Range 32 East; then east to the southwest corner of Section 31, Township 28 South, Range 32 East; then north along the range line common to Range 31 East and Range 32 East to the northwest corner of Section 6, Township 28 South, Range 32 East, then west to the southeast corner of Section 36, Township 27 South, Range 31 East, then north along the range line common to Range 31 East and Range 32 East to the Kern-Tulare County boundary.		
Indian Wells Valley:		
Kern County (part)	.....	Unclassifiable/Attainment.
That portion of Kern County that lies inside Hydrologic Unit Number 18090205.		
Western Mojave Desert and Antelope Valley:		
Los Angeles County (part)	.....	Unclassifiable
That portion of Los Angeles County which lies north and east of a line described as follows: Beginning at the Los Angeles—San Bernardino County boundary and running west along the Township line common to Township 3 North and Township 2 North, San Bernardino Base and Meridian; then north along the range line common to Range 8 West and Range 9 West; then west along the Township line common to Township 4 North and Township 3 North; then north along the range line common to Range 12 West and Range 13 West to the southeast corner of Section 12, Township 5 North and Range 13 West; then west along the south boundaries of Sections 12, 11, 10, 9, 8, and 7, Township 5 North and Range 13 West to the boundary of the Angeles National Forest which is collinear with the range line common to Range 13 West and Range 14 West; then north and west along the Angeles National Forest boundary to the point of intersection with the Township line common to Township 7 North and Township 6 North (point is at the northwest corner of Section 4 in Township 6 North and Range 14 West); then west along the Township line common to Township 7 North and Township 6 North; then north along the range line common to Range 15 West and Range 16 West to the southeast corner of Section 13, Township 7 North and Range 16 West; then along the south boundaries of Sections 13, 14, 15, 16, 17, and 18, Township 7 North and Range 16 West; then north along the range line common to Range 16 West and Range 17 West to the north boundary of the Angeles National Forest (collinear with the Township line common to Township 8 North and Township 7 North); then west and north along the Angeles National Forest boundary to the point of intersection with the south boundary of the Rancho La Liebre Land Grant; then west and north along this land grant boundary to the Los Angeles-Kern County boundary.		
San Bernardino County (part)	.....	Unclassifiable/Attainment.
That portion of San Bernardino County (with the exception of that portion in Hydrologic Unit Number 18090205) which lies north and east of a line described as follows: Beginning at the San Bernardino—Riverside County boundary and running north along the range line common to Range 3 East and Range 2 East, San Bernardino Base and Meridian; then west along the Township line common to Township 3 North and Township 2 North to the San Bernardino—Los Angeles County boundary; And that portion of San Bernardino County which lies south and west of a line described as follows: latitude 35 degrees, 10 minutes north and longitude 115 degrees, 45 minutes west.		
Trona:		
San Bernardino County (part)	.....	Unclassifiable/Attainment.
That portion of San Bernardino County that lies inside Hydrologic Unit Number 18090205.		
Coachella Valley:		
Riverside County (part)	.....	Unclassifiable/Attainment.

CALIFORNIA.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
That portion of Riverside County which lies to the east of a line described as follows: Beginning at the Riverside—San Diego County boundary and running north along the range line common to Range 4 East and Range 3 East, San Bernardino Base and Meridian; then east along the Township line common to Township 8 South and Township 7 South; then north along the range line common to Range 5 East and Range 4 East; then west along the Township line common to Township 6 South and Township 7 South to the southwest corner of Section 34, Township 6 South, Range 4 East; then north along the west boundaries of Sections 34, 27, 22, 15, 10, and 3, Township 6 South, Range 4 East; then west along the Township line common to Township 5 South and Township 6 South; then north along the range line common to Range 4 East and Range 3 East; then west along the south boundaries of Sections 13, 14, 15, 16, 17, and 18, Township 5 South, Range 3 East; then north along the range line common to Range 2 East and Range 3 East;, to the Riverside-San Bernardino County line: And that portion of Riverside County which lies to the west of a line described as follows: That segment of the southwestern boundary line of Hydrologic Unit Number 18100100 within Riverside County, further described as follows: Beginning at the Riverside-Imperial County boundary and running north along the range line common to Range 17 East and Range 16 East, San Bernardino Base and Meridian; then northwest along the ridge line of the Chuckwalla Mountains, through Township 8 South, Range 16 East and Township 7 South, Range 16 East, until the Black Butte Mountain, elevation 4504'; then west and northwest along the ridge line to the southwest corner of Township 5 South, Range 14 East; then north along the range line common to Range 14 East and Range 13 East; then west and northwest along the ridge line to Monument Mountain, elevation 4834'; then southwest and then northwest along the ridge line of the Little San Bernardino Mountains to Quail Mountain, elev. 5814'; then northwest along the ridge line to the Riverside-San Bernardino County line.		
Far Eastern Riverside and San Bernardino Counties:		
San Bernardino County (remainder)	.....	Unclassifiable/Attainment.
Riverside County (remainder)	.....	Unclassifiable/Attainment.
Imperial County:		
Imperial County	.....	Unclassifiable/Attainment.
San Diego County Tribal Area:		
San Diego County (part).		
La Posta Areas #1 and #2[b]	.....	Unclassifiable/Attainment.
Cuyapaipe Area[b]	.....	Unclassifiable/Attainment.
Manzanita Area[b]	.....	Unclassifiable/Attainment.
Campo Areas #1 and #2[b]	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.
[b] The boundaries for these designated areas are based on coordinates of latitude and longitude derived from EPA Region 9's GIS database and are illustrated in a map entitled "Southeastern San Diego County Unclassifiable/Attainment. Areas for the PM–2.5 NAAQS," dated December 10, 2004, including an attached set of coordinates. The map and attached set of coordinates are available at EPA's Region 9 Air Division office. The designated areas roughly approximate the boundaries of the reservations for these tribes, but their inclusion in this table is intended for the CAA planning purposes only and is not intended to be a federal determination of the exact boundaries of the reservations. Also, the specific listing of these areas in this table does not confer, deny, or withdraw Federal recognition of any of the tribes so listed nor any of the tribes not listed.

■ 7. In § 81.306, the table entitled "Colorado—PM2.5" is added to the end of the section to read as follows:

§ 81.306 Colorado.

* * * * *

COLORADO.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
Denver-Boulder Area:		
Adams County (part)	.....	Unclassifiable/Attainment.
West of Kiowa Creek		
Arapahoe County (part)	.....	Unclassifiable/Attainment.
West of Kiowa Creek		
Boulder County (part)	.....	Unclassifiable/Attainment.
Excluding Rocky Mountain National Park		
Broomfield County	.....	Unclassifiable/Attainment.
Denver County	.....	Unclassifiable/Attainment.
Douglas County	.....	Unclassifiable/Attainment.
Jefferson County	.....	Unclassifiable/Attainment.
State AQCR 01:		

COLORADO.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Logan County	.....	Unclassifiable/Attainment.
Morgan County	.....	Unclassifiable/Attainment.
Phillips County	.....	Unclassifiable/Attainment.
Sedgwick County	.....	Unclassifiable/Attainment.
Washington County	.....	Unclassifiable/Attainment.
Yuma County	.....	Unclassifiable/Attainment.
State AQCR 02:		
Larimer County	.....	Unclassifiable/Attainment.
Weld County	.....	Unclassifiable/Attainment.
State AQCR 03 (remainder of):		
Adams County (remainder)	.....	Unclassifiable/Attainment.
Arapahoe County (remainder)	.....	Unclassifiable/Attainment.
Boulder County (remainder)	.....	Unclassifiable/Attainment.
Clear Creek County	.....	Unclassifiable/Attainment.
Gilpin County	.....	Unclassifiable/Attainment.
State AQCR 04:		
El Paso County	.....	Unclassifiable/Attainment.
Park County	.....	Unclassifiable/Attainment.
Teller County	.....	Unclassifiable/Attainment.
State AQCR 05:		
Cheyenne County	.....	Unclassifiable/Attainment.
Elbert County	.....	Unclassifiable/Attainment.
Kit Carson County	.....	Unclassifiable/Attainment.
Lincoln County	.....	Unclassifiable/Attainment.
State AQCR 06:		
Baca County	.....	Unclassifiable/Attainment.
Bent County	.....	Unclassifiable/Attainment.
Crowley County	.....	Unclassifiable/Attainment.
Kiowa County	.....	Unclassifiable/Attainment.
Otero County	.....	Unclassifiable/Attainment.
Prowers County	.....	Unclassifiable/Attainment.
State AQCR 07:		
Huerfano County	.....	Unclassifiable/Attainment.
Las Animas County	.....	Unclassifiable/Attainment.
Pueblo County	.....	Unclassifiable/Attainment.
State AQCR 08:		
Alamosa County	.....	Unclassifiable/Attainment.
Conejos County	.....	Unclassifiable/Attainment.
Costilla County	.....	Unclassifiable/Attainment.
Mineral County	.....	Unclassifiable/Attainment.
Rio Grande County	.....	Unclassifiable/Attainment.
Saguache County	.....	Unclassifiable/Attainment.
State AQCR 09:		
Archuleta County	.....	Unclassifiable/Attainment.
Dolores County	.....	Unclassifiable/Attainment.
La Plata County	.....	Unclassifiable/Attainment.
Montezuma County	.....	Unclassifiable/Attainment.
San Juan County	.....	Unclassifiable/Attainment.
State AQCR 10:		
Delta County	.....	Unclassifiable/Attainment.
Gunnison County	.....	Unclassifiable/Attainment.
Hinsdale County	.....	Unclassifiable/Attainment.
Montrose County	.....	Unclassifiable/Attainment.
Ouray County	.....	Unclassifiable/Attainment.
San Miguel County	.....	Unclassifiable/Attainment.
State AQCR 11:		
Garfield County	.....	Unclassifiable/Attainment.
Mesa County	.....	Unclassifiable/Attainment.
Moffat County	.....	Unclassifiable/Attainment.
Rio Blanco County	.....	Unclassifiable/Attainment.
State AQCR 12:		
Eagle County	.....	Unclassifiable/Attainment.
Grand County	.....	Unclassifiable/Attainment.
Jackson County	.....	Unclassifiable/Attainment.
Pitkin County	.....	Unclassifiable/Attainment.
Routt County	.....	Unclassifiable/Attainment.
Summit County	.....	Unclassifiable/Attainment.
State AQCR 13:		
Chaffee County	.....	Unclassifiable/Attainment.
Custer County	.....	Unclassifiable/Attainment.

COLORADO.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Fremont County	.....	Unclassifiable/Attainment.
Lake County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 8. In § 81.307, the table entitled "Connecticut.—PM2.5" is added to the end of the section to read as follows:

§ 81.307 Connecticut.

* * * * *

CONNECTICUT.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
New York-N. New Jersey-Long Island, NY-NJ-CT:		
Fairfield County	.....	Nonattainment.
New Haven County	.....	Nonattainment.
Rest of State:		
Hartford County	.....	Unclassifiable/Attainment.
Litchfield County	.....	Unclassifiable/Attainment.
Middlesex County	.....	Unclassifiable/Attainment.
New London County	.....	Unclassifiable/Attainment.
Tolland County	.....	Unclassifiable/Attainment.
Windham County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 9. In § 81.308, the table entitled "Delaware.—PM2.5" is added to the end of the section to read as follows:

§ 81.308 Delaware.

* * * * *

DELAWARE.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
Philadelphia-Wilmington, PA–NJ–DE:		
New Castle County	.....	Nonattainment.
Southern Delaware Intrastate AQCR:		
Kent County	.....	Unclassifiable/Attainment.
Sussex County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 10. In § 81.309, the table entitled "District of Columbia.—PM2.5" is added to the end of the section to read as follows:

§ 81.309 District of Columbia.

* * * * *

DISTRICT OF COLUMBIA.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
Washington, DC-MD-VA:		
District of Columbia	.....	Nonattainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 11. In § 81.310, the table entitled "Florida.—PM2.5" is added to the end of the section to read as follows:

§ 81.310 Florida.

* * * * *

FLORIDA.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
Statewide:		
Alachua County	.....	Unclassifiable/Attainment.
Baker County	.....	Unclassifiable/Attainment.
Bay County	.....	Unclassifiable/Attainment.
Bradford County	.....	Unclassifiable/Attainment.
Brevard County	.....	Unclassifiable/Attainment.
Broward County	.....	Unclassifiable/Attainment.
Calhoun County	.....	Unclassifiable/Attainment.
Charlotte County	.....	Unclassifiable/Attainment.
Citrus County	.....	Unclassifiable/Attainment.
Clay County	.....	Unclassifiable/Attainment.
Collier County	.....	Unclassifiable/Attainment.
Columbia County	.....	Unclassifiable/Attainment.
DeSoto County	.....	Unclassifiable/Attainment.
Dixie County	.....	Unclassifiable/Attainment.
Duval County	.....	Unclassifiable/Attainment.
Escambia County	.....	Unclassifiable/Attainment.
Flagler County	.....	Unclassifiable/Attainment.
Franklin County	.....	Unclassifiable/Attainment.
Gadsden County	.....	Unclassifiable/Attainment.
Gilchrist County	.....	Unclassifiable/Attainment.
Glades County	.....	Unclassifiable/Attainment.
Gulf County	.....	Unclassifiable/Attainment.
Hamilton County	.....	Unclassifiable/Attainment.
Hardee County	.....	Unclassifiable/Attainment.
Hendry County	.....	Unclassifiable/Attainment.
Hernando County	.....	Unclassifiable/Attainment.
Highlands County	.....	Unclassifiable/Attainment.
Hillsborough County	.....	Unclassifiable/Attainment.
Holmes County	.....	Unclassifiable/Attainment.
Indian River County	.....	Unclassifiable/Attainment.
Jackson County	.....	Unclassifiable/Attainment.
Jefferson County	.....	Unclassifiable/Attainment.
Lafayette County	.....	Unclassifiable/Attainment.
Lake County	.....	Unclassifiable/Attainment.
Lee County	.....	Unclassifiable/Attainment.
Leon County	.....	Unclassifiable/Attainment.
Levy County	.....	Unclassifiable/Attainment.
Liberty County	.....	Unclassifiable/Attainment.
Madison County	.....	Unclassifiable/Attainment.
Manatee County	.....	Unclassifiable/Attainment.
Marion County	.....	Unclassifiable/Attainment.
Martin County	.....	Unclassifiable/Attainment.
Miami-Dade County	.....	Unclassifiable/Attainment.
Monroe County	.....	Unclassifiable/Attainment.
Nassau County	.....	Unclassifiable/Attainment.
Okaloosa County	.....	Unclassifiable/Attainment.
Okeechobee County	.....	Unclassifiable/Attainment.
Orange County	.....	Unclassifiable/Attainment.
Osceola County	.....	Unclassifiable/Attainment.
Palm Beach County	.....	Unclassifiable/Attainment.
Pasco County	.....	Unclassifiable/Attainment.
Pinellas County	.....	Unclassifiable/Attainment.
Polk County	.....	Unclassifiable/Attainment.
Putnam County	.....	Unclassifiable/Attainment.
St. Johns County	.....	Unclassifiable/Attainment.
St. Lucie County	.....	Unclassifiable/Attainment.
Santa Rosa County	.....	Unclassifiable/Attainment.
Sarasota County	.....	Unclassifiable/Attainment.
Seminole County	.....	Unclassifiable/Attainment.
Sumter County	.....	Unclassifiable/Attainment.
Suwannee County	.....	Unclassifiable/Attainment.
Taylor County	.....	Unclassifiable/Attainment.
Union County	.....	Unclassifiable/Attainment.
Volusia County	.....	Unclassifiable/Attainment.
Wakulla County	.....	Unclassifiable/Attainment.
Walton County	.....	Unclassifiable/Attainment.
Washington County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 12. In § 81.311, the table entitled "Georgia.—PM2.5" is added to the end of the section to read as follows:

§ 81.311 Georgia.

* * * * *

GEORGIA.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
Athens, GA:		
Clarke County	.....	Nonattainment.
Atlanta, GA:		
Barrow County	.....	Nonattainment.
Bartow County	.....	Nonattainment.
Carroll County	.....	Nonattainment.
Cherokee County	.....	Nonattainment.
Clayton County	.....	Nonattainment.
Cobb County	.....	Nonattainment.
Coweta County	.....	Nonattainment.
DeKalb County	.....	Nonattainment.
Douglas County	.....	Nonattainment.
Fayette County	.....	Nonattainment.
Forsyth County	.....	Nonattainment.
Fulton County	.....	Nonattainment.
Gwinnett County	.....	Nonattainment.
Hall County	.....	Nonattainment.
Heard County (part)	.....	Nonattainment.
The northeast portion that extends north of 33 degrees 24 minutes (north) to the Carroll County border and east of 85 degrees 3 minutes (west) to the Coweta County border.		
Henry County	.....	Nonattainment.
Newton County	.....	Nonattainment.
Paulding County	.....	Nonattainment.
Putnam County (part)	.....	Nonattainment.
The area described by U.S. Census 2000 block group identifier 13–237–9603–1.		
Rockdale County	.....	Nonattainment.
Spalding County	.....	Nonattainment.
Walton County	.....	Nonattainment.
Chattanooga, TN–GA:		
Catoosa County	.....	Nonattainment.
Walker County	.....	Nonattainment.
Columbus, GA–AL:		
Muscogee County	.....	Nonattainment.
Rome, GA:		
Floyd County	.....	Nonattainment.
Macon, GA:		
Bibb County	.....	Nonattainment.
Monroe County (part)	.....	Nonattainment.
From the point where Bibb and Monroe Counties meet at U.S. Hwy 23/Georgia Hwy 98 follow the Bibb/Monroe County line westward 150′ from the U.S. Hwy 23/Georgia Hwy 87 centerline, proceed northward 150′ west of and parallel to the U.S. Hwy 23/Georgia Hwy 87 centerline to 33 degrees, 04 minutes, 30 seconds; proceeed westward to 83 degrees, 49 minutes, 45 seconds; proceed due south to 150′ north of the Georgia Hwy 18 centerline, proceed eastward 150′ north of and parallel to the Georgia Hwy 18 centerline to 1150′ west of the U.S. Hwy 23/ Georgia Hwy 87 centerline, proceed southward 1150′ west of and parallel to the U.S. Hwy 23/Georgia Hwy 87 centerline to the Monroe/Bibb County line; then follow the Monroe/Bibb County line to 150′ west of the U.S. Hwy 23/ Georgia Hwy 87 centerline.		
Rest of State:		
Appling County	.....	Unclassifiable/Attainment.
Atkinson County	.....	Unclassifiable/Attainment.
Bacon County	.....	Unclassifiable/Attainment.
Baker County	.....	Unclassifiable/Attainment.
Baldwin County	.....	Unclassifiable/Attainment.
Banks County	.....	Unclassifiable/Attainment.
Ben Hill County	.....	Unclassifiable/Attainment.
Berrien County	.....	Unclassifiable/Attainment.
Bleckley County	.....	Unclassifiable/Attainment.
Brantley County	.....	Unclassifiable/Attainment.
Brooks County	.....	Unclassifiable/Attainment.
Bryan County	.....	Unclassifiable/Attainment.
Bulloch County	.....	Unclassifiable/Attainment.
Burke County	.....	Unclassifiable/Attainment.
Butts County	.....	Unclassifiable/Attainment.
Calhoun County	.....	Unclassifiable/Attainment.
Camden County	.....	Unclassifiable/Attainment.

GEORGIA.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Candler County	.....	Unclassifiable/Attainment.
Charlton County	.....	Unclassifiable/Attainment.
Chatham County	.....	Unclassifiable/Attainment.
Chattahoochee County	.....	Unclassifiable/Attainment.
Chattooga County	.....	Unclassifiable/Attainment.
Clay County	.....	Unclassifiable/Attainment.
Clinch County	.....	Unclassifiable/Attainment.
Coffee County	.....	Unclassifiable/Attainment.
Colquitt County	.....	Unclassifiable/Attainment.
Columbia County	.....	Unclassifiable/Attainment.
Cook County	.....	Unclassifiable/Attainment.
Crawford County	.....	Unclassifiable/Attainment.
Crisp County	.....	Unclassifiable/Attainment.
Dade County	.....	Unclassifiable/Attainment.
Dawson County	.....	Unclassifiable/Attainment.
Decatur County	.....	Unclassifiable/Attainment.
Dodge County	.....	Unclassifiable/Attainment.
Dooly County	.....	Unclassifiable/Attainment.
Dougherty County	.....	Unclassifiable/Attainment.
Early County	.....	Unclassifiable/Attainment.
Echols County	.....	Unclassifiable/Attainment.
Effingham County	.....	Unclassifiable/Attainment.
Elbert County	.....	Unclassifiable/Attainment.
Emanuel County	.....	Unclassifiable/Attainment.
Evans County	.....	Unclassifiable/Attainment.
Fannin County	.....	Unclassifiable/Attainment.
Franklin County	.....	Unclassifiable/Attainment.
Gilmer County	.....	Unclassifiable/Attainment.
Glascock County	.....	Unclassifiable/Attainment.
Glynn County	.....	Unclassifiable/Attainment.
Gordon County	.....	Unclassifiable/Attainment.
Grady County	.....	Unclassifiable/Attainment.
Greene County	.....	Unclassifiable/Attainment.
Habersham County	.....	Unclassifiable/Attainment.
Hancock County	.....	Unclassifiable/Attainment.
Haralson County	.....	Unclassifiable/Attainment.
Harris County	.....	Unclassifiable/Attainment.
Hart County	.....	Unclassifiable/Attainment.
Heard County (remainder)	.....	Unclassifiable/Attainment.
Houston County	.....	Unclassifiable/Attainment.
Irwin County	.....	Unclassifiable/Attainment.
Jackson County	.....	Unclassifiable/Attainment.
Jasper County	.....	Unclassifiable/Attainment.
Jeff Davis County	.....	Unclassifiable/Attainment.
Jefferson County	.....	Unclassifiable/Attainment.
Jenkins County	.....	Unclassifiable/Attainment.
Johnson County	.....	Unclassifiable/Attainment.
Jones County	.....	Unclassifiable/Attainment.
Lamar County	.....	Unclassifiable/Attainment.
Lanier County	.....	Unclassifiable/Attainment.
Laurens County	.....	Unclassifiable/Attainment.
Lee County	.....	Unclassifiable/Attainment.
Liberty County	.....	Unclassifiable/Attainment.
Lincoln County	.....	Unclassifiable/Attainment.
Long County	.....	Unclassifiable/Attainment.
Lowndes County	.....	Unclassifiable/Attainment.
Lumpkin County	.....	Unclassifiable/Attainment.
McDuffie County	.....	Unclassifiable/Attainment.
McIntosh County	.....	Unclassifiable/Attainment.
Macon County	.....	Unclassifiable/Attainment.
Madison County	.....	Unclassifiable/Attainment.
Marion County	.....	Unclassifiable/Attainment.
Meriwether County	.....	Unclassifiable/Attainment.
Miller County	.....	Unclassifiable/Attainment.
Mitchell County	.....	Unclassifiable/Attainment.
Monroe County (remainder)	.....	Unclassifiable/Attainment.
Montgomery County	.....	Unclassifiable/Attainment.
Morgan County	.....	Unclassifiable/Attainment.
Murray County	.....	Unclassifiable/Attainment.
Oconee County	.....	Unclassifiable/Attainment.

GEORGIA.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Oglethorpe County	.....	Unclassifiable/Attainment.
Peach County	.....	Unclassifiable/Attainment.
Pickens County	.....	Unclassifiable/Attainment.
Pierce County	.....	Unclassifiable/Attainment.
Pike County	.....	Unclassifiable/Attainment.
Polk County	.....	Unclassifiable/Attainment.
Pulaski County	.....	Unclassifiable/Attainment.
Putnam County (remainder)	.....	Unclassifiable/Attainment.
Quitman County	.....	Unclassifiable/Attainment.
Rabun County	.....	Unclassifiable/Attainment.
Randolph County	.....	Unclassifiable/Attainment.
Richmond County	.....	Unclassifiable/Attainment.
Schley County	.....	Unclassifiable/Attainment.
Screven County	.....	Unclassifiable/Attainment.
Seminole County	.....	Unclassifiable/Attainment.
Stephens County	.....	Unclassifiable/Attainment.
Stewart County	.....	Unclassifiable/Attainment.
Sumter County	.....	Unclassifiable/Attainment.
Talbot County	.....	Unclassifiable/Attainment.
Taliaferro County	.....	Unclassifiable/Attainment.
Tattnall County	.....	Unclassifiable/Attainment.
Taylor County	.....	Unclassifiable/Attainment.
Telfair County	.....	Unclassifiable/Attainment.
Terrell County	.....	Unclassifiable/Attainment.
Thomas County	.....	Unclassifiable/Attainment.
Tift County	.....	Unclassifiable/Attainment.
Toombs County	.....	Unclassifiable/Attainment.
Towns County	.....	Unclassifiable/Attainment.
Treutlen County	.....	Unclassifiable/Attainment.
Troup County	.....	Unclassifiable/Attainment.
Turner County	.....	Unclassifiable/Attainment.
Twiggs County	.....	Unclassifiable/Attainment.
Union County	.....	Unclassifiable/Attainment.
Upson County	.....	Unclassifiable/Attainment.
Ware County	.....	Unclassifiable/Attainment.
Warren County	.....	Unclassifiable/Attainment.
Washington County	.....	Unclassifiable/Attainment.
Wayne County	.....	Unclassifiable/Attainment.
Webster County	.....	Unclassifiable/Attainment.
Wheeler County	.....	Unclassifiable/Attainment.
White County	.....	Unclassifiable/Attainment.
Whitfield County	.....	Unclassifiable/Attainment.
Wilcox County	.....	Unclassifiable/Attainment.
Wilkes County	.....	Unclassifiable/Attainment.
Wilkinson County	.....	Unclassifiable/Attainment.
Worth County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 13. In § 81.312, the table entitled "Hawaii.—PM2.5" is added to the end of the section to read as follows:

§ 81.312 Hawaii.

* * * * *

HAWAII.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
Statewide:		
Hawaii County	.....	Unclassifiable/Attainment.
Honolulu County	.....	Unclassifiable/Attainment.
Kalawao County	.....	Unclassifiable/Attainment.
Kauai County	.....	Unclassifiable/Attainment.
Maui County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 14. In § 81.313, the table entitled "Idaho.—PM2.5" is added to the end of the section to read as follows:

§ 81.313 Idaho.

* * * * *

IDAHO.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
AQCR 61 Eastern Idaho Intrastate:		
Bannock County	.....	Unclassifiable/Attainment.
Bear Lake County	.....	Unclassifiable/Attainment.
Bingham County	.....	Unclassifiable/Attainment.
Bonneville County	.....	Unclassifiable/Attainment.
Butte County	.....	Unclassifiable/Attainment.
Caribou County	.....	Unclassifiable/Attainment.
Clark County	.....	Unclassifiable/Attainment.
Franklin County	.....	Unclassifiable/Attainment.
Fremont County	.....	Unclassifiable/Attainment.
Jefferson County	.....	Unclassifiable/Attainment.
Madison County	.....	Unclassifiable/Attainment.
Oneida County	.....	Unclassifiable/Attainment.
Power County	.....	Unclassifiable/Attainment.
Teton County	.....	Unclassifiable/Attainment.
AQCR 62 E Washington-N Idaho Interstate:		
Benewah County	.....	Unclassifiable/Attainment.
Kootenai County	.....	Unclassifiable/Attainment.
Latah County	.....	Unclassifiable/Attainment.
Nez Perce County	.....	Unclassifiable/Attainment.
Shoshone County	.....	Unclassifiable/Attainment.
AQCR 63 Idaho Intrastate:		
Adams County	.....	Unclassifiable/Attainment.
Blaine County	.....	Unclassifiable/Attainment.
Boise County	.....	Unclassifiable/Attainment.
Bonner County	.....	Unclassifiable/Attainment.
Boundary County	.....	Unclassifiable/Attainment.
Camas County	.....	Unclassifiable/Attainment.
Cassia County	.....	Unclassifiable/Attainment.
Clearwater County	.....	Unclassifiable/Attainment.
Custer County	.....	Unclassifiable/Attainment.
Elmore County	.....	Unclassifiable/Attainment.
Gem County	.....	Unclassifiable/Attainment.
Gooding County	.....	Unclassifiable/Attainment.
Idaho County	.....	Unclassifiable/Attainment.
Jerome County	.....	Unclassifiable/Attainment.
Lemhi County	.....	Unclassifiable/Attainment.
Lewis County	.....	Unclassifiable/Attainment.
Lincoln County	.....	Unclassifiable/Attainment.
Minidoka County	.....	Unclassifiable/Attainment.
Owyhee County	.....	Unclassifiable/Attainment.
Payette County	.....	Unclassifiable/Attainment.
Twin Falls County	.....	Unclassifiable/Attainment.
Valley County	.....	Unclassifiable/Attainment.
Washington County	.....	Unclassifiable/Attainment.
AQCR 64 Metropolitan Boise Interstate:		
Ada County	.....	Unclassifiable/Attainment.
Canyon County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 15. In § 81.314, the table entitled "Illinois.—PM2.5" is added to the end of the section to read as follows:

§ 81.314 Illinois.

* * * * *

ILLINOIS.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
Chicago-Gary-Lake County, IL-IN:		
Cook County	.....	Nonattainment.
DuPage County	.....	Nonattainment.

ILLINOIS.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Grundy County (part)	.....	Nonattainment.
Goose Lake and Aux Sable Townships		
Kane County	.....	Nonattainment.
Kendall County (part)	.....	Nonattainment.
Oswego Township		
Lake County	.....	Nonattainment.
McHenry County	.....	Nonattainment.
Will County	.....	Nonattainment.
St. Louis, MO-IL:		
Madison County	.....	Nonattainment.
Monroe County	.....	Nonattainment.
Randolph County (part)	.....	Nonattainment.
Baldwin Village		
St. Clair County	.....	Nonattainment.
Rest of State:		
Adams County	.....	Unclassifiable/Attainment.
Alexander County	.....	Unclassifiable/Attainment.
Bond County	.....	Unclassifiable/Attainment.
Boone County	.....	Unclassifiable/Attainment.
Brown County	.....	Unclassifiable/Attainment.
Bureau County	.....	Unclassifiable/Attainment.
Calhoun County	.....	Unclassifiable/Attainment.
Carroll County	.....	Unclassifiable/Attainment.
Cass County	.....	Unclassifiable/Attainment.
Champaign County	.....	Unclassifiable/Attainment.
Christian County	.....	Unclassifiable/Attainment.
Clark County	.....	Unclassifiable/Attainment.
Clay County	.....	Unclassifiable/Attainment.
Clinton County	.....	Unclassifiable/Attainment.
Coles County	.....	Unclassifiable/Attainment.
Crawford County	.....	Unclassifiable/Attainment.
Cumberland County	.....	Unclassifiable/Attainment.
DeKalb County	.....	Unclassifiable/Attainment.
De Witt County	.....	Unclassifiable/Attainment.
Douglas County	.....	Unclassifiable/Attainment.
Edgar County	.....	Unclassifiable/Attainment.
Edwards County	.....	Unclassifiable/Attainment.
Effingham County	.....	Unclassifiable/Attainment.
Fayette County	.....	Unclassifiable/Attainment.
Ford County	.....	Unclassifiable/Attainment.
Franklin County	.....	Unclassifiable/Attainment.
Fulton County	.....	Unclassifiable/Attainment.
Gallatin County	.....	Unclassifiable/Attainment.
Greene County	.....	Unclassifiable/Attainment.
Grundy County (remainder)	.....	Unclassifiable/Attainment.
Hamilton County	.....	Unclassifiable/Attainment.
Hancock County	.....	Unclassifiable/Attainment.
Hardin County	.....	Unclassifiable/Attainment.
Henderson County	.....	Unclassifiable/Attainment.
Henry County	.....	Unclassifiable/Attainment.
Iroquois County	.....	Unclassifiable/Attainment.
Jackson County	.....	Unclassifiable/Attainment.
Jasper County	.....	Unclassifiable/Attainment.
Jefferson County	.....	Unclassifiable/Attainment.
Jersey County	.....	Unclassifiable/Attainment.
Jo Daviess County	.....	Unclassifiable/Attainment.
Johnson County	.....	Unclassifiable/Attainment.
Kankakee County	.....	Unclassifiable/Attainment.
Kendall County (remainder)	.....	Unclassifiable/Attainment.
Knox County	.....	Unclassifiable/Attainment.
La Salle County	.....	Unclassifiable/Attainment.
Lawrence County	.....	Unclassifiable/Attainment.
Lee County	.....	Unclassifiable/Attainment.
Livingston County	.....	Unclassifiable/Attainment.
Logan County	.....	Unclassifiable/Attainment.
McDonough County	.....	Unclassifiable/Attainment.
McLean County	.....	Unclassifiable/Attainment.
Macon County	.....	Unclassifiable/Attainment.
Macoupin County	.....	Unclassifiable/Attainment.
Marion County	.....	Unclassifiable/Attainment.

ILLINOIS.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Marshall County	.....	Unclassifiable/Attainment.
Mason County	.....	Unclassifiable/Attainment.
Massac County	.....	Unclassifiable/Attainment.
Menard County	.....	Unclassifiable/Attainment.
Mercer County	.....	Unclassifiable/Attainment.
Montgomery County	.....	Unclassifiable/Attainment.
Morgan County	.....	Unclassifiable/Attainment.
Moultrie County	.....	Unclassifiable/Attainment.
Ogle County	.....	Unclassifiable/Attainment.
Peoria County	.....	Unclassifiable/Attainment.
Perry County	.....	Unclassifiable/Attainment.
Piatt County	.....	Unclassifiable/Attainment.
Pike County	.....	Unclassifiable/Attainment.
Pope County	.....	Unclassifiable/Attainment.
Pulaski County	.....	Unclassifiable/Attainment.
Putnam County	.....	Unclassifiable/Attainment.
Randolph County (remainder)	.....	Unclassifiable/Attainment.
Richland County	.....	Unclassifiable/Attainment.
Rock Island County	.....	Unclassifiable/Attainment.
Saline County	.....	Unclassifiable/Attainment.
Sangamon County	.....	Unclassifiable/Attainment.
Schuyler County	.....	Unclassifiable/Attainment.
Scott County	.....	Unclassifiable/Attainment.
Shelby County	.....	Unclassifiable/Attainment.
Stark County	.....	Unclassifiable/Attainment.
Stephenson County	.....	Unclassifiable/Attainment.
Tazewell County	.....	Unclassifiable/Attainment.
Union County	.....	Unclassifiable/Attainment.
Vermilion County	.....	Unclassifiable/Attainment.
Wabash County	.....	Unclassifiable/Attainment.
Warren County	.....	Unclassifiable/Attainment.
Washington County	.....	Unclassifiable/Attainment.
Wayne County	.....	Unclassifiable/Attainment.
White County	.....	Unclassifiable/Attainment.
Whiteside County	.....	Unclassifiable/Attainment.
Williamson County	.....	Unclassifiable/Attainment.
Winnebago County	.....	Unclassifiable/Attainment.
Woodford County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 16. In § 81.315, the table entitled "Indiana.—PM2.5" is added to the end of the section to read as follows:

§ 81.315 Indiana.

* * * * *

INDIANA.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
Chicago-Gary-Lake County, IL-IN:		
Lake County	.....	Nonattainment.
Porter County	.....	Nonattainment.
Cincinnati-Hamilton, OH-KY-IN:		
Dearborn County (part)	.....	Nonattainment.
Lawrenceburg Township		
Elkhart, IN:		
Elkhart County	.....	Nonattainment.
St. Joseph County	.....	Nonattainment.
Evansville, IN:		
Dubois County	.....	Nonattainment.
Gibson County (part)	.....	Nonattainment.
Montgomery Township		
Pike County (part)	.....	Nonattainment.
Washington Township		
Spencer County (part)	.....	Nonattainment.
Ohio Township		

INDIANA.—PM2.5—Continued

Designated area	Designation[a]	
	Date[1]	Type
Vanderburgh County	.....	Nonattainment.
Warrick County	.....	Nonattainment.
Indianapolis, IN:		
Hamilton County	.....	Nonattainment.
Hendricks County	.....	Nonattainment.
Johnson County	.....	Nonattainment.
Marion County	.....	Nonattainment.
Morgan County	.....	Nonattainment.
Louisville, KY-IN:		
Clark County	.....	Nonattainment.
Floyd County	.....	Nonattainment.
Jefferson County (part)	.....	Nonattainment.
Madison Township		
Muncie, IN:		
Delaware County	.....	Unclassifiable.
Rest of State:		
Adams County	.....	Unclassifiable/Attainment.
Allen County	.....	Unclassifiable/Attainment.
Bartholomew County	.....	Unclassifiable/Attainment.
Benton County	.....	Unclassifiable/Attainment.
Blackford County	.....	Unclassifiable/Attainment.
Boone County	.....	Unclassifiable/Attainment.
Brown County	.....	Unclassifiable/Attainment.
Carroll County	.....	Unclassifiable/Attainment.
Cass County	.....	Unclassifiable/Attainment.
Clay County	.....	Unclassifiable/Attainment.
Clinton County	.....	Unclassifiable/Attainment.
Crawford County	.....	Unclassifiable/Attainment.
Daviess County	.....	Unclassifiable/Attainment.
Dearborn County (remainder)	.....	Unclassifiable/Attainment.
Decatur County	.....	Unclassifiable/Attainment.
De Kalb County	.....	Unclassifiable/Attainment.
Fayette County	.....	Unclassifiable/Attainment.
Fountain County	.....	Unclassifiable/Attainment.
Franklin County	.....	Unclassifiable/Attainment.
Fulton County	.....	Unclassifiable/Attainment.
Gibson County (remainder)	.....	Unclassifiable/Attainment.
Grant County	.....	Unclassifiable/Attainment.
Greene County	.....	Unclassifiable/Attainment.
Hancock County	.....	Unclassifiable/Attainment.
Harrison County	.....	Unclassifiable/Attainment.
Henry County	.....	Unclassifiable/Attainment.
Howard County	.....	Unclassifiable/Attainment.
Huntington County	.....	Unclassifiable/Attainment.
Jackson County	.....	Unclassifiable/Attainment.
Jasper County	.....	Unclassifiable/Attainment.
Jay County	.....	Unclassifiable/Attainment.
Jefferson County (remainder)	.....	Unclassifiable/Attainment.
Jennings County	.....	Unclassifiable/Attainment.
Knox County	.....	Unclassifiable/Attainment.
Kosciusko County	.....	Unclassifiable/Attainment.
LaGrange County	.....	Unclassifiable/Attainment.
La Porte County	.....	Unclassifiable/Attainment.
Lawrence County	.....	Unclassifiable/Attainment.
Madison County	.....	Unclassifiable/Attainment.
Marshall County	.....	Unclassifiable/Attainment.
Martin County	.....	Unclassifiable/Attainment.
Miami County	.....	Unclassifiable/Attainment.
Monroe County	.....	Unclassifiable/Attainment.
Montgomery County	.....	Unclassifiable/Attainment.
Newton County	.....	Unclassifiable/Attainment.
Noble County	.....	Unclassifiable/Attainment.
Ohio County	.....	Unclassifiable/Attainment.
Orange County	.....	Unclassifiable/Attainment.
Owen County	.....	Unclassifiable/Attainment.
Parke County	.....	Unclassifiable/Attainment.
Perry County	.....	Unclassifiable/Attainment.
Pike County (remainder)	.....	Unclassifiable/Attainment.
Posey County	.....	Unclassifiable/Attainment.
Pulaski County	.....	Unclassifiable/Attainment.

INDIANA.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Putnam County	.....	Unclassifiable/Attainment.
Randolph County	.....	Unclassifiable/Attainment.
Ripley County	.....	Unclassifiable/Attainment.
Rush County	.....	Unclassifiable/Attainment.
Scott County	.....	Unclassifiable/Attainment.
Shelby County	.....	Unclassifiable/Attainment.
Spencer County (remainder)	.....	Unclassifiable/Attainment.
Starke County	.....	Unclassifiable/Attainment.
Steuben County	.....	Unclassifiable/Attainment.
Sullivan County	.....	Unclassifiable/Attainment.
Switzerland County	.....	Unclassifiable/Attainment.
Tippecanoe County	.....	Unclassifiable/Attainment.
Tipton County	.....	Unclassifiable/Attainment.
Union County	.....	Unclassifiable/Attainment.
Vermillion County	.....	Unclassifiable/Attainment.
Vigo County	.....	Unclassifiable/Attainment.
Wabash County	.....	Unclassifiable/Attainment.
Warren County	.....	Unclassifiable/Attainment.
Washington County	.....	Unclassifiable/Attainment.
Wayne County	.....	Unclassifiable/Attainment.
Wells County	.....	Unclassifiable/Attainment.
White County	.....	Unclassifiable/Attainment.
Whitley County	.....	Unclassifiable/Attainment.

[1] Includes Indian Country located in each county or area, except as otherwise specified.
[a] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 17. In § 81.316, the table entitled "Iowa.—PM2.5" is added to the end of the section to read as follows:

§ 81.316 Iowa.

* * * * *

IOWA.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
Statewide:		
Adair County	.....	Unclassifiable/Attainment.
Adams County	.....	Unclassifiable/Attainment.
Allamakee County	.....	Unclassifiable/Attainment.
Appanoose County	.....	Unclassifiable/Attainment.
Audubon County	.....	Unclassifiable/Attainment.
Benton County	.....	Unclassifiable/Attainment.
Black Hawk County	.....	Unclassifiable/Attainment.
Boone County	.....	Unclassifiable/Attainment.
Bremer County	.....	Unclassifiable/Attainment.
Buchanan County	.....	Unclassifiable/Attainment.
Buena Vista County	.....	Unclassifiable/Attainment.
Butler County	.....	Unclassifiable/Attainment.
Calhoun County	.....	Unclassifiable/Attainment.
Carroll County	.....	Unclassifiable/Attainment.
Cass County	.....	Unclassifiable/Attainment.
Cedar County	.....	Unclassifiable/Attainment.
Cerro Gordo County	.....	Unclassifiable/Attainment.
Cherokee County	.....	Unclassifiable/Attainment.
Chickasaw County	.....	Unclassifiable/Attainment.
Clarke County	.....	Unclassifiable/Attainment.
Clay County	.....	Unclassifiable/Attainment.
Clayton County	.....	Unclassifiable/Attainment.
Clinton County	.....	Unclassifiable/Attainment.
Crawford County	.....	Unclassifiable/Attainment.
Dallas County	.....	Unclassifiable/Attainment.
Davis County	.....	Unclassifiable/Attainment.
Decatur County	.....	Unclassifiable/Attainment.
Delaware County	.....	Unclassifiable/Attainment.
Des Moines County	.....	Unclassifiable/Attainment.
Dickinson County	.....	Unclassifiable/Attainment.
Dubuque County	.....	Unclassifiable/Attainment.

IOWA.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Emmet County	.....	Unclassifiable/Attainment.
Fayette County	.....	Unclassifiable/Attainment.
Floyd County	.....	Unclassifiable/Attainment.
Franklin County	.....	Unclassifiable/Attainment.
Fremont County	.....	Unclassifiable/Attainment.
Greene County	.....	Unclassifiable/Attainment.
Grundy County	.....	Unclassifiable/Attainment.
Guthrie County	.....	Unclassifiable/Attainment.
Hamilton County	.....	Unclassifiable/Attainment.
Hancock County	.....	Unclassifiable/Attainment.
Hardin County	.....	Unclassifiable/Attainment.
Harrison County	.....	Unclassifiable/Attainment.
Henry County	.....	Unclassifiable/Attainment.
Howard County	.....	Unclassifiable/Attainment.
Humboldt County	.....	Unclassifiable/Attainment.
Ida County	.....	Unclassifiable/Attainment.
Iowa County	.....	Unclassifiable/Attainment.
Jackson County	.....	Unclassifiable/Attainment.
Jasper County	.....	Unclassifiable/Attainment.
Jefferson County	.....	Unclassifiable/Attainment.
Johnson County	.....	Unclassifiable/Attainment.
Jones County	.....	Unclassifiable/Attainment.
Keokuk County	.....	Unclassifiable/Attainment.
Kossuth County	.....	Unclassifiable/Attainment.
Lee County	.....	Unclassifiable/Attainment.
Linn County	.....	Unclassifiable/Attainment.
Louisa County	.....	Unclassifiable/Attainment.
Lucas County	.....	Unclassifiable/Attainment.
Lyon County	.....	Unclassifiable/Attainment.
Madison County	.....	Unclassifiable/Attainment.
Mahaska County	.....	Unclassifiable/Attainment.
Marion County	.....	Unclassifiable/Attainment.
Marshall County	.....	Unclassifiable/Attainment.
Mills County	.....	Unclassifiable/Attainment.
Mitchell County	.....	Unclassifiable/Attainment.
Monona County	.....	Unclassifiable/Attainment.
Monroe County	.....	Unclassifiable/Attainment.
Montgomery County	.....	Unclassifiable/Attainment.
Muscatine County	.....	Unclassifiable/Attainment.
O'Brien County	.....	Unclassifiable/Attainment.
Osceola County	.....	Unclassifiable/Attainment.
Page County	.....	Unclassifiable/Attainment.
Palo Alto County	.....	Unclassifiable/Attainment.
Plymouth County	.....	Unclassifiable/Attainment.
Pocahontas County	.....	Unclassifiable/Attainment.
Polk County	.....	Unclassifiable/Attainment.
Pottawattamie County	.....	Unclassifiable/Attainment.
Poweshiek County	.....	Unclassifiable/Attainment.
Ringgold County	.....	Unclassifiable/Attainment.
Sac County	.....	Unclassifiable/Attainment.
Scott County	.....	Unclassifiable/Attainment.
Shelby County	.....	Unclassifiable/Attainment.
Sioux County	.....	Unclassifiable/Attainment.
Story County	.....	Unclassifiable/Attainment.
Tama County	.....	Unclassifiable/Attainment.
Taylor County	.....	Unclassifiable/Attainment.
Union County	.....	Unclassifiable/Attainment.
Van Buren County	.....	Unclassifiable/Attainment.
Wapello County	.....	Unclassifiable/Attainment.
Warren County	.....	Unclassifiable/Attainment.
Washington County	.....	Unclassifiable/Attainment.
Wayne County	.....	Unclassifiable/Attainment.
Webster County	.....	Unclassifiable/Attainment.
Winnebago County	.....	Unclassifiable/Attainment.
Winneshiek County	.....	Unclassifiable/Attainment.
Woodbury County	.....	Unclassifiable/Attainment.
Worth County	.....	Unclassifiable/Attainment.
Wright County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 18. In § 81.317, the table entitled "Kansas—PM2.5" is added to the end of the section to read as follows:

§ 81.317 Kansas.

* * * * *

KANSAS.—PM2.5

Designated area	Designation[a]	
	Date[1]	Type
Statewide:		
Allen County	.....	Unclassifiable/Attainment.
Anderson County	.....	Unclassifiable/Attainment.
Atchison County	.....	Unclassifiable/Attainment.
Barber County	.....	Unclassifiable/Attainment.
Barton County	.....	Unclassifiable/Attainment.
Bourbon County	.....	Unclassifiable/Attainment.
Brown County	.....	Unclassifiable/Attainment.
Butler County	.....	Unclassifiable/Attainment.
Chase County	.....	Unclassifiable/Attainment.
Chautauqua County	.....	Unclassifiable/Attainment.
Cherokee County	.....	Unclassifiable/Attainment.
Cheyenne County	.....	Unclassifiable/Attainment.
Clark County	.....	Unclassifiable/Attainment.
Clay County	.....	Unclassifiable/Attainment.
Cloud County	.....	Unclassifiable/Attainment.
Coffey County	.....	Unclassifiable/Attainment.
Comanche County	.....	Unclassifiable/Attainment.
Cowley County	.....	Unclassifiable/Attainment.
Crawford County	.....	Unclassifiable/Attainment.
Decatur County	.....	Unclassifiable/Attainment.
Dickinson County	.....	Unclassifiable/Attainment.
Doniphan County	.....	Unclassifiable/Attainment.
Douglas County	.....	Unclassifiable/Attainment.
Edwards County	.....	Unclassifiable/Attainment.
Elk County	.....	Unclassifiable/Attainment.
Ellis County	.....	Unclassifiable/Attainment.
Ellsworth County	.....	Unclassifiable/Attainment.
Finney County	.....	Unclassifiable/Attainment.
Ford County	.....	Unclassifiable/Attainment.
Franklin County	.....	Unclassifiable/Attainment.
Geary County	.....	Unclassifiable/Attainment.
Gove County	.....	Unclassifiable/Attainment.
Graham County	.....	Unclassifiable/Attainment.
Grant County	.....	Unclassifiable/Attainment.
Gray County	.....	Unclassifiable/Attainment.
Greeley County	.....	Unclassifiable/Attainment.
Greenwood County	.....	Unclassifiable/Attainment.
Hamilton County	.....	Unclassifiable/Attainment.
Harper County	.....	Unclassifiable/Attainment.
Harvey County	.....	Unclassifiable/Attainment.
Haskell County	.....	Unclassifiable/Attainment.
Hodgeman County	.....	Unclassifiable/Attainment.
Jackson County	.....	Unclassifiable/Attainment.
Jefferson County	.....	Unclassifiable/Attainment.
Jewell County	.....	Unclassifiable/Attainment.
Johnson County	.....	Unclassifiable/Attainment.
Kearny County	.....	Unclassifiable/Attainment.
Kingman County	.....	Unclassifiable/Attainment.
Kiowa County	.....	Unclassifiable/Attainment.
Labette County	.....	Unclassifiable/Attainment.
Lane County	.....	Unclassifiable/Attainment.
Leavenworth County	.....	Unclassifiable/Attainment.
Lincoln County	.....	Unclassifiable/Attainment.
Linn County	.....	Unclassifiable/Attainment.
Logan County	.....	Unclassifiable/Attainment.
Lyon County	.....	Unclassifiable/Attainment.
McPherson County	.....	Unclassifiable/Attainment.
Marion County	.....	Unclassifiable/Attainment.
Marshall County	.....	Unclassifiable/Attainment.
Meade County	.....	Unclassifiable/Attainment.
Miami County	.....	Unclassifiable/Attainment.
Mitchell County	.....	Unclassifiable/Attainment.
Montgomery County	.....	Unclassifiable/Attainment.
Morris County	.....	Unclassifiable/Attainment.
Morton County	.....	Unclassifiable/Attainment.

KANSAS.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Nemaha County	.....	Unclassifiable/Attainment.
Neosho County	.....	Unclassifiable/Attainment.
Ness County	.....	Unclassifiable/Attainment.
Norton County	.....	Unclassifiable/Attainment.
Osage County	.....	Unclassifiable/Attainment.
Osborne County	.....	Unclassifiable/Attainment.
Ottawa County	.....	Unclassifiable/Attainment.
Pawnee County	.....	Unclassifiable/Attainment.
Phillips County	.....	Unclassifiable/Attainment.
Pottawatomie County	.....	Unclassifiable/Attainment.
Pratt County	.....	Unclassifiable/Attainment.
Rawlins County	.....	Unclassifiable/Attainment.
Reno County	.....	Unclassifiable/Attainment.
Republic County	.....	Unclassifiable/Attainment.
Rice County	.....	Unclassifiable/Attainment.
Riley County	.....	Unclassifiable/Attainment.
Rooks County	.....	Unclassifiable/Attainment.
Rush County	.....	Unclassifiable/Attainment.
Russell County	.....	Unclassifiable/Attainment.
Saline County	.....	Unclassifiable/Attainment.
Scott County	.....	Unclassifiable/Attainment.
Sedgwick County	.....	Unclassifiable/Attainment.
Seward County	.....	Unclassifiable/Attainment.
Shawnee County	.....	Unclassifiable/Attainment.
Sheridan County	.....	Unclassifiable/Attainment.
Sherman County	.....	Unclassifiable/Attainment.
Smith County	.....	Unclassifiable/Attainment.
Stafford County	.....	Unclassifiable/Attainment.
Stanton County	.....	Unclassifiable/Attainment.
Stevens County	.....	Unclassifiable/Attainment.
Sumner County	.....	Unclassifiable/Attainment.
Thomas County	.....	Unclassifiable/Attainment.
Trego County	.....	Unclassifiable/Attainment.
Wabaunsee County	.....	Unclassifiable/Attainment.
Wallace County	.....	Unclassifiable/Attainment.
Washington County	.....	Unclassifiable/Attainment.
Wichita County	.....	Unclassifiable/Attainment.
Wilson County	.....	Unclassifiable/Attainment.
Woodson County	.....	Unclassifiable/Attainment.
Wyandotte County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 19. In § 81.318, the table entitled "Kentucky.—PM2.5" is added to the end of the section to read as follows:

§ 81.318 Kentucky.

* * * * *

KENTUCKY.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
Cincinnati-Hamilton, OH-KY-IN:		
Boone County	.....	Nonattainment.
Campbell County	.....	Nonattainment.
Kenton County	.....	Nonattainment.
Huntington-Ashland, WV-KY-OH:		
Boyd County	.....	Nonattainment.
Lawrence County (part)	.....	Nonattainment.
The area described by U.S. Census 2000 block group identifier 21–127–9901–6.		
Lexington, KY:		
Fayette County	.....	Nonattainment.
Mercer County (part)	.....	Nonattainment.
The area described by U.S. Census 2000 block group identifier 21–167–9605–1.		
Louisville, KY-IN:		
Bullitt County	.....	Nonattainment.
Jefferson County	.....	Nonattainment.

KENTUCKY.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Rest of State:		
Adair County	.....	Unclassifiable/Attainment.
Allen County	.....	Unclassifiable/Attainment.
Anderson County	.....	Unclassifiable/Attainment.
Ballard County	.....	Unclassifiable/Attainment.
Barren County	.....	Unclassifiable/Attainment.
Bath County	.....	Unclassifiable/Attainment.
Bell County	.....	Unclassifiable/Attainment.
Bourbon County	.....	Unclassifiable/Attainment.
Boyle County	.....	Unclassifiable/Attainment.
Bracken County	.....	Unclassifiable/Attainment.
Breathitt County	.....	Unclassifiable/Attainment.
Breckinridge County	.....	Unclassifiable/Attainment.
Butler County	.....	Unclassifiable/Attainment.
Caldwell County	.....	Unclassifiable/Attainment.
Calloway County	.....	Unclassifiable/Attainment.
Carlisle County	.....	Unclassifiable/Attainment.
Carroll County	.....	Unclassifiable/Attainment.
Carter County	.....	Unclassifiable/Attainment.
Casey County	.....	Unclassifiable/Attainment.
Christian County	.....	Unclassifiable/Attainment.
Clark County	.....	Unclassifiable/Attainment.
Clay County	.....	Unclassifiable/Attainment.
Clinton County	.....	Unclassifiable/Attainment.
Crittenden County	.....	Unclassifiable/Attainment.
Cumberland County	.....	Unclassifiable/Attainment.
Daviess County	.....	Unclassifiable/Attainment.
Edmonson County	.....	Unclassifiable/Attainment.
Elliott County	.....	Unclassifiable/Attainment.
Estill County	.....	Unclassifiable/Attainment.
Fleming County	.....	Unclassifiable/Attainment.
Floyd County	.....	Unclassifiable/Attainment.
Franklin County	.....	Unclassifiable/Attainment.
Fulton County	.....	Unclassifiable/Attainment.
Gallatin County	.....	Unclassifiable/Attainment.
Garrard County	.....	Unclassifiable/Attainment.
Grant County	.....	Unclassifiable/Attainment.
Graves County	.....	Unclassifiable/Attainment.
Grayson County	.....	Unclassifiable/Attainment.
Green County	.....	Unclassifiable/Attainment.
Greenup County	.....	Unclassifiable/Attainment.
Hancock County	.....	Unclassifiable/Attainment.
Hardin County	.....	Unclassifiable/Attainment.
Harlan County	.....	Unclassifiable/Attainment.
Harrison County	.....	Unclassifiable/Attainment.
Hart County	.....	Unclassifiable/Attainment.
Henderson County	.....	Unclassifiable/Attainment.
Henry County	.....	Unclassifiable/Attainment.
Hickman County	.....	Unclassifiable/Attainment.
Hopkins County	.....	Unclassifiable/Attainment.
Jackson County	.....	Unclassifiable/Attainment.
Jessamine County	.....	Unclassifiable/Attainment.
Johnson County	.....	Unclassifiable/Attainment.
Knott County	.....	Unclassifiable/Attainment.
Knox County	.....	Unclassifiable/Attainment.
Larue County	.....	Unclassifiable/Attainment.
Laurel County	.....	Unclassifiable/Attainment.
Lawrence County (remainder)	.....	Unclassifiable/Attainment.
Lee County	.....	Unclassifiable/Attainment.
Leslie County	.....	Unclassifiable/Attainment.
Letcher County	.....	Unclassifiable/Attainment.
Lewis County	.....	Unclassifiable/Attainment.
Lincoln County	.....	Unclassifiable/Attainment.
Livingston County	.....	Unclassifiable/Attainment.
Logan County	.....	Unclassifiable/Attainment.
Lyon County	.....	Unclassifiable/Attainment.
McCracken County	.....	Unclassifiable/Attainment.
McCreary County	.....	Unclassifiable/Attainment.
McLean County	.....	Unclassifiable/Attainment.
Madison County	.....	Unclassifiable/Attainment.

KENTUCKY.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Magoffin County	.....	Unclassifiable/Attainment.
Marion County	.....	Unclassifiable/Attainment.
Marshall County	.....	Unclassifiable/Attainment.
Martin County	.....	Unclassifiable/Attainment.
Mason County	.....	Unclassifiable/Attainment.
Meade County	.....	Unclassifiable/Attainment.
Menifee County	.....	Unclassifiable/Attainment.
Mercer County (remainder)	.....	Unclassifiable/Attainment.
Metcalfe County	.....	Unclassifiable/Attainment.
Monroe County	.....	Unclassifiable/Attainment.
Montgomery County	.....	Unclassifiable/Attainment.
Morgan County	.....	Unclassifiable/Attainment.
Muhlenberg County	.....	Unclassifiable/Attainment.
Nelson County	.....	Unclassifiable/Attainment.
Nicholas County	.....	Unclassifiable/Attainment.
Ohio County	.....	Unclassifiable/Attainment.
Oldham County	.....	Unclassifiable/Attainment.
Owen County	.....	Unclassifiable/Attainment.
Owsley County	.....	Unclassifiable/Attainment.
Pendleton County	.....	Unclassifiable/Attainment.
Perry County	.....	Unclassifiable/Attainment.
Pike County	.....	Unclassifiable/Attainment.
Powell County	.....	Unclassifiable/Attainment.
Pulaski County	.....	Unclassifiable/Attainment.
Robertson County	.....	Unclassifiable/Attainment.
Rockcastle County	.....	Unclassifiable/Attainment.
Rowan County	.....	Unclassifiable/Attainment.
Russell County	.....	Unclassifiable/Attainment.
Scott County	.....	Unclassifiable/Attainment.
Shelby County	.....	Unclassifiable/Attainment.
Simpson County	.....	Unclassifiable/Attainment.
Spencer County	.....	Unclassifiable/Attainment.
Taylor County	.....	Unclassifiable/Attainment.
Todd County	.....	Unclassifiable/Attainment.
Trigg County	.....	Unclassifiable/Attainment.
Trimble County	.....	Unclassifiable/Attainment.
Union County	.....	Unclassifiable/Attainment.
Warren County	.....	Unclassifiable/Attainment.
Washington County	.....	Unclassifiable/Attainment.
Wayne County	.....	Unclassifiable/Attainment.
Webster County	.....	Unclassifiable/Attainment.
Whitley County	.....	Unclassifiable/Attainment.
Wolfe County	.....	Unclassifiable/Attainment.
Woodford County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 20. In § 81.319, the table entitled "Louisiana—PM2.5" is added to the end of the section to read as follows:

§ 81.319 Louisiana.

* * * * *

LOUISIANA.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
AQCR 019 Monroe-El Dorado Interstate:		
Caldwell Parish	.....	Unclassifiable/Attainment.
Catahoula Parish	.....	Unclassifiable/Attainment.
Concordia Parish	.....	Unclassifiable/Attainment.
East Carroll Parish	.....	Unclassifiable/Attainment.
Franklin Parish	.....	Unclassifiable/Attainment.
La Salle Parish	.....	Unclassifiable/Attainment.
Madison Parish	.....	Unclassifiable/Attainment.
Morehouse Parish	.....	Unclassifiable/Attainment.
Ouachita Parish	.....	Unclassifiable/Attainment.
Richland Parish	.....	Unclassifiable/Attainment.

LOUISIANA.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Tensas Parish	.....	Unclassifiable/Attainment.
Union Parish	.....	Unclassifiable/Attainment.
West Carroll Parish	.....	Unclassifiable/Attainment.
AQCR 022 Shreveport-Texarkana-Tyler Interstate:		
Bienville Parish	.....	Unclassifiable/Attainment.
Bossier Parish	.....	Unclassifiable/Attainment.
Caddo Parish	.....	Unclassifiable/Attainment.
Claiborne Parish	.....	Unclassifiable/Attainment.
De Soto Parish	.....	Unclassifiable/Attainment.
Jackson Parish	.....	Unclassifiable/Attainment.
Lincoln Parish	.....	Unclassifiable/Attainment.
Natchitoches Parish	.....	Unclassifiable/Attainment.
Red River Parish	.....	Unclassifiable/Attainment.
Sabine Parish	.....	Unclassifiable/Attainment.
Webster Parish	.....	Unclassifiable/Attainment.
Winn Parish	.....	Unclassifiable/Attainment.
AQCR 106 S. Louisiana-S.E. Texas Interstate:		
Acadia Parish	.....	Unclassifiable/Attainment.
Allen Parish	.....	Unclassifiable/Attainment.
Assumption Parish	.....	Unclassifiable/Attainment.
Avoyelles Parish	.....	Unclassifiable/Attainment.
Cameron Parish	.....	Unclassifiable/Attainment.
East Feliciana Parish	.....	Unclassifiable/Attainment.
Evangeline Parish	.....	Unclassifiable/Attainment.
Iberia Parish	.....	Unclassifiable/Attainment.
Jefferson Davis Parish	.....	Unclassifiable/Attainment.
Plaquemines Parish	.....	Unclassifiable/Attainment.
Rapides Parish	.....	Unclassifiable/Attainment.
St. Helena Parish	.....	Unclassifiable/Attainment.
St. John the Baptist Parish	.....	Unclassifiable/Attainment.
St. Landry Parish	.....	Unclassifiable/Attainment.
St. Martin Parish	.....	Unclassifiable/Attainment.
St. Tammany Parish	.....	Unclassifiable/Attainment.
Tangipahoa Parish	.....	Unclassifiable/Attainment.
Terrebonne Parish	.....	Unclassifiable/Attainment.
Vermilion Parish	.....	Unclassifiable/Attainment.
Vernon Parish	.....	Unclassifiable/Attainment.
Washington Parish	.....	Unclassifiable/Attainment.
West Feliciana Parish	.....	Unclassifiable/Attainment.
Baton Rouge, LA:		
Ascension Parish	.....	Unclassifiable/Attainment.
East Baton Rouge Parish	.....	Unclassifiable/Attainment.
Iberville Parish	.....	Unclassifiable/Attainment.
Livingston Parish	.....	Unclassifiable/Attainment.
West Baton Rouge Parish	.....	Unclassifiable/Attainment.
Beauregard Parish Area, LA:		
Beauregard Parish	.....	Unclassifiable/Attainment.
Grant Parish Area:		
Grant Parish	.....	Unclassifiable/Attainment.
Lafayette Area:		
Lafayette Parish	.....	Unclassifiable/Attainment.
Lafourche Parish Area:		
Lafourche Parish	.....	Unclassifiable/Attainment.
Lake Charles Area:		
Calcasieu Parish	.....	Unclassifiable/Attainment.
New Orleans Area:		
Jefferson Parish	.....	Unclassifiable/Attainment.
Orleans Parish	.....	Unclassifiable/Attainment.
St. Bernard Parish	.....	Unclassifiable/Attainment.
St. Charles Parish	.....	Unclassifiable/Attainment.
Pointe Coupee Area:		
Pointe Coupee Parish	.....	Unclassifiable/Attainment.
St. James Parish Area:		
St. James Parish	.....	Unclassifiable/Attainment.
St. Mary Parish Area:		
St. Mary Parish	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 21. In § 81.320, the table entitled "Maine—PM2.5" is added to the end of the section to read as follows:

§ 81.320 Maine.

* * * * *

MAINE.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
Statewide:		
Androscoggin County	.....	Unclassifiable/Attainment.
Aroostook County	.....	Unclassifiable/Attainment.
Cumberland County	.....	Unclassifiable/Attainment.
Franklin County	.....	Unclassifiable/Attainment.
Hancock County	.....	Unclassifiable/Attainment.
Kennebec County	.....	Unclassifiable/Attainment.
Knox County	.....	Unclassifiable/Attainment.
Lincoln County	.....	Unclassifiable/Attainment.
Oxford County	.....	Unclassifiable/Attainment.
Penobscot County	.....	Unclassifiable/Attainment.
Piscataquis County	.....	Unclassifiable/Attainment.
Sagadahoc County	.....	Unclassifiable/Attainment.
Somerset County	.....	Unclassifiable/Attainment.
Waldo County	.....	Unclassifiable/Attainment.
Washington County	.....	Unclassifiable/Attainment.
York County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 22. In § 81.321, the table entitled "Maryland.—PM2.5" is added to the end of the section to read as follows:

§ 81.321 Maryland.

* * * * *

MARYLAND.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
Baltimore, MD:		
Anne Arundel County	.....	NonAttainment.
Baltimore County	.....	NonAttainment.
Carroll County	.....	NonAttainment.
Harford County	.....	NonAttainment.
Howard County	.....	NonAttainment.
City of Baltimore	.....	NonAttainment.
Martinsburg, WV-Hagerstown, MD:		
Washington County	.....	NonAttainment.
Washington, DC-MD-VA:		
Charles County	.....	NonAttainment.
Frederick County	.....	NonAttainment.
Montgomery County	.....	NonAttainment.
Prince George's County	.....	NonAttainment.
AQCR 113 Cumberland-Keyser Interstate:		
Allegany County	.....	Unclassifiable/Attainment.
Garrett County	.....	Unclassifiable/Attainment.
AQCR 114 Eastern Shore Interstate (remainder of):		
Caroline County	.....	Unclassifiable/Attainment.
Cecil County	.....	Unclassifiable/Attainment.
Dorchester County	.....	Unclassifiable/Attainment.
Kent County	.....	Unclassifiable/Attainment.
Queen Anne's County	.....	Unclassifiable/Attainment.
Somerset County	.....	Unclassifiable/Attainment.
Talbot County	.....	Unclassifiable/Attainment.
Wicomico County	.....	Unclassifiable/Attainment.
Worcester County	.....	Unclassifiable/Attainment.
AQCR 116 Southern Maryland Intrastate (remainder of):		
Calvert County	.....	Unclassifiable/Attainment.
St. Mary's County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 23. In § 81.322, the table entitled "Massachusetts.—PM2.5" is added to the end of the section to read as follows:

§ 81.322 Massachusetts.

* * * * *

MASSACHUSETTS.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
Statewide:		
Barnstable County	.....	Unclassifiable/Attainment.
Berkshire County	.....	Unclassifiable/Attainment.
Bristol County	.....	Unclassifiable/Attainment.
Dukes County	.....	Unclassifiable/Attainment.
Essex County	.....	Unclassifiable/Attainment.
Franklin County	.....	Unclassifiable/Attainment.
Hampden County	.....	Unclassifiable/Attainment.
Hampshire County	.....	Unclassifiable/Attainment.
Middlesex County	.....	Unclassifiable/Attainment.
Nantucket County	.....	Unclassifiable/Attainment.
Norfolk County	.....	Unclassifiable/Attainment.
Plymouth County	.....	Unclassifiable/Attainment.
Suffolk County	.....	Unclassifiable/Attainment.
Worcester County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 24. In § 81.323, the table entitled "Michigan.—PM2.5" is added to the end of the section to read as follows:

§ 81.323 Michigan.

* * * * *

MICHIGAN.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
Detroit-Ann Arbor, MI:		
Livingston County	.....	Nonattainment.
Macomb County	.....	Nonattainment.
Monroe County	.....	Nonattainment.
Oakland County	.....	Nonattainment.
St. Clair County	.....	Nonattainment.
Washtenaw County	.....	Nonattainment.
Wayne County	.....	Nonattainment.
Rest of State:		
Alcona County	.....	Unclassifiable/Attainment.
Alger County	.....	Unclassifiable/Attainment.
Allegan County	.....	Unclassifiable/Attainment.
Alpena County	.....	Unclassifiable/Attainment.
Antrim County	.....	Unclassifiable/Attainment.
Arenac County	.....	Unclassifiable/Attainment.
Baraga County	.....	Unclassifiable/Attainment.
Barry County	.....	Unclassifiable/Attainment.
Bay County	.....	Unclassifiable/Attainment.
Benzie County	.....	Unclassifiable/Attainment.
Berrien County	.....	Unclassifiable/Attainment.
Branch County	.....	Unclassifiable/Attainment.
Calhoun County	.....	Unclassifiable/Attainment.
Cass County	.....	Unclassifiable/Attainment.
Charlevoix County	.....	Unclassifiable/Attainment.
Cheboygan County	.....	Unclassifiable/Attainment.
Chippewa County	.....	Unclassifiable/Attainment.
Clare County	.....	Unclassifiable/Attainment.
Clinton County	.....	Unclassifiable/Attainment.
Crawford County	.....	Unclassifiable/Attainment.
Delta County	.....	Unclassifiable/Attainment.
Dickinson County	.....	Unclassifiable/Attainment.
Eaton County	.....	Unclassifiable/Attainment.
Emmet County	.....	Unclassifiable/Attainment.
Genesee County	.....	Unclassifiable/Attainment.
Gladwin County	.....	Unclassifiable/Attainment.
Gogebic County	.....	Unclassifiable/Attainment.

MICHIGAN.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Grand Traverse County	.....	Unclassifiable/Attainment.
Gratiot County	.....	Unclassifiable/Attainment.
Hillsdale County	.....	Unclassifiable/Attainment.
Houghton County	.....	Unclassifiable/Attainment.
Huron County	.....	Unclassifiable/Attainment.
Ingham County	.....	Unclassifiable/Attainment.
Ionia County	.....	Unclassifiable/Attainment.
Iosco County	.....	Unclassifiable/Attainment.
Iron County	.....	Unclassifiable/Attainment.
Isabella County	.....	Unclassifiable/Attainment.
Jackson County	.....	Unclassifiable/Attainment.
Kalamazoo County	.....	Unclassifiable/Attainment.
Kalkaska County	.....	Unclassifiable/Attainment.
Kent County	.....	Unclassifiable/Attainment.
Keweenaw County	.....	Unclassifiable/Attainment.
Lake County	.....	Unclassifiable/Attainment.
Lapeer County	.....	Unclassifiable/Attainment.
Leelanau County	.....	Unclassifiable/Attainment.
Lenawee County	.....	Unclassifiable/Attainment.
Luce County	.....	Unclassifiable/Attainment.
Mackinac County	.....	Unclassifiable/Attainment.
Manistee County	.....	Unclassifiable/Attainment.
Marquette County	.....	Unclassifiable/Attainment.
Mason County	.....	Unclassifiable/Attainment.
Mecosta County	.....	Unclassifiable/Attainment.
Menominee County	.....	Unclassifiable/Attainment.
Midland County	.....	Unclassifiable/Attainment.
Missaukee County	.....	Unclassifiable/Attainment.
Montcalm County	.....	Unclassifiable/Attainment.
Montmorency County	.....	Unclassifiable/Attainment.
Muskegon County	.....	Unclassifiable/Attainment.
Newaygo County	.....	Unclassifiable/Attainment.
Oceana County	.....	Unclassifiable/Attainment.
Ogemaw County	.....	Unclassifiable/Attainment.
Ontonagon County	.....	Unclassifiable/Attainment.
Osceola County	.....	Unclassifiable/Attainment.
Oscoda County	.....	Unclassifiable/Attainment.
Otsego County	.....	Unclassifiable/Attainment.
Ottawa County	.....	Unclassifiable/Attainment.
Presque Isle County	.....	Unclassifiable/Attainment.
Roscommon County	.....	Unclassifiable/Attainment.
Saginaw County	.....	Unclassifiable/Attainment.
St. Joseph County	.....	Unclassifiable/Attainment.
Sanilac County	.....	Unclassifiable/Attainment.
Schoolcraft County	.....	Unclassifiable/Attainment.
Shiawassee County	.....	Unclassifiable/Attainment.
Tuscola County	.....	Unclassifiable/Attainment.
Van Buren County	.....	Unclassifiable/Attainment.
Wexford County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 25. In § 81324, the table entitled "Minnesota.—PM2.5" is added to the end of the section to read as follows:

§ 81.324 Minnesota.

* * * * *

MINNESOTA.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
Statewide:		
Aitkin County	.....	Unclassifiable/Attainment.
Anoka County	.....	Unclassifiable/Attainment.
Becker County	.....	Unclassifiable/Attainment.
Beltrami County	.....	Unclassifiable/Attainment.
Benton County	.....	Unclassifiable/Attainment.

MINNESOTA.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Big Stone County	.....	Unclassifiable/Attainment.
Blue Earth County	.....	Unclassifiable/Attainment.
Brown County	.....	Unclassifiable/Attainment.
Carlton County	.....	Unclassifiable/Attainment.
Carver County	.....	Unclassifiable/Attainment.
Cass County	.....	Unclassifiable/Attainment.
Chippewa County	.....	Unclassifiable/Attainment.
Chisago County	.....	Unclassifiable/Attainment.
Clay County	.....	Unclassifiable/Attainment.
Clearwater County	.....	Unclassifiable/Attainment.
Cook County	.....	Unclassifiable/Attainment.
Cottonwood County	.....	Unclassifiable/Attainment.
Crow Wing County	.....	Unclassifiable/Attainment.
Dakota County	.....	Unclassifiable/Attainment.
Dodge County	.....	Unclassifiable/Attainment.
Douglas County	.....	Unclassifiable/Attainment.
Faribault County	.....	Unclassifiable/Attainment.
Fillmore County	.....	Unclassifiable/Attainment.
Freeborn County	.....	Unclassifiable/Attainment.
Goodhue County	.....	Unclassifiable/Attainment.
Grant County	.....	Unclassifiable/Attainment.
Hennepin County	.....	Unclassifiable/Attainment.
Houston County	.....	Unclassifiable/Attainment.
Hubbard County	.....	Unclassifiable/Attainment.
Isanti County	.....	Unclassifiable/Attainment.
Itasca County	.....	Unclassifiable/Attainment.
Jackson County	.....	Unclassifiable/Attainment.
Kanabec County	.....	Unclassifiable/Attainment.
Kandiyohi County	.....	Unclassifiable/Attainment.
Kittson County	.....	Unclassifiable/Attainment.
Koochiching County	.....	Unclassifiable/Attainment.
Lac qui Parle County	.....	Unclassifiable/Attainment.
Lake County	.....	Unclassifiable/Attainment.
Lake of the Woods County	.....	Unclassifiable/Attainment.
Le Sueur County	.....	Unclassifiable/Attainment.
Lincoln County	.....	Unclassifiable/Attainment.
Lyon County	.....	Unclassifiable/Attainment.
McLeod County	.....	Unclassifiable/Attainment.
Mahnomen County	.....	Unclassifiable/Attainment.
Marshall County	.....	Unclassifiable/Attainment.
Martin County	.....	Unclassifiable/Attainment.
Meeker County	.....	Unclassifiable/Attainment.
Mille Lacs County	.....	Unclassifiable/Attainment.
Morrison County	.....	Unclassifiable/Attainment.
Mower County	.....	Unclassifiable/Attainment.
Murray County	.....	Unclassifiable/Attainment.
Nicollet County	.....	Unclassifiable/Attainment.
Nobles County	.....	Unclassifiable/Attainment.
Norman County	.....	Unclassifiable/Attainment.
Olmsted County	.....	Unclassifiable/Attainment.
Otter Tail County	.....	Unclassifiable/Attainment.
Pennington County	.....	Unclassifiable/Attainment.
Pine County	.....	Unclassifiable/Attainment.
Pipestone County	.....	Unclassifiable/Attainment.
Polk County	.....	Unclassifiable/Attainment.
Pope County	.....	Unclassifiable/Attainment.
Ramsey County	.....	Unclassifiable/Attainment.
Red Lake County	.....	Unclassifiable/Attainment.
Redwood County	.....	Unclassifiable/Attainment.
Renville County	.....	Unclassifiable/Attainment.
Rice County	.....	Unclassifiable/Attainment.
Rock County	.....	Unclassifiable/Attainment.
Roseau County	.....	Unclassifiable/Attainment.
St. Louis County	.....	Unclassifiable/Attainment.
Scott County	.....	Unclassifiable/Attainment.
Sherburne County	.....	Unclassifiable/Attainment.
Sibley County	.....	Unclassifiable/Attainment.
Stearns County	.....	Unclassifiable/Attainment.
Steele County	.....	Unclassifiable/Attainment.
Stevens County	.....	Unclassifiable/Attainment.

MINNESOTA.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Swift County	.....	Unclassifiable/Attainment.
Todd County	.....	Unclassifiable/Attainment.
Traverse County	.....	Unclassifiable/Attainment.
Wabasha County	.....	Unclassifiable/Attainment.
Wadena County	.....	Unclassifiable/Attainment.
Waseca County	.....	Unclassifiable/Attainment.
Washington County	.....	Unclassifiable/Attainment.
Watonwan County	.....	Unclassifiable/Attainment.
Wilkin County	.....	Unclassifiable/Attainment.
Winona County	.....	Unclassifiable/Attainment.
Wright County	.....	Unclassifiable/Attainment.
Yellow Medicine County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 26. In § 81.325, the table entitled "Mississippi.—PM2.5" is added to the end of the section to read as follows:

§ 81.325 Mississippi.

* * * * *

MISSISSIPPI.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
Statewide:		
Adams County	.....	Unclassifiable/Attainment.
Alcorn County	.....	Unclassifiable/Attainment.
Amite County	.....	Unclassifiable/Attainment.
Attala County	.....	Unclassifiable/Attainment.
Benton County	.....	Unclassifiable/Attainment.
Bolivar County	.....	Unclassifiable/Attainment.
Calhoun County	.....	Unclassifiable/Attainment.
Carroll County	.....	Unclassifiable/Attainment.
Chickasaw County	.....	Unclassifiable/Attainment.
Choctaw County	.....	Unclassifiable/Attainment.
Claiborne County	.....	Unclassifiable/Attainment.
Clarke County	.....	Unclassifiable/Attainment.
Clay County	.....	Unclassifiable/Attainment.
Coahoma County	.....	Unclassifiable/Attainment.
Copiah County	.....	Unclassifiable/Attainment.
Covington County	.....	Unclassifiable/Attainment.
DeSoto County	.....	Unclassifiable/Attainment.
Forrest County	.....	Unclassifiable/Attainment.
Franklin County	.....	Unclassifiable/Attainment.
George County	.....	Unclassifiable/Attainment.
Greene County	.....	Unclassifiable/Attainment.
Grenada County	.....	Unclassifiable/Attainment.
Hancock County	.....	Unclassifiable/Attainment.
Harrison County	.....	Unclassifiable/Attainment.
Hinds County	.....	Unclassifiable/Attainment.
Holmes County	.....	Unclassifiable/Attainment.
Humphreys County	.....	Unclassifiable/Attainment.
Issaquena County	.....	Unclassifiable/Attainment.
Itawamba County	.....	Unclassifiable/Attainment.
Jackson County	.....	Unclassifiable/Attainment.
Jasper County	.....	Unclassifiable/Attainment.
Jefferson County	.....	Unclassifiable/Attainment.
Jefferson Davis County	.....	Unclassifiable/Attainment.
Jones County	.....	Unclassifiable/Attainment.
Kemper County	.....	Unclassifiable/Attainment.
Lafayette County	.....	Unclassifiable/Attainment.
Lamar County	.....	Unclassifiable/Attainment.
Lauderdale County	.....	Unclassifiable/Attainment.
Lawrence County	.....	Unclassifiable/Attainment.
Leake County	.....	Unclassifiable/Attainment.
Lee County	.....	Unclassifiable/Attainment.
Leflore County	.....	Unclassifiable/Attainment.
Lincoln County	.....	Unclassifiable/Attainment.

MISSISSIPPI.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Lowndes County	.....	Unclassifiable/Attainment.
Madison County	.....	Unclassifiable/Attainment.
Marion County	.....	Unclassifiable/Attainment.
Marshall County	.....	Unclassifiable/Attainment.
Monroe County	.....	Unclassifiable/Attainment.
Montgomery County	.....	Unclassifiable/Attainment.
Neshoba County	.....	Unclassifiable/Attainment.
Newton County	.....	Unclassifiable/Attainment.
Noxubee County	.....	Unclassifiable/Attainment.
Oktibbeha County	.....	Unclassifiable/Attainment.
Panola County	.....	Unclassifiable/Attainment.
Pearl River County	.....	Unclassifiable/Attainment.
Perry County	.....	Unclassifiable/Attainment.
Pike County	.....	Unclassifiable/Attainment.
Pontotoc County	.....	Unclassifiable/Attainment.
Prentiss County	.....	Unclassifiable/Attainment.
Quitman County	.....	Unclassifiable/Attainment.
Rankin County	.....	Unclassifiable/Attainment.
Scott County	.....	Unclassifiable/Attainment.
Sharkey County	.....	Unclassifiable/Attainment.
Simpson County	.....	Unclassifiable/Attainment.
Smith County	.....	Unclassifiable/Attainment.
Stone County	.....	Unclassifiable/Attainment.
Sunflower County	.....	Unclassifiable/Attainment.
Tallahatchie County	.....	Unclassifiable/Attainment.
Tate County	.....	Unclassifiable/Attainment.
Tippah County	.....	Unclassifiable/Attainment.
Tishomingo County	.....	Unclassifiable/Attainment.
Tunica County	.....	Unclassifiable/Attainment.
Union County	.....	Unclassifiable/Attainment.
Walthall County	.....	Unclassifiable/Attainment.
Warren County	.....	Unclassifiable/Attainment.
Washington County	.....	Unclassifiable/Attainment.
Wayne County	.....	Unclassifiable/Attainment.
Webster County	.....	Unclassifiable/Attainment.
Wilkinson County	.....	Unclassifiable/Attainment.
Winston County	.....	Unclassifiable/Attainment.
Yalobusha County	.....	Unclassifiable/Attainment.
Yazoo County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 27. In § 81.326, the table entitled "Missouri.—PM2.5" is added to the end of the section to read as follows:

§ 81.326 Missouri.

* * * * *

MISSOURI.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
St. Louis, MO-IL:		
Franklin County	.....	Nonattainment.
Jefferson County	.....	Nonattainment.
St. Charles County	.....	Nonattainment.
St. Louis County	.....	Nonattainment.
St. Louis City	.....	Nonattainment.
Rest of State:		
Adair County	.....	Unclassifiable/Attainment.
Andrew County	.....	Unclassifiable/Attainment.
Atchison County	.....	Unclassifiable/Attainment.
Audrain County	.....	Unclassifiable/Attainment.
Barry County	.....	Unclassifiable/Attainment.
Barton County	.....	Unclassifiable/Attainment.
Bates County	.....	Unclassifiable/Attainment.
Benton County	.....	Unclassifiable/Attainment.
Bollinger County	.....	Unclassifiable/Attainment.

MISSOURI.—PM2.5—Continued

Designated area	Designation[a]	
	Date[1]	Type
Boone County	.....	Unclassifiable/Attainment.
Buchanan County	.....	Unclassifiable/Attainment.
Butler County	.....	Unclassifiable/Attainment.
Caldwell County	.....	Unclassifiable/Attainment.
Callaway County	.....	Unclassifiable/Attainment.
Camden County	.....	Unclassifiable/Attainment.
Cape Girardeau County	.....	Unclassifiable/Attainment.
Carroll County	.....	Unclassifiable/Attainment.
Carter County	.....	Unclassifiable/Attainment.
Cass County	.....	Unclassifiable/Attainment.
Cedar County	.....	Unclassifiable/Attainment.
Chariton County	.....	Unclassifiable/Attainment.
Christian County	.....	Unclassifiable/Attainment.
Clark County	.....	Unclassifiable/Attainment.
Clay County	.....	Unclassifiable/Attainment.
Clinton County	.....	Unclassifiable/Attainment.
Cole County	.....	Unclassifiable/Attainment.
Cooper County	.....	Unclassifiable/Attainment.
Crawford County	.....	Unclassifiable/Attainment.
Dade County	.....	Unclassifiable/Attainment.
Dallas County	.....	Unclassifiable/Attainment.
Daviess County	.....	Unclassifiable/Attainment.
DeKalb County	.....	Unclassifiable/Attainment.
Dent County	.....	Unclassifiable/Attainment.
Douglas County	.....	Unclassifiable/Attainment.
Dunklin County	.....	Unclassifiable/Attainment.
Gasconade County	.....	Unclassifiable/Attainment.
Gentry County	.....	Unclassifiable/Attainment.
Greene County	.....	Unclassifiable/Attainment.
Grundy County	.....	Unclassifiable/Attainment.
Harrison County	.....	Unclassifiable/Attainment.
Henry County	.....	Unclassifiable/Attainment.
Hickory County	.....	Unclassifiable/Attainment.
Holt County	.....	Unclassifiable/Attainment.
Howard County	.....	Unclassifiable/Attainment.
Howell County	.....	Unclassifiable/Attainment.
Iron County	.....	Unclassifiable/Attainment.
Jackson County	.....	Unclassifiable/Attainment.
Jasper County	.....	Unclassifiable/Attainment.
Johnson County	.....	Unclassifiable/Attainment.
Knox County	.....	Unclassifiable/Attainment.
Laclede County	.....	Unclassifiable/Attainment.
Lafayette County	.....	Unclassifiable/Attainment.
Lawrence County	.....	Unclassifiable/Attainment.
Lewis County	.....	Unclassifiable/Attainment.
Lincoln County	.....	Unclassifiable/Attainment.
Linn County	.....	Unclassifiable/Attainment.
Livingston County	.....	Unclassifiable/Attainment.
McDonald County	.....	Unclassifiable/Attainment.
Macon County	.....	Unclassifiable/Attainment.
Madison County	.....	Unclassifiable/Attainment.
Maries County	.....	Unclassifiable/Attainment.
Marion County	.....	Unclassifiable/Attainment.
Mercer County	.....	Unclassifiable/Attainment.
Miller County	.....	Unclassifiable/Attainment.
Mississippi County	.....	Unclassifiable/Attainment.
Moniteau County	.....	Unclassifiable/Attainment.
Monroe County	.....	Unclassifiable/Attainment.
Montgomery County	.....	Unclassifiable/Attainment.
Morgan County	.....	Unclassifiable/Attainment.
New Madrid County	.....	Unclassifiable/Attainment.
Newton County	.....	Unclassifiable/Attainment.
Oregon County	.....	Unclassifiable/Attainment.
Osage County	.....	Unclassifiable/Attainment.
Ozark County	.....	Unclassifiable/Attainment.
Pemiscot County	.....	Unclassifiable/Attainment.
Perry County	.....	Unclassifiable/Attainment.
Pettis County	.....	Unclassifiable/Attainment.
Phelps County	.....	Unclassifiable/Attainment.
Pike County	.....	Unclassifiable/Attainment.

MISSOURI.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Platte County	.....	Unclassifiable/Attainment.
Polk County	.....	Unclassifiable/Attainment.
Pulaski County	.....	Unclassifiable/Attainment.
Putnam County	.....	Unclassifiable/Attainment.
Ralls County	.....	Unclassifiable/Attainment.
Randolph County	.....	Unclassifiable/Attainment.
Ray County	.....	Unclassifiable/Attainment.
Reynolds County	.....	Unclassifiable/Attainment.
Ripley County	.....	Unclassifiable/Attainment.
St. Clair County	.....	Unclassifiable/Attainment.
St. Genevieve County	.....	Unclassifiable/Attainment.
St. Francois County	.....	Unclassifiable/Attainment.
Saline County	.....	Unclassifiable/Attainment.
Schuyler County	.....	Unclassifiable/Attainment.
Scotland County	.....	Unclassifiable/Attainment.
Scott County	.....	Unclassifiable/Attainment.
Shannon County	.....	Unclassifiable/Attainment.
Shelby County	.....	Unclassifiable/Attainment.
Stoddard County	.....	Unclassifiable/Attainment.
Stone County	.....	Unclassifiable/Attainment.
Sullivan County	.....	Unclassifiable/Attainment.
Taney County	.....	Unclassifiable/Attainment.
Texas County	.....	Unclassifiable/Attainment.
Vernon County	.....	Unclassifiable/Attainment.
Warren County	.....	Unclassifiable/Attainment.
Washington County	.....	Unclassifiable/Attainment.
Wayne County	.....	Unclassifiable/Attainment.
Webster County	.....	Unclassifiable/Attainment.
Worth County	.....	Unclassifiable/Attainment.
Wright County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 28. In § 81.327, the table entitled "Montana—PM2.5" is added to the end of the section to read as follows:

§ 81.327 Montana.

* * * * *

MONTANA.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
Libby, MT:		
Lincoln County (part)	.....	Nonattainment.
The area bounded by lines from Universal Transverse Mercador Zone 11 (North American Datum 1983) coordinates beginning at 600,000mE, 5,370,000mN east to 620,000mE, 5370,000mN south to 620,000mE, 5340,000mN west to 600,000mE, 5,340,000mN north to 600,000mE, 5,370,000mN		
Rest of State:		
Beaverhead County	.....	Unclassifiable/Attainment.
Big Horn County	.....	Unclassifiable/Attainment.
Blaine County	.....	Unclassifiable/Attainment.
Broadwater County	.....	Unclassifiable/Attainment.
Carbon County	.....	Unclassifiable/Attainment.
Carter County	.....	Unclassifiable/Attainment.
Cascade County	.....	Unclassifiable/Attainment.
Chouteau County	.....	Unclassifiable/Attainment.
Custer County	.....	Unclassifiable/Attainment.
Daniels County	.....	Unclassifiable/Attainment.
Dawson County	.....	Unclassifiable/Attainment.
Deer Lodge County	.....	Unclassifiable/Attainment.
Fallon County	.....	Unclassifiable/Attainment.
Fergus County	.....	Unclassifiable/Attainment.
Flathead County	.....	Unclassifiable/Attainment.
Gallatin County	.....	Unclassifiable/Attainment.
Garfield County	.....	Unclassifiable/Attainment.
Glacier County	.....	Unclassifiable/Attainment.

MONTANA.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Golden Valley County	.....	Unclassifiable/Attainment.
Granite County	.....	Unclassifiable/Attainment.
Hill County	.....	Unclassifiable/Attainment.
Jefferson County	.....	Unclassifiable/Attainment.
Judith Basin County	.....	Unclassifiable/Attainment.
Lake County	.....	Unclassifiable/Attainment.
Lewis and Clark County	.....	Unclassifiable/Attainment.
Liberty County	.....	Unclassifiable/Attainment.
Lincoln County (remainder)	.....	Unclassifiable/Attainment.
McCone County	.....	Unclassifiable/Attainment.
Madison County	.....	Unclassifiable/Attainment.
Meagher County	.....	Unclassifiable/Attainment.
Mineral County	.....	Unclassifiable/Attainment.
Missoula County	.....	Unclassifiable/Attainment.
Musselshell County	.....	Unclassifiable/Attainment.
Park County	.....	Unclassifiable/Attainment.
Petroleum County	.....	Unclassifiable/Attainment.
Phillips County	.....	Unclassifiable/Attainment.
Pondera County	.....	Unclassifiable/Attainment.
Powder River County	.....	Unclassifiable/Attainment.
Powell County	.....	Unclassifiable/Attainment.
Prairie County	.....	Unclassifiable/Attainment.
Ravalli County	.....	Unclassifiable/Attainment.
Richland County	.....	Unclassifiable/Attainment.
Roosevelt County	.....	Unclassifiable/Attainment.
Rosebud County	.....	Unclassifiable/Attainment.
Sanders County	.....	Unclassifiable/Attainment.
Sheridan County	.....	Unclassifiable/Attainment.
Silver Bow County	.....	Unclassifiable/Attainment.
Stillwater County	.....	Unclassifiable/Attainment.
Sweet Grass County	.....	Unclassifiable/Attainment.
Teton County	.....	Unclassifiable/Attainment.
Toole County	.....	Unclassifiable/Attainment.
Treasure County	.....	Unclassifiable/Attainment.
Valley County	.....	Unclassifiable/Attainment.
Wheatland County	.....	Unclassifiable/Attainment.
Wibaux County	.....	Unclassifiable/Attainment.
Yellowstone County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 29. In § 81.328, the table entitled "Nebraska—PM2.5" is added to the end of the section to read as follows:

§ 81.328 Nebraska.

* * * * *

NEBRASKA.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
Statewide:		
Adams County	.....	Unclassifiable/Attainment.
Antelope County	.....	Unclassifiable/Attainment.
Arthur County	.....	Unclassifiable/Attainment.
Banner County	.....	Unclassifiable/Attainment.
Blaine County	.....	Unclassifiable/Attainment.
Boone County	.....	Unclassifiable/Attainment.
Box Butte County	.....	Unclassifiable/Attainment.
Boyd County	.....	Unclassifiable/Attainment.
Brown County	.....	Unclassifiable/Attainment.
Buffalo County	.....	Unclassifiable/Attainment.
Burt County	.....	Unclassifiable/Attainment.
Butler County	.....	Unclassifiable/Attainment.
Cass County	.....	Unclassifiable/Attainment.
Cedar County	.....	Unclassifiable/Attainment.
Chase County	.....	Unclassifiable/Attainment.
Cherry County	.....	Unclassifiable/Attainment.

NEBRASKA.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Cheyenne County	.....	Unclassifiable/Attainment.
Clay County	.....	Unclassifiable/Attainment.
Colfax County	.....	Unclassifiable/Attainment.
Cuming County	.....	Unclassifiable/Attainment.
Custer County	.....	Unclassifiable/Attainment.
Dakota County	.....	Unclassifiable/Attainment.
Dawes County	.....	Unclassifiable/Attainment.
Dawson County	.....	Unclassifiable/Attainment.
Deuel County	.....	Unclassifiable/Attainment.
Dixon County	.....	Unclassifiable/Attainment.
Dodge County	.....	Unclassifiable/Attainment.
Douglas County	.....	Unclassifiable/Attainment.
Dundy County	.....	Unclassifiable/Attainment.
Fillmore County	.....	Unclassifiable/Attainment.
Franklin County	.....	Unclassifiable/Attainment.
Frontier County	.....	Unclassifiable/Attainment.
Furnas County	.....	Unclassifiable/Attainment.
Gage County	.....	Unclassifiable/Attainment.
Garden County	.....	Unclassifiable/Attainment.
Garfield County	.....	Unclassifiable/Attainment.
Gosper County	.....	Unclassifiable/Attainment.
Grant County	.....	Unclassifiable/Attainment.
Greeley County	.....	Unclassifiable/Attainment.
Hall County	.....	Unclassifiable/Attainment.
Hamilton County	.....	Unclassifiable/Attainment.
Harlan County	.....	Unclassifiable/Attainment.
Hayes County	.....	Unclassifiable/Attainment.
Hitchcock County	.....	Unclassifiable/Attainment.
Holt County	.....	Unclassifiable/Attainment.
Hooker County	.....	Unclassifiable/Attainment.
Howard County	.....	Unclassifiable/Attainment.
Jefferson County	.....	Unclassifiable/Attainment.
Johnson County	.....	Unclassifiable/Attainment.
Kearney County	.....	Unclassifiable/Attainment.
Keith County	.....	Unclassifiable/Attainment.
Keya Paha County	.....	Unclassifiable/Attainment.
Kimball County	.....	Unclassifiable/Attainment.
Knox County	.....	Unclassifiable/Attainment.
Lancaster County	.....	Unclassifiable/Attainment.
Lincoln County	.....	Unclassifiable/Attainment.
Logan County	.....	Unclassifiable/Attainment.
Loup County	.....	Unclassifiable/Attainment.
McPherson County	.....	Unclassifiable/Attainment.
Madison County	.....	Unclassifiable/Attainment.
Merrick County	.....	Unclassifiable/Attainment.
Morrill County	.....	Unclassifiable/Attainment.
Nance County	.....	Unclassifiable/Attainment.
Nemaha County	.....	Unclassifiable/Attainment.
Nuckolls County	.....	Unclassifiable/Attainment.
Otoe County	.....	Unclassifiable/Attainment.
Pawnee County	.....	Unclassifiable/Attainment.
Perkins County	.....	Unclassifiable/Attainment.
Phelps County	.....	Unclassifiable/Attainment.
Pierce County	.....	Unclassifiable/Attainment.
Platte County	.....	Unclassifiable/Attainment.
Polk County	.....	Unclassifiable/Attainment.
Red Willow County	.....	Unclassifiable/Attainment.
Richardson County	.....	Unclassifiable/Attainment.
Rock County	.....	Unclassifiable/Attainment.
Saline County	.....	Unclassifiable/Attainment.
Sarpy County	.....	Unclassifiable/Attainment.
Saunders County	.....	Unclassifiable/Attainment.
Scotts Bluff County	.....	Unclassifiable/Attainment.
Seward County	.....	Unclassifiable/Attainment.
Sheridan County	.....	Unclassifiable/Attainment.
Sherman County	.....	Unclassifiable/Attainment.
Sioux County	.....	Unclassifiable/Attainment.
Stanton County	.....	Unclassifiable/Attainment.
Thayer County	.....	Unclassifiable/Attainment.
Thomas County	.....	Unclassifiable/Attainment.

NEBRASKA.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Thurston County	.....	Unclassifiable/Attainment.
Valley County	.....	Unclassifiable/Attainment.
Washington County	.....	Unclassifiable/Attainment.
Wayne County	.....	Unclassifiable/Attainment.
Webster County	.....	Unclassifiable/Attainment.
Wheeler County	.....	Unclassifiable/Attainment.
York County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 30. In § 81.329, the table entitled "Nevada.—PM2.5" is added to the end of the section to read as follows:

§ 81.329 Nevada.

* * * * *

NEVADA.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
Statewide [2]	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.
[2] Statewide refers to hydrographic areas as shown on the State of Nevada Division of Water Resources' map titled "Water Resources and Inter-basin Flows" (September 1971), as revised to include a division of Carson Desert (area 101) into two areas, a smaller area 101 and area 101A, and a division of Boulder Flat (area 61) into an Upper Unit 61 and a Lower Unit 61. See also 67 FR 12474 (March 19, 2002).

■ 31. In § 81.330, the table entitled "New Hampshire.—PM2.5" is added to the end of the section to read as follows:

§ 81.330 New Hampshire.

* * * * *

NEW HAMPSHIRE.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
Statewide:		
Belknap County	.....	Unclassifiable/Attainment.
Carroll County	.....	Unclassifiable/Attainment.
Cheshire County	.....	Unclassifiable/Attainment.
Coos County	.....	Unclassifiable/Attainment.
Grafton County	.....	Unclassifiable/Attainment.
Hillsborough County	.....	Unclassifiable/Attainment.
Merrimack County	.....	Unclassifiable/Attainment.
Rockingham County	.....	Unclassifiable/Attainment.
Strafford County	.....	Unclassifiable/Attainment.
Sullivan County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 32. In § 81.331, the table entitled "New Jersey.—PM2.5" is added to the end of the section to read as follows:

§ 81.331 New Jersey.

* * * * *

NEW JERSEY.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
New York–N. New Jersey–Long Island, NY-NJ-CT:		
Bergen County	.....	Nonattainment.
Essex County	.....	Nonattainment.
Hudson County	.....	Nonattainment.

NEW JERSEY.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Mercer County	.....	Nonattainment.
Middlesex County	.....	Nonattainment.
Monmouth County	.....	Nonattainment.
Morris County	.....	Nonattainment.
Passaic County	.....	Nonattainment.
Somerset County	.....	Nonattainment.
Union County	.....	Nonattainment.
Philadelphia–Wilmington, PA-NJ-DE:		
Burlington County	.....	Nonattainment.
Camden County	.....	Nonattainment.
Gloucester County	.....	Nonattainment.
New York–N. New Jersey–Long Island, NY-NJ-CT:		
Hunterdon County	.....	Unclassifiable/Attainment.
Sussex County	.....	Unclassifiable/Attainment.
Warren County	.....	Unclassifiable/Attainment.
Atlantic City, NJ:		
Atlantic County	.....	Unclassifiable/Attainment.
Cape May County	.....	Unclassifiable/Attainment.
Cumberland County	.....	Unclassifiable/Attainment.
Ocean County	.....	Unclassifiable/Attainment.
Salem County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 33. In § 81.332, the table entitled "New Mexico.—PM25" is added to the end of the section to read as follows:

§ 81.332 New Mexico.

* * * * *

NEW MEXICO.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
AQCR 012 New Mexico-Southern Border Intrastate:		
Grant County	.....	Unclassifiable/Attainment.
Hidalgo County	.....	Unclassifiable/Attainment.
Luna County	.....	Unclassifiable/Attainment.
AQCR 014 Four Corners Interstate (see 40 CFR 81.121):		
McKinley County (part)	.....	Unclassifiable/Attainment.
Río Arriba County (part)	.....	Unclassifiable/Attainment.
Sandoval County (part)	.....	Unclassifiable/Attainment.
San Juan County	.....	Unclassifiable/Attainment.
Valencia County (part)	.....	Unclassifiable/Attainment.
AQCR 152 Albuquerque-Mid Rio Grande Intrastate:		
Bernalillo County	.....	Unclassifiable/Attainment.
Sandoval County (part) see 40 CFR 81.83	.....	Unclassifiable/Attainment.
Valencia County (part) see 40 CFR 81.83	.....	Unclassifiable/Attainment.
AQCR 153 El Paso-Las Cruces-Alamogordo:		
Doña Ana County (part)	.....	Unclassifiable/Attainment.
(Sunland Park Area) The area bounded by the New Mexico-Texas State line on the east, New Mexico-Mexico international line on the south, the range 3E-Range 2E line on the west, and the N3200 latitude line on the north.		
Doña Ana County (remainder)	.....	Unclassifiable/Attainment.
Lincoln County	.....	Unclassifiable/Attainment.
Otero County	.....	Unclassifiable/Attainment.
Sierra County	.....	Unclassifiable/Attainment.
AQCR 154 Northeastern Plains Intrastate:		
Colfax County	.....	Unclassifiable/Attainment.
Guadalupe County	.....	Unclassifiable/Attainment.
Harding County	.....	Unclassifiable/Attainment.
Mora County	.....	Unclassifiable/Attainment.
San Miguel County	.....	Unclassifiable/Attainment.
Torrance County	.....	Unclassifiable/Attainment.
Union County	.....	Unclassifiable/Attainment.
AQCR 155 Pecos-Permian Basin Intrastate:		
Chaves County	.....	Unclassifiable/Attainment.
Curry County	.....	Unclassifiable/Attainment.

NEW MEXICO.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
De Baca County	.....	Unclassifiable/Attainment.
Eddy County	.....	Unclassifiable/Attainment.
Lea County	.....	Unclassifiable/Attainment.
Quay County	.....	Unclassifiable/Attainment.
Roosevelt County	.....	Unclassifiable/Attainment.
AQCR 156 SW Mountains-Augustine Plains:		
Catron County	.....	Unclassifiable/Attainment.
Cibola County	.....	Unclassifiable/Attainment.
McKinley County (part) see 40 CFR 81.241	.....	Unclassifiable/Attainment.
Socorro County	.....	Unclassifiable/Attainment.
Valencia County (part) see 40 CFR 81.241	.....	Unclassifiable/Attainment.
AQCR 157 Upper Rio Grande Valley Intrastate:		
Los Alamos County	.....	Unclassifiable/Attainment.
Río Arriba County (part) see 40 CFR 81.239	.....	Unclassifiable/Attainment.
Santa Fe County	.....	Unclassifiable/Attainment.
Taos County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 34. In § 81.333, the table entitled "New York.—PM2.5" is added to the end of the section to read as follows:

§ 81.333 New York.

* * * * *

NEW YORK.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
New York–N. New Jersey-Long Island, NY-NJ-CT:		
Bronx County	.....	Nonattainment.
Kings County	.....	Nonattainment.
Nassau County	.....	Nonattainment.
New York County	.....	Nonattainment.
Orange County	.....	Nonattainment.
Queens County	.....	Nonattainment.
Richmond County	.....	Nonattainment.
Rockland County	.....	Nonattainment.
Suffolk County	.....	Nonattainment.
Westchester County	.....	Nonattainment.
AQCR 158 Central New York Intrastate (remainder of):		
Cortland County	.....	Unclassifiable/Attainment.
Herkimer County	.....	Unclassifiable/Attainment.
Lewis County	.....	Unclassifiable/Attainment.
Oneida County	.....	Unclassifiable/Attainment.
AQCR 159 Champlain Valley Interstate (remainder of):		
Clinton County	.....	Unclassifiable/Attainment.
Franklin County	.....	Unclassifiable/Attainment.
Hamilton County	.....	Unclassifiable/Attainment.
St. Lawrence County	.....	Unclassifiable/Attainment.
Warren County	.....	Unclassifiable/Attainment.
Washington County	.....	Unclassifiable/Attainment.
AQCR 160 Finger Lake Intrastate:		
Seneca County	.....	Unclassifiable/Attainment.
Wyoming County	.....	Unclassifiable/Attainment.
Yates County	.....	Unclassifiable/Attainment.
AQCR 161 Hudson Valley Intrastate (remainder of):		
Columbia County	.....	Unclassifiable/Attainment.
Fulton County	.....	Unclassifiable/Attainment.
Ulster County	.....	Unclassifiable/Attainment.
AQCR 163 Southern Tier East Intrastate:		
Broome County	.....	Unclassifiable/Attainment.
Chenango County	.....	Unclassifiable/Attainment.
Delaware County	.....	Unclassifiable/Attainment.
Otsego County	.....	Unclassifiable/Attainment.
Sullivan County	.....	Unclassifiable/Attainment.
Tioga County	.....	Unclassifiable/Attainment.
AQCR 164 Southern Tier West Intrastate:		
Allegany County	.....	Unclassifiable/Attainment.

NEW YORK.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Cattaraugus County	.....	Unclassifiable/Attainment.
Chemung County	.....	Unclassifiable/Attainment.
Schuyler County	.....	Unclassifiable/Attainment.
Steuben County	.....	Unclassifiable/Attainment.
Tompkins County	.....	Unclassifiable/Attainment.
Albany-Schenectady-Troy, NY:		
Albany County	.....	Unclassifiable/Attainment.
Greene County	.....	Unclassifiable/Attainment.
Montgomery County	.....	Unclassifiable/Attainment.
Rensselaer County	.....	Unclassifiable/Attainment.
Saratoga County	.....	Unclassifiable/Attainment.
Schenectady County	.....	Unclassifiable/Attainment.
Schoharie County	.....	Unclassifiable/Attainment.
Buffalo-Niagara Falls, NY:		
Erie County	.....	Unclassifiable/Attainment.
Niagara County	.....	Unclassifiable/Attainment.
Essex County, NY:		
Essex County	.....	Unclassifiable/Attainment.
Jamestown, NY:		
Chautauqua County	.....	Unclassifiable/Attainment.
Jefferson County, NY:		
Jefferson County	.....	Unclassifiable/Attainment.
Poughkeepsie, NY:		
Dutchess County	.....	Unclassifiable/Attainment.
Putnam County	.....	Unclassifiable/Attainment.
Rochester, NY:		
Genesee County	.....	Unclassifiable/Attainment.
Livingston County	.....	Unclassifiable/Attainment.
Monroe County	.....	Unclassifiable/Attainment.
Ontario County	.....	Unclassifiable/Attainment.
Orleans County	.....	Unclassifiable/Attainment.
Wayne County	.....	Unclassifiable/Attainment.
Syracuse, NY:		
Cayuga County	.....	Unclassifiable/Attainment.
Madison County	.....	Unclassifiable/Attainment.
Onondaga County	.....	Unclassifiable/Attainment.
Oswego County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 35. In § 81334, the table entitled "North Carolina.—PM25" is added to the end of the section to read as follows:

§ 81.334 North Carolina.

* * * * *

NORTH CAROLINA.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
Greensboro-Winston Salem-High Point, NC:		
Davidson County	.....	Nonattainment.
Guilford County	.....	Nonattainment.
Hickory-Morganton-Lenoir, NC:		
Catawba County	.....	Nonattainment.
Rest of State:		
Alamance County	.....	Unclassifiable/Attainment.
Alexander County	.....	Unclassifiable/Attainment.
Alleghany County	.....	Unclassifiable/Attainment.
Anson County	.....	Unclassifiable/Attainment.
Ashe County	.....	Unclassifiable/Attainment.
Avery County	.....	Unclassifiable/Attainment.
Beaufort County	.....	Unclassifiable/Attainment.
Bertie County	.....	Unclassifiable/Attainment.
Bladen County	.....	Unclassifiable/Attainment.
Brunswick County	.....	Unclassifiable/Attainment.
Buncombe County	.....	Unclassifiable/Attainment.
Burke County	.....	Unclassifiable/Attainment.

NORTH CAROLINA.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Cabarrus County	.....	Unclassifiable/Attainment.
Caldwell County	.....	Unclassifiable/Attainment.
Camden County	.....	Unclassifiable/Attainment.
Carteret County	.....	Unclassifiable/Attainment.
Caswell County	.....	Unclassifiable/Attainment.
Chatham County	.....	Unclassifiable/Attainment.
Cherokee County	.....	Unclassifiable/Attainment.
Chowan County	.....	Unclassifiable/Attainment.
Clay County	.....	Unclassifiable/Attainment.
Cleveland County	.....	Unclassifiable/Attainment.
Columbus County	.....	Unclassifiable/Attainment.
Craven County	.....	Unclassifiable/Attainment.
Cumberland County	.....	Unclassifiable/Attainment.
Currituck County	.....	Unclassifiable/Attainment.
Dare County	.....	Unclassifiable/Attainment.
Davie County	.....	Unclassifiable/Attainment.
Duplin County	.....	Unclassifiable/Attainment.
Durham County	.....	Unclassifiable/Attainment.
Edgecombe County	.....	Unclassifiable/Attainment.
Forsyth County	.....	Unclassifiable/Attainment.
Franklin County	.....	Unclassifiable/Attainment.
Gaston County	.....	Unclassifiable/Attainment.
Gates County	.....	Unclassifiable/Attainment.
Graham County	.....	Unclassifiable/Attainment.
Granville County	.....	Unclassifiable/Attainment.
Greene County	.....	Unclassifiable/Attainment.
Halifax County	.....	Unclassifiable/Attainment.
Harnett County	.....	Unclassifiable/Attainment.
Haywood County	.....	Unclassifiable/Attainment.
Henderson County	.....	Unclassifiable/Attainment.
Hertford County	.....	Unclassifiable/Attainment.
Hoke County	.....	Unclassifiable/Attainment.
Hyde County	.....	Unclassifiable/Attainment.
Iredell County	.....	Unclassifiable/Attainment.
Jackson County	.....	Unclassifiable/Attainment.
Johnston County	.....	Unclassifiable/Attainment.
Jones County	.....	Unclassifiable/Attainment.
Lee County	.....	Unclassifiable/Attainment.
Lenoir County	.....	Unclassifiable/Attainment.
Lincoln County	.....	Unclassifiable/Attainment.
McDowell County	.....	Unclassifiable/Attainment.
Macon County	.....	Unclassifiable/Attainment.
Madison County	.....	Unclassifiable/Attainment.
Martin County	.....	Unclassifiable/Attainment.
Mecklenburg County	.....	Unclassifiable/Attainment.
Mitchell County	.....	Unclassifiable/Attainment.
Montgomery County	.....	Unclassifiable/Attainment.
Moore County	.....	Unclassifiable/Attainment.
Nash County	.....	Unclassifiable/Attainment.
New Hanover County	.....	Unclassifiable/Attainment.
Northampton County	.....	Unclassifiable/Attainment.
Onslow County	.....	Unclassifiable/Attainment.
Orange County	.....	Unclassifiable/Attainment.
Pamlico County	.....	Unclassifiable/Attainment.
Pasquotank County	.....	Unclassifiable/Attainment.
Pender County	.....	Unclassifiable/Attainment.
Perquimans County	.....	Unclassifiable/Attainment.
Person County	.....	Unclassifiable/Attainment.
Pitt County	.....	Unclassifiable/Attainment.
Polk County	.....	Unclassifiable/Attainment.
Randolph County	.....	Unclassifiable/Attainment.
Richmond County	.....	Unclassifiable/Attainment.
Robeson County	.....	Unclassifiable/Attainment.
Rockingham County	.....	Unclassifiable/Attainment.
Rowan County	.....	Unclassifiable/Attainment.
Rutherford County	.....	Unclassifiable/Attainment.
Sampson County	.....	Unclassifiable/Attainment.
Scotland County	.....	Unclassifiable/Attainment.
Stanly County	.....	Unclassifiable/Attainment.
Stokes County	.....	Unclassifiable/Attainment.

NORTH CAROLINA.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Surry County	.....	Unclassifiable/Attainment.
Swain County	.....	Unclassifiable/Attainment.
Transylvania County	.....	Unclassifiable/Attainment.
Tyrrell County	.....	Unclassifiable/Attainment.
Union County	.....	Unclassifiable/Attainment.
Vance County	.....	Unclassifiable/Attainment.
Wake County	.....	Unclassifiable/Attainment.
Warren County	.....	Unclassifiable/Attainment.
Washington County	.....	Unclassifiable/Attainment.
Watauga County	.....	Unclassifiable/Attainment.
Wayne County	.....	Unclassifiable/Attainment.
Wilkes County	.....	Unclassifiable/Attainment.
Wilson County	.....	Unclassifiable/Attainment.
Yadkin County	.....	Unclassifiable/Attainment.
Yancey County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 36. In § 81.335, the table entitled "North Dakota.—PM2.5" is added to the end of the section to read as follows:

§ 81.335 North Dakota

* * * * *

NORTH DAKOTA.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
AQCR 130 Metropolitan Fargo-Moorhead Interstate:		
Cass County	.....	Unclassifiable/Attainment.
Rest of State, AQCR 172:		
Adams County	.....	Unclassifiable/Attainment.
Barnes County	.....	Unclassifiable/Attainment.
Benson County	.....	Unclassifiable/Attainment.
Billings County	.....	Unclassifiable/Attainment.
Bottineau County	.....	Unclassifiable/Attainment.
Bowman County	.....	Unclassifiable/Attainment.
Burke County	.....	Unclassifiable/Attainment.
Burleigh County	.....	Unclassifiable/Attainment.
Cavalier County	.....	Unclassifiable/Attainment.
Dickey County	.....	Unclassifiable/Attainment.
Divide County	.....	Unclassifiable/Attainment.
Dunn County	.....	Unclassifiable/Attainment.
Eddy County	.....	Unclassifiable/Attainment.
Emmons County	.....	Unclassifiable/Attainment.
Foster County	.....	Unclassifiable/Attainment.
Golden Valley County	.....	Unclassifiable/Attainment.
Grand Forks County	.....	Unclassifiable/Attainment.
Grant County	.....	Unclassifiable/Attainment.
Griggs County	.....	Unclassifiable/Attainment.
Hettinger County	.....	Unclassifiable/Attainment.
Kidder County	.....	Unclassifiable/Attainment.
LaMoure County	.....	Unclassifiable/Attainment.
Logan County	.....	Unclassifiable/Attainment.
McHenry County	.....	Unclassifiable/Attainment.
McIntosh County	.....	Unclassifiable/Attainment.
McKenzie County	.....	Unclassifiable/Attainment.
McLean County	.....	Unclassifiable/Attainment.
Mercer County	.....	Unclassifiable/Attainment.
Morton County	.....	Unclassifiable/Attainment.
Mountrail County	.....	Unclassifiable/Attainment.
Nelson County	.....	Unclassifiable/Attainment.
Oliver County	.....	Unclassifiable/Attainment.
Pembina County	.....	Unclassifiable/Attainment.
Pierce County	.....	Unclassifiable/Attainment.
Ramsey County	.....	Unclassifiable/Attainment.
Ransom County	.....	Unclassifiable/Attainment.
Renville County	.....	Unclassifiable/Attainment.
Richland County	.....	Unclassifiable/Attainment.

NORTH DAKOTA.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Rolette County	.....	Unclassifiable/Attainment.
Sargent County	.....	Unclassifiable/Attainment.
Sheridan County	.....	Unclassifiable/Attainment.
Sioux County	.....	Unclassifiable/Attainment.
Slope County	.....	Unclassifiable/Attainment.
Stark County	.....	Unclassifiable/Attainment.
Steele County	.....	Unclassifiable/Attainment.
Stutsman County	.....	Unclassifiable/Attainment.
Towner County	.....	Unclassifiable/Attainment.
Traill County	.....	Unclassifiable/Attainment.
Walsh County	.....	Unclassifiable/Attainment.
Ward County	.....	Unclassifiable/Attainment.
Wells County	.....	Unclassifiable/Attainment.
Williams County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 37. In § 81.336, the table entitled "Ohio.—PM2.5" is added to the end of the section to read as follows:

§ 81.336 Ohio.

* * * * *

OHIO.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
Canton-Massillon, OH:		
Stark County	.....	Nonattainment.
Cincinnati-Hamilton, OH-KY-IN:		
Butler County	.....	Nonattainment.
Clermont County	.....	Nonattainment.
Hamilton County	.....	Nonattainment.
Warren County	.....	Nonattainment.
Cleveland-Akron-Lorain, OH:		
Ashtabula County (part)	.....	Nonattainment.
Ashtabula Township	.....	
Cuyahoga County	.....	Nonattainment.
Lake County	.....	Nonattainment.
Lorain County	.....	Nonattainment.
Medina County	.....	Nonattainment.
Portage County	.....	Nonattainment.
Summit County	.....	Nonattainment.
Columbus, OH:		
Coshocton County (part)	.....	Nonattainment.
Franklin Township	.....	
Delaware County	.....	Nonattainment.
Fairfield County	.....	Nonattainment.
Franklin County	.....	Nonattainment.
Licking County	.....	Nonattainment.
Dayton-Springfield, OH:		
Clark County	.....	Nonattainment.
Greene County	.....	Nonattainment.
Montgomery County	.....	Nonattainment.
Huntington-Ashland, WV-KY-OH:		
Adams County (part)	.....	Nonattainment.
Monroe Township, Sprigg Township	.....	
Gallia County (part)	.....	Nonattainment.
Addison Township, Cheshire Township	.....	
Lawrence County	.....	Nonattainment.
Scioto County	.....	Nonattainment.
Parkersburg-Marietta, WV-OH:		
Washington County	.....	Nonattainment.
Steubenville-Weirton, OH-WV:		
Jefferson County	.....	Nonattainment.
Toledo, OH:		
Lucas County	.....	Nonattainment.
Wood County	.....	Nonattainment.
Wheeling, WV-OH:		

OHIO.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Belmont County	.....	Nonattainment.
Youngstown-Warren-Sharon, OH-PA:		
Columbiana County	.....	Nonattainment.
Mahoning County	.....	Nonattainment.
Trumbull County	.....	Nonattainment.
Rest of State:		
Adams County (remainder)	.....	Unclassifiable/Attainment.
Allen County	.....	Unclassifiable/Attainment.
Ashland County	.....	Unclassifiable/Attainment.
Ashtabula County (remainder)	.....	Unclassifiable/Attainment.
Athens County	.....	Unclassifiable/Attainment.
Auglaize County	.....	Unclassifiable/Attainment.
Brown County	.....	Unclassifiable/Attainment.
Carroll County	.....	Unclassifiable/Attainment.
Champaign County	.....	Unclassifiable/Attainment.
Clinton County	.....	Unclassifiable/Attainment.
Coshocton County (remainder)	.....	Unclassifiable/Attainment.
Crawford County	.....	Unclassifiable/Attainment.
Darke County	.....	Unclassifiable/Attainment.
Defiance County	.....	Unclassifiable/Attainment.
Erie County	.....	Unclassifiable/Attainment.
Fayette County	.....	Unclassifiable/Attainment.
Fulton County	.....	Unclassifiable/Attainment.
Gallia County (remainder)	.....	Unclassifiable/Attainment.
Geauga County	.....	Unclassifiable/Attainment.
Guernsey County	.....	Unclassifiable/Attainment.
Hancock County	.....	Unclassifiable/Attainment.
Hardin County	.....	Unclassifiable/Attainment.
Harrison County	.....	Unclassifiable/Attainment.
Henry County	.....	Unclassifiable/Attainment.
Highland County	.....	Unclassifiable/Attainment.
Hocking County	.....	Unclassifiable/Attainment.
Holmes County	.....	Unclassifiable/Attainment.
Huron County	.....	Unclassifiable/Attainment.
Jackson County	.....	Unclassifiable/Attainment.
Knox County	.....	Unclassifiable/Attainment.
Logan County	.....	Unclassifiable/Attainment.
Madison County	.....	Unclassifiable/Attainment.
Marion County	.....	Unclassifiable/Attainment.
Meigs County	.....	Unclassifiable/Attainment.
Mercer County	.....	Unclassifiable/Attainment.
Miami County	.....	Unclassifiable/Attainment.
Monroe County	.....	Unclassifiable/Attainment.
Morgan County	.....	Unclassifiable/Attainment.
Morrow County	.....	Unclassifiable/Attainment.
Muskingum County	.....	Unclassifiable/Attainment.
Noble County	.....	Unclassifiable/Attainment.
Ottawa County	.....	Unclassifiable/Attainment.
Paulding County	.....	Unclassifiable/Attainment.
Perry County	.....	Unclassifiable/Attainment.
Pickaway County	.....	Unclassifiable/Attainment.
Pike County	.....	Unclassifiable/Attainment.
Preble County	.....	Unclassifiable/Attainment.
Putnam County	.....	Unclassifiable/Attainment.
Richland County	.....	Unclassifiable/Attainment.
Ross County	.....	Unclassifiable/Attainment.
Sandusky County	.....	Unclassifiable/Attainment.
Seneca County	.....	Unclassifiable/Attainment.
Shelby County	.....	Unclassifiable/Attainment.
Tuscarawas County	.....	Unclassifiable/Attainment.
Union County	.....	Unclassifiable/Attainment.
Van Wert County	.....	Unclassifiable/Attainment.
Vinton County	.....	Unclassifiable/Attainment.
Wayne County	.....	Unclassifiable/Attainment.
Williams County	.....	Unclassifiable/Attainment.
Wyandot County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 38. In § 81.337, the table entitled "Oklahoma—PM2.5" is added to the end of the section to read as follows:

§ 81.337 Oklahoma.

* * * * *

OKLAHOMA.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
AQCR 017 Metropolitan Fort Smith Interstate:		
Adair County	.....	Unclassifiable/Attainment.
Cherokee County	.....	Unclassifiable/Attainment.
Le Flore County	.....	Unclassifiable/Attainment.
Sequoyah County	.....	Unclassifiable/Attainment.
AQCR 022 Shreveport-Texarkana-Tyler Intrastate:		
McCurtain County	.....	Unclassifiable/Attainment.
AQCR 184 Central Oklahoma Intrastate (part):		
Cleveland County	.....	Unclassifiable/Attainment.
Oklahoma County	.....	Unclassifiable/Attainment.
AQCR 184 Central Oklahoma Intrastate (remainder of):		
Canadian County	.....	Unclassifiable/Attainment.
Grady County	.....	Unclassifiable/Attainment.
Kingfisher County	.....	Unclassifiable/Attainment.
Lincoln County	.....	Unclassifiable/Attainment.
Logan County	.....	Unclassifiable/Attainment.
McClain County	.....	Unclassifiable/Attainment.
Pottawatomie County	.....	Unclassifiable/Attainment.
AQCR 185 North Central Oklahoma Intrastate:	.....	
Garfield County	.....	Unclassifiable/Attainment.
Grant County	.....	Unclassifiable/Attainment.
Kay County	.....	Unclassifiable/Attainment.
Noble County	.....	Unclassifiable/Attainment.
Payne County	.....	Unclassifiable/Attainment.
AQCR 186 Northeastern Oklahoma Intrastate:		
Craig County	.....	Unclassifiable/Attainment.
Creek County	.....	Unclassifiable/Attainment.
Delaware County	.....	Unclassifiable/Attainment.
Mayes County	.....	Unclassifiable/Attainment.
Muskogee County	.....	Unclassifiable/Attainment.
Nowata County	.....	Unclassifiable/Attainment.
Okmulgee County	.....	Unclassifiable/Attainment.
Osage County	.....	Unclassifiable/Attainment.
Ottawa County	.....	Unclassifiable/Attainment.
Pawnee County	.....	Unclassifiable/Attainment.
Rogers County	.....	Unclassifiable/Attainment.
Tulsa County	.....	Unclassifiable/Attainment.
Wagoner County	.....	Unclassifiable/Attainment.
Washington County	.....	Unclassifiable/Attainment.
AQCR 187 Northwestern Oklahoma Intrastate:	.....	
Alfalfa County	.....	Unclassifiable/Attainment.
Beaver County	.....	Unclassifiable/Attainment.
Blaine County	.....	Unclassifiable/Attainment.
Cimarron County	.....	Unclassifiable/Attainment.
Custer County	.....	Unclassifiable/Attainment.
Dewey County	.....	Unclassifiable/Attainment.
Ellis County	.....	Unclassifiable/Attainment.
Harper County	.....	Unclassifiable/Attainment.
Major County	.....	Unclassifiable/Attainment.
Roger Mills County	.....	Unclassifiable/Attainment.
Texas County	.....	Unclassifiable/Attainment.
Woods County	.....	Unclassifiable/Attainment.
Woodward County	.....	Unclassifiable/Attainment.
AQCR 188 Southeastern Oklahoma Intrastate:		
Atoka County	.....	Unclassifiable/Attainment.
Bryan County	.....	Unclassifiable/Attainment.
Carter County	.....	Unclassifiable/Attainment.
Choctaw County	.....	Unclassifiable/Attainment.
Coal County	.....	Unclassifiable/Attainment.
Garvin County	.....	Unclassifiable/Attainment.
Haskell County	.....	Unclassifiable/Attainment.
Hughes County	.....	Unclassifiable/Attainment.
Johnston County	.....	Unclassifiable/Attainment.
Latimer County	.....	Unclassifiable/Attainment.
Love County	.....	Unclassifiable/Attainment.
McIntosh County	.....	Unclassifiable/Attainment.

OKLAHOMA.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Marshall County	.....	Unclassifiable/Attainment.
Murray County	.....	Unclassifiable/Attainment.
Okfuskee County	.....	Unclassifiable/Attainment.
Pittsburg County	.....	Unclassifiable/Attainment.
Pontotoc County	.....	Unclassifiable/Attainment.
Pushmataha County	.....	Unclassifiable/Attainment.
Seminole County	.....	Unclassifiable/Attainment.
AQCR 189 Southwestern Oklahoma Intrastate:		
Beckham County	.....	Unclassifiable/Attainment.
Caddo County	.....	Unclassifiable/Attainment.
Comanche County	.....	Unclassifiable/Attainment.
Cotton County	.....	Unclassifiable/Attainment.
Greer County	.....	Unclassifiable/Attainment.
Harmon County	.....	Unclassifiable/Attainment.
Jackson County	.....	Unclassifiable/Attainment.
Jefferson County	.....	Unclassifiable/Attainment.
Kiowa County	.....	Unclassifiable/Attainment.
Stephens County	.....	Unclassifiable/Attainment.
Tillman County	.....	Unclassifiable/Attainment.
Washita County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 39. In § 81.338, the table entitled "Oregon.—PM2.5" is added to the end of the section to read as follows:

§ 81.338 Oregon.

* * * * *

OREGON.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
Portland-Vancouver AQMA:		
(Air Quality Maintenance Area)		
Clackamas County (part)	.....	Unclassifiable/Attainment.
Multnomah County (part)	.....	Unclassifiable/Attainment.
Washington County (part)	.....	Unclassifiable/Attainment.
Salem Area:		
(Salem Area Transportation Study):		
Marion County (part)	.....	Unclassifiable/Attainment.
Polk County	.....	Unclassifiable/Attainment.
AQCR 190 Central Oregon Intrastate (remainder of):		
Crook County	.....	Unclassifiable/Attainment.
Deschutes County	.....	Unclassifiable/Attainment.
Hood River County	.....	Unclassifiable/Attainment.
Jefferson County	.....	Unclassifiable/Attainment.
Klamath County	.....	Unclassifiable/Attainment.
Lake County	.....	Unclassifiable/Attainment.
Sherman County	.....	Unclassifiable/Attainment.
Wasco County	.....	Unclassifiable/Attainment.
AQCR 191 Eastern Oregon Intrastate:		
Baker County	.....	Unclassifiable/Attainment.
Gilliam County	.....	Unclassifiable/Attainment.
Grant County	.....	Unclassifiable/Attainment.
Harney County	.....	Unclassifiable/Attainment.
Malheur County	.....	Unclassifiable/Attainment.
Morrow County	.....	Unclassifiable/Attainment.
Umatilla County	.....	Unclassifiable/Attainment.
Union County	.....	Unclassifiable/Attainment.
Wallowa County	.....	Unclassifiable/Attainment.
Wheeler County	.....	Unclassifiable/Attainment.
AQCR 192 Northwest Oregon Intrastate:		
Clatsop County	.....	Unclassifiable/Attainment.
Lincoln County	.....	Unclassifiable/Attainment.
Tillamook County	.....	Unclassifiable/Attainment.
AQCR 193 Portland Interstate (part):		
Lane County (part)	.....	Unclassifiable/Attainment.

OREGON.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Eugene Springfield Air Quality Maintenance Area		
AQCR 193 Portland Interstate (remainder of):		
Benton County	.....	Unclassifiable/Attainment.
Clackamas County (remainder)	.....	Unclassifiable/Attainment.
Columbia County	.....	Unclassifiable/Attainment.
Lane County (remainder)	.....	Unclassifiable/Attainment.
Linn County	.....	Unclassifiable/Attainment.
Marion County (part)	.....	Unclassifiable/Attainment.
The area outside the Salem Area Transportation Study		
Multnomah County (remainder)	.....	Unclassifiable/Attainment.
Polk County (part)	.....	Unclassifiable/Attainment.
The area outside the Salem Area Transportation Study		
Washington County (remainder)	.....	Unclassifiable/Attainment.
Yamhill County	.....	Unclassifiable/Attainment.
AQCR 194 Southwest Oregon Intrastate (part):		
Jackson County (part)	.....	Unclassifiable/Attainment.
Medford-Ashland Air Quality Maintenance Area		
AQCR 194 Southwest Oregon Intrastate (remainder of):		
Coos County	.....	Unclassifiable/Attainment.
Curry County	.....	Unclassifiable/Attainment.
Douglas County	.....	Unclassifiable/Attainment.
Jackson County (remainder)	.....	Unclassifiable/Attainment.
Josephine County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 40. In § 81.339, the table entitled "Pennsylvania.—PM2.5" is added to the end of the section to read as follows:

§ 81339 Pennsylvania.

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PENNSYLVANIA.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
Harrisburg-Lebanon-Carlisle, PA:		
Cumberland County	.....	Nonattainment.
Dauphin County	.....	Nonattainment.
Lebanon County	.....	Nonattainment.
Johnstown, PA:		
Cambria County	.....	Nonattainment.
Indiana County (part)	.....	Nonattainment.
Townships of West Wheatfield, Center, East Wheatfield, and Armagh Borough and Homer City Borough		
Lancaster, PA:		
Lancaster County	.....	Nonattainment.
Liberty-Clairton, PA:		
Allegheny County (part)	.....	Nonattainment.
Lincoln Borough, Clairton City, Glassport Borough, Liberty Borough, Port Vue Borough		
Philadelphia-Wilmington, PA-NJ-DE:		
Bucks County	.....	Nonattainment.
Chester County	.....	Nonattainment.
Delaware County	.....	Nonattainment.
Montgomery County	.....	Nonattainment.
Philadelphia County	.....	Nonattainment.
Pittsburgh-Beaver Valley, PA:		
Allegheny County (remainder)	.....	Nonattainment.
Armstrong County (part)	.....	Nonattainment.
Elderton Borough and Plumcreek and Washington Townships		
Beaver County	.....	Nonattainment.
Butler County	.....	Nonattainment.
Greene County (part)	.....	Nonattainment.
Monongahela Township		
Lawrence County (part)	.....	Nonattainment.
Township of Taylor south of New Castle City		
Washington County	.....	Nonattainment.
Westmoreland County	.....	Nonattainment.

PENNSYLVANIA.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Reading, PA:		
Berks County	.....	Nonattainment.
York, PA:		
York County	.....	Nonattainment.
Youngstown-Warren-Sharon, OH-PA:		
Mercer County	.....	Nonattainment.
AQCR 151 Northeast Pennsylvania-Upper Delaware Valley Interstate:		
Bradford County	.....	Unclassifiable/Attainment.
Carbon County	.....	Unclassifiable/Attainment.
Lackawanna County	.....	Unclassifiable/Attainment.
Lehigh County	.....	Unclassifiable/Attainment.
Luzerne County	.....	Unclassifiable/Attainment.
Monroe County	.....	Unclassifiable/Attainment.
Northampton County	.....	Unclassifiable/Attainment.
Pike County	.....	Unclassifiable/Attainment.
Schuylkill County	.....	Unclassifiable/Attainment.
Sullivan County	.....	Unclassifiable/Attainment.
Susquehanna County	.....	Unclassifiable/Attainment.
Tioga County	.....	Unclassifiable/Attainment.
Wayne County	.....	Unclassifiable/Attainment.
Wyoming County	.....	Unclassifiable/Attainment.
AQCR 178 Northwest Pennsylvania-Youngstown Interstate:		
Cameron County	.....	Unclassifiable/Attainment.
Clarion County	.....	Unclassifiable/Attainment.
Clearfield County	.....	Unclassifiable/Attainment.
Crawford County	.....	Unclassifiable/Attainment.
Elk County	.....	Unclassifiable/Attainment.
Erie County	.....	Unclassifiable/Attainment.
Forest County	.....	Unclassifiable/Attainment.
Jefferson County	.....	Unclassifiable/Attainment.
Lawrence County (remainder)	.....	Unclassifiable/Attainment.
McKean County	.....	Unclassifiable/Attainment.
Potter County	.....	Unclassifiable/Attainment.
Venango County	.....	Unclassifiable/Attainment.
Warren County	.....	Unclassifiable/Attainment.
AQCR 195 Central Pennsylvania Intrastate:		
Bedford County	.....	Unclassifiable/Attainment.
Blair County	.....	Unclassifiable/Attainment.
Centre County	.....	Unclassifiable/Attainment.
Clinton County	.....	Unclassifiable/Attainment.
Columbia County	.....	Unclassifiable/Attainment.
Fulton County	.....	Unclassifiable/Attainment.
Huntingdon County	.....	Unclassifiable/Attainment.
Juniata County	.....	Unclassifiable/Attainment.
Lycoming County	.....	Unclassifiable/Attainment.
Mifflin County	.....	Unclassifiable/Attainment.
Montour County	.....	Unclassifiable/Attainment.
Northumberland County	.....	Unclassifiable/Attainment.
Snyder County	.....	Unclassifiable/Attainment.
Somerset County	.....	Unclassifiable/Attainment.
Union County	.....	Unclassifiable/Attainment.
AQCR 196 South Central Pennsylvania Intrastate:		
Adams County	.....	Unclassifiable/Attainment.
Franklin County	.....	Unclassifiable/Attainment.
Perry County	.....	Unclassifiable/Attainment.
AQCR 197 Southwest Pennsylvania Intrastate:		
Armstrong County (remainder)	.....	Unclassifiable/Attainment.
Fayette County	.....	Unclassifiable/Attainment.
Greene County (remainder)	.....	Unclassifiable/Attainment.
Indiana County (remainder)	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 41. In § 81.340, the table entitled "Rhode Island.—PM2.5" is added to the end of the section to read as follows:

§ 81.340 Rhode Island.

* * * * *

RHODE ISLAND.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
Statewide:		
Bristol County	.....	Unclassifiable/Attainment.
Kent County	.....	Unclassifiable/Attainment.
Newport County	.....	Unclassifiable/Attainment.
Providence County	.....	Unclassifiable/Attainment.
Washington County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 42. In § 81.341, the table entitled "South Carolina.—PM2.5" is added to the end of the section to read as follows:

§ 81.341 South Carolina.

* * * * *

SOUTH CAROLINA.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
Greenville-Spartanburg, SC:		
Anderson County	.....	Unclassifiable
Greenville County	.....	Unclassifiable
Spartanburg County	.....	Unclassifiable
Rest of State:		
Abbeville County	.....	Unclassifiable/Attainment.
Aiken County	.....	Unclassifiable/Attainment.
Allendale County	.....	Unclassifiable/Attainment.
Bamberg County	.....	Unclassifiable/Attainment.
Barnwell County	.....	Unclassifiable/Attainment.
Beaufort County	.....	Unclassifiable/Attainment.
Berkeley County	.....	Unclassifiable/Attainment.
Calhoun County	.....	Unclassifiable/Attainment.
Charleston County	.....	Unclassifiable/Attainment.
Cherokee County	.....	Unclassifiable/Attainment.
Chester County	.....	Unclassifiable/Attainment.
Chesterfield County	.....	Unclassifiable/Attainment.
Clarendon County	.....	Unclassifiable/Attainment.
Colleton County	.....	Unclassifiable/Attainment.
Darlington County	.....	Unclassifiable/Attainment.
Dillon County	.....	Unclassifiable/Attainment.
Dorchester County	.....	Unclassifiable/Attainment.
Edgefield County	.....	Unclassifiable/Attainment.
Fairfield County	.....	Unclassifiable/Attainment.
Florence County	.....	Unclassifiable/Attainment.
Georgetown County	.....	Unclassifiable/Attainment.
Greenwood County	.....	Unclassifiable/Attainment.
Hampton County	.....	Unclassifiable/Attainment.
Horry County	.....	Unclassifiable/Attainment.
Jasper County	.....	Unclassifiable/Attainment.
Kershaw County	.....	Unclassifiable/Attainment.
Lancaster County	.....	Unclassifiable/Attainment.
Laurens County	.....	Unclassifiable/Attainment.
Lee County	.....	Unclassifiable/Attainment
Lexington County	.....	Unclassifiable/Attainment.
McCormick County	.....	Unclassifiable/Attainment.
Marion County	.....	Unclassifiable/Attainment.
Marlboro County	.....	Unclassifiable/Attainment.
Newberry County	.....	Unclassifiable/Attainment.
Oconee County	.....	Unclassifiable/Attainment.
Orangeburg County	.....	Unclassifiable/Attainment.
Pickens County	.....	Unclassifiable/Attainment.
Richland County	.....	Unclassifiable/Attainment.
Saluda County	.....	Unclassifiable/Attainment.
Sumter County	.....	Unclassifiable/Attainment.
Union County	.....	Unclassifiable/Attainment.
Williamsburg County	.....	Unclassifiable/Attainment.
York County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.

[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 43. In § 81.342, the table entitled "South Dakota.—PM2.5" is added to the end of the section to read as follows:

§ 81.342 South Dakota.

* * * * *

SOUTH DAKOTA.—PM2.5

Designated area	Designation[a]	
	Date[1]	Type
Statewide:		
Aurora County		Unclassifiable/Attainment.
Beadle County		Unclassifiable/Attainment.
Bennett County		Unclassifiable/Attainment.
Bon Homme County		Unclassifiable/Attainment.
Brookings County		Unclassifiable/Attainment.
Brown County		Unclassifiable/Attainment.
Brule County		Unclassifiable/Attainment.
Buffalo County		Unclassifiable/Attainment.
Butte County		Unclassifiable/Attainment.
Campbell County		Unclassifiable/Attainment.
Charles Mix County		Unclassifiable/Attainment.
Clark County		Unclassifiable/Attainment.
Clay County		Unclassifiable/Attainment.
Codington County		Unclassifiable/Attainment.
Corson County		Unclassifiable/Attainment.
Custer County		Unclassifiable/Attainment.
Davison County		Unclassifiable/Attainment.
Day County		Unclassifiable/Attainment.
Deuel County		Unclassifiable/Attainment.
Dewey County		Unclassifiable/Attainment.
Douglas County		Unclassifiable/Attainment.
Edmunds County		Unclassifiable/Attainment.
Fall River County		Unclassifiable/Attainment.
Faulk County		Unclassifiable/Attainment.
Grant County		Unclassifiable/Attainment.
Gregory County		Unclassifiable/Attainment.
Haakon County		Unclassifiable/Attainment.
Hamlin County		Unclassifiable/Attainment.
Hand County		Unclassifiable/Attainment.
Hanson County		Unclassifiable/Attainment.
Harding County		Unclassifiable/Attainment.
Hughes County		Unclassifiable/Attainment.
Hutchinson County		Unclassifiable/Attainment.
Hyde County		Unclassifiable/Attainment.
Jackson County		Unclassifiable/Attainment.
Jerauld County		Unclassifiable/Attainment.
Jones County		Unclassifiable/Attainment.
Kingsbury County		Unclassifiable/Attainment.
Lake County		Unclassifiable/Attainment.
Lawrence County		Unclassifiable/Attainment.
Lincoln County		Unclassifiable/Attainment.
Lyman County		Unclassifiable/Attainment.
McCook County		Unclassifiable/Attainment.
McPherson County		Unclassifiable/Attainment.
Marshall County		Unclassifiable/Attainment.
Meade County		Unclassifiable/Attainment.
Mellette County		Unclassifiable/Attainment.
Miner County		Unclassifiable/Attainment.
Minnehaha County		Unclassifiable/Attainment.
Moody County		Unclassifiable/Attainment.
Pennington County		Unclassifiable/Attainment.
Perkins County		Unclassifiable/Attainment.
Potter County		Unclassifiable/Attainment.
Roberts County		Unclassifiable/Attainment.
Sanborn County		Unclassifiable/Attainment.
Shannon County		Unclassifiable/Attainment.
Spink County		Unclassifiable/Attainment.
Stanley County		Unclassifiable/Attainment.
Sully Count		Unclassifiable/Attainment.
Todd County		Unclassifiable/Attainment.
Tripp County		Unclassifiable/Attainment.
Turner County		Unclassifiable/Attainment.

SOUTH DAKOTA.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Union County	.....	Unclassifiable/Attainment.
Walworth County	.....	Unclassifiable/Attainment.
Yankton County	.....	Unclassifiable/Attainment.
Ziebach County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 44. In § 81.343, the table entitled "Tennessee.—PM2.5" is added to the end of the section to read as follows:

§ 81.343 Tennessee.

* * * * *

TENNESSEE.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
Chattanooga, TN-GA:		
Hamilton County	.....	Nonattainment.
Knoxville, TN:		
Anderson County	.....	Nonattainment.
Blount County	.....	Nonattainment.
Knox County	.....	Nonattainment.
Loudon County	.....	Nonattainment.
Roane County (part)	.....	Nonattainment.
The area described by U.S. Census 2000 block group identifier 47–145–0307–2.		
McMinn County, TN:		
McMinn County	.....	Unclassifiable
Rest of State:		
Bedford County	.....	Unclassifiable/Attainment.
Benton County	.....	Unclassifiable/Attainment.
Bledsoe County	.....	Unclassifiable/Attainment.
Bradley County	.....	Unclassifiable/Attainment.
Campbell County	.....	Unclassifiable/Attainment.
Cannon County	.....	Unclassifiable/Attainment.
Carroll County	.....	Unclassifiable/Attainment.
Carter County	.....	Unclassifiable/Attainment.
Cheatham County	.....	Unclassifiable/Attainment.
Chester County	.....	Unclassifiable/Attainment.
Claiborne County	.....	Unclassifiable/Attainment.
Clay County	.....	Unclassifiable/Attainment.
Cocke County	.....	Unclassifiable/Attainment.
Coffee County	.....	Unclassifiable/Attainment.
Crockett County	.....	Unclassifiable/Attainment.
Cumberland County	.....	Unclassifiable/Attainment.
Davidson County	.....	Unclassifiable/Attainment.
Decatur County	.....	Unclassifiable/Attainment.
DeKalb County	.....	Unclassifiable/Attainment.
Dickson County	.....	Unclassifiable/Attainment.
Dyer County	.....	Unclassifiable/Attainment.
Fayette County	.....	Unclassifiable/Attainment.
Fentress County	.....	Unclassifiable/Attainment.
Franklin County	.....	Unclassifiable/Attainment.
Gibson County	.....	Unclassifiable/Attainment.
Giles County	.....	Unclassifiable/Attainment.
Grainger County	.....	Unclassifiable/Attainment.
Greene County	.....	Unclassifiable/Attainment.
Grundy County	.....	Unclassifiable/Attainment.
Hamblen County	.....	Unclassifiable/Attainment.
Hancock County	.....	Unclassifiable/Attainment.
Hardeman County	.....	Unclassifiable/Attainment.
Hardin County	.....	Unclassifiable/Attainment.
Hawkins County	.....	Unclassifiable/Attainment.
Haywood County	.....	Unclassifiable/Attainment.
Henderson County	.....	Unclassifiable/Attainment.
Henry County	.....	Unclassifiable/Attainment.
Hickman County	.....	Unclassifiable/Attainment.
Houston County	.....	Unclassifiable/Attainment.
Humphreys County	.....	Unclassifiable/Attainment.

TENNESSEE.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Jackson County	.....	Unclassifiable/Attainment.
Jefferson County	.....	Unclassifiable/Attainment.
Johnson County	.....	Unclassifiable/Attainment.
Lake County	.....	Unclassifiable/Attainment.
Lauderdale County	.....	Unclassifiable/Attainment.
Lawrence County	.....	Unclassifiable/Attainment.
Lewis County	.....	Unclassifiable/Attainment.
Lincoln County	.....	Unclassifiable/Attainment.
McNairy County	.....	Unclassifiable/Attainment.
Macon County	.....	Unclassifiable/Attainment.
Madison County	.....	Unclassifiable/Attainment.
Marion County	.....	Unclassifiable/Attainment.
Marshall County	.....	Unclassifiable/Attainment.
Maury County	.....	Unclassifiable/Attainment.
Meigs County	.....	Unclassifiable/Attainment.
Monroe County	.....	Unclassifiable/Attainment.
Montgomery County	.....	Unclassifiable/Attainment.
Moore County	.....	Unclassifiable/Attainment.
Morgan County	.....	Unclassifiable/Attainment.
Obion County	.....	Unclassifiable/Attainment.
Overton County	.....	Unclassifiable/Attainment.
Perry County	.....	Unclassifiable/Attainment.
Pickett County	.....	Unclassifiable/Attainment.
Polk County	.....	Unclassifiable/Attainment.
Putnam County	.....	Unclassifiable/Attainment.
Rhea County	.....	Unclassifiable/Attainment.
Roane County (remainder)	.....	Unclassifiable/Attainment.
Robertson County	.....	Unclassifiable/Attainment.
Rutherford County	.....	Unclassifiable/Attainment.
Scott County	.....	Unclassifiable/Attainment.
Sequatchie County	.....	Unclassifiable/Attainment.
Sevier County	.....	Unclassifiable/Attainment.
Shelby County	.....	Unclassifiable/Attainment.
Smith County	.....	Unclassifiable/Attainment.
Stewart County	.....	Unclassifiable/Attainment.
Sullivan County	.....	Unclassifiable/Attainment.
Sumner County	.....	Unclassifiable/Attainment.
Tipton County	.....	Unclassifiable/Attainment.
Trousdale County	.....	Unclassifiable/Attainment.
Unicoi County	.....	Unclassifiable/Attainment.
Union County	.....	Unclassifiable/Attainment.
Van Buren County	.....	Unclassifiable/Attainment.
Warren County	.....	Unclassifiable/Attainment.
Washington County	.....	Unclassifiable/Attainment.
Wayne County	.....	Unclassifiable/Attainment.
Weakley County	.....	Unclassifiable/Attainment.
White County	.....	Unclassifiable/Attainment.
Williamson County	.....	Unclassifiable/Attainment.
Wilson County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 45. In § 81.344, the table entitled "Texas.—PM2.5" is added to the end of the section to read as follows:

§ 81.344 Texas.

* * * * *

TEXAS.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
AQCR 022 Shreveport-Texarkana-Tyler Interstate:		
Anderson County	.....	Unclassifiable/Attainment.
Bowie County	.....	Unclassifiable/Attainment.
Camp County	.....	Unclassifiable/Attainment.
Cass County	.....	Unclassifiable/Attainment.
Cherokee County	.....	Unclassifiable/Attainment.

TEXAS.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Delta County	.....	Unclassifiable/Attainment.
Franklin County	.....	Unclassifiable/Attainment.
Gregg County	.....	Unclassifiable/Attainment.
Harrison County	.....	Unclassifiable/Attainment.
Hopkins County	.....	Unclassifiable/Attainment.
Lamar County	.....	Unclassifiable/Attainment.
Marion County	.....	Unclassifiable/Attainment.
Morris County	.....	Unclassifiable/Attainment.
Panola County	.....	Unclassifiable/Attainment.
Rains County	.....	Unclassifiable/Attainment.
Red River County	.....	Unclassifiable/Attainment.
Rusk County	.....	Unclassifiable/Attainment.
Smith County	.....	Unclassifiable/Attainment.
Titus County	.....	Unclassifiable/Attainment.
Upshur County	.....	Unclassifiable/Attainment.
Van Zandt County	.....	Unclassifiable/Attainment.
Wood County	.....	Unclassifiable/Attainment.
AQCR 106 S Louisiana-SE Texas Interstate (remainder of):		
Angelina County	.....	Unclassifiable/Attainment.
Houston County	.....	Unclassifiable/Attainment.
Jasper County	.....	Unclassifiable/Attainment.
Nacogdoches County	.....	Unclassifiable/Attainment.
Newton County	.....	Unclassifiable/Attainment.
Polk County	.....	Unclassifiable/Attainment.
Sabine County	.....	Unclassifiable/Attainment.
San Augustine County	.....	Unclassifiable/Attainment.
San Jacinto County	.....	Unclassifiable/Attainment.
Shelby County	.....	Unclassifiable/Attainment.
Trinity County	.....	Unclassifiable/Attainment.
Tyler County	.....	Unclassifiable/Attainment.
AQCR 153 El Paso-Las Cruces-Alamogordo Interstate:		
Brewster County	.....	Unclassifiable/Attainment.
Culberson County	.....	Unclassifiable/Attainment.
El Paso County	.....	Unclassifiable/Attainment.
Hudspeth County	.....	Unclassifiable/Attainment.
Jeff Davis County	.....	Unclassifiable/Attainment.
Presidio County	.....	Unclassifiable/Attainment.
AQCR 210 Abilene-Wichita Falls Intrastate:		
Archer County	.....	Unclassifiable/Attainment.
Baylor County	.....	Unclassifiable/Attainment.
Brown County	.....	Unclassifiable/Attainment.
Callahan County	.....	Unclassifiable/Attainment.
Clay County	.....	Unclassifiable/Attainment.
Coleman County	.....	Unclassifiable/Attainment.
Comanche County	.....	Unclassifiable/Attainment.
Cottle County	.....	Unclassifiable/Attainment.
Eastland County	.....	Unclassifiable/Attainment.
Fisher County	.....	Unclassifiable/Attainment.
Foard County	.....	Unclassifiable/Attainment.
Hardeman County	.....	Unclassifiable/Attainment.
Haskell County	.....	Unclassifiable/Attainment.
Jack County	.....	Unclassifiable/Attainment.
Jones County	.....	Unclassifiable/Attainment.
Kent County	.....	Unclassifiable/Attainment.
Knox County	.....	Unclassifiable/Attainment.
Mitchell County	.....	Unclassifiable/Attainment.
Montague County	.....	Unclassifiable/Attainment.
Nolan County	.....	Unclassifiable/Attainment.
Runnels County	.....	Unclassifiable/Attainment.
Scurry County	.....	Unclassifiable/Attainment.
Shackelford County	.....	Unclassifiable/Attainment.
Stephens County	.....	Unclassifiable/Attainment.
Stonewall County	.....	Unclassifiable/Attainment.
Taylor County	.....	Unclassifiable/Attainment.
Throckmorton County	.....	Unclassifiable/Attainment.
Wichita County	.....	Unclassifiable/Attainment.
Wilbarger County	.....	Unclassifiable/Attainment.
Young County	.....	Unclassifiable/Attainment.
AQCR 211 Amarillo-Lubbock Intrastate:		
Armstrong County	.....	Unclassifiable/Attainment.

TEXAS.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Bailey County	.....	Unclassifiable/Attainment.
Briscoe County	.....	Unclassifiable/Attainment.
Carson County	.....	Unclassifiable/Attainment.
Castro County	.....	Unclassifiable/Attainment.
Childress County	.....	Unclassifiable/Attainment.
Cochran County	.....	Unclassifiable/Attainment.
Collingsworth County	.....	Unclassifiable/Attainment.
Crosby County	.....	Unclassifiable/Attainment.
Dallam County	.....	Unclassifiable/Attainment.
Deaf Smith County	.....	Unclassifiable/Attainment.
Dickens County	.....	Unclassifiable/Attainment.
Donley County	.....	Unclassifiable/Attainment.
Floyd County	.....	Unclassifiable/Attainment.
Garza County	.....	Unclassifiable/Attainment.
Gray County	.....	Unclassifiable/Attainment.
Hale County	.....	Unclassifiable/Attainment.
Hall County	.....	Unclassifiable/Attainment.
Hansford County	.....	Unclassifiable/Attainment.
Hartley County	.....	Unclassifiable/Attainment.
Hemphill County	.....	Unclassifiable/Attainment.
Hockley County	.....	Unclassifiable/Attainment.
Hutchinson County	.....	Unclassifiable/Attainment.
King County	.....	Unclassifiable/Attainment.
Lamb County	.....	Unclassifiable/Attainment.
Lipscomb County	.....	Unclassifiable/Attainment.
Lubbock County	.....	Unclassifiable/Attainment.
Lynn County	.....	Unclassifiable/Attainment.
Moore County	.....	Unclassifiable/Attainment.
Motley County	.....	Unclassifiable/Attainment.
Ochiltree County	.....	Unclassifiable/Attainment.
Oldham County	.....	Unclassifiable/Attainment.
Parmer County	.....	Unclassifiable/Attainment.
Potter County	.....	Unclassifiable/Attainment.
Randall County	.....	Unclassifiable/Attainment.
Roberts County	.....	Unclassifiable/Attainment.
Sherman County	.....	Unclassifiable/Attainment.
Swisher County	.....	Unclassifiable/Attainment.
Terry County	.....	Unclassifiable/Attainment.
Wheeler County	.....	Unclassifiable/Attainment.
Yoakum County	.....	Unclassifiable/Attainment.
AQCR 212 Austin-Waco Intrastate:		
Bastrop County	.....	Unclassifiable/Attainment.
Bell County	.....	Unclassifiable/Attainment.
Blanco County	.....	Unclassifiable/Attainment.
Bosque County	.....	Unclassifiable/Attainment.
Brazos County	.....	Unclassifiable/Attainment.
Burleson County	.....	Unclassifiable/Attainment.
Burnet County	.....	Unclassifiable/Attainment.
Caldwell County	.....	Unclassifiable/Attainment.
Coryell County	.....	Unclassifiable/Attainment.
Falls County	.....	Unclassifiable/Attainment.
Fayette County	.....	Unclassifiable/Attainment.
Freestone County	.....	Unclassifiable/Attainment.
Grimes County	.....	Unclassifiable/Attainment.
Hamilton County	.....	Unclassifiable/Attainment.
Hays County	.....	Unclassifiable/Attainment.
Hill County	.....	Unclassifiable/Attainment.
Lampasas County	.....	Unclassifiable/Attainment.
Lee County	.....	Unclassifiable/Attainment.
Leon County	.....	Unclassifiable/Attainment.
Limestone County	.....	Unclassifiable/Attainment.
Llano County	.....	Unclassifiable/Attainment.
McLennan County	.....	Unclassifiable/Attainment.
Madison County	.....	Unclassifiable/Attainment.
Milam County	.....	Unclassifiable/Attainment.
Mills County	.....	Unclassifiable/Attainment.
Robertson County	.....	Unclassifiable/Attainment.
San Saba County	.....	Unclassifiable/Attainment.
Travis County	.....	Unclassifiable/Attainment.
Washington County	.....	Unclassifiable/Attainment.

TEXAS.—PM2.5—Continued

Designated area	Designation[a]	
	Date[1]	Type
Williamson County	.....	Unclassifiable/Attainment.
AQCR 213 Brownsville-Laredo Intrastate:		
Cameron County	.....	Unclassifiable/Attainment.
Hidalgo County	.....	Unclassifiable/Attainment.
Jim Hogg County	.....	Unclassifiable/Attainment.
Starr County	.....	Unclassifiable/Attainment.
Webb County	.....	Unclassifiable/Attainment.
Willacy County	.....	Unclassifiable/Attainment.
Zapata County	.....	Unclassifiable/Attainment.
AQCR 214 Corpus Christi-Victoria Intrastate (part):		
Nueces County	.....	Unclassifiable/Attainment.
AQCR 214 Corpus Christi-Victoria Intrastate (remainder of):		
Aransas County	.....	Unclassifiable/Attainment.
Bee County	.....	Unclassifiable/Attainment.
Brooks County	.....	Unclassifiable/Attainment.
Calhoun County	.....	Unclassifiable/Attainment.
DeWitt County	.....	Unclassifiable/Attainment.
Duval County	.....	Unclassifiable/Attainment.
Goliad County	.....	Unclassifiable/Attainment.
Gonzales County	.....	Unclassifiable/Attainment.
Jackson County	.....	Unclassifiable/Attainment.
Jim Wells County	.....	Unclassifiable/Attainment.
Kenedy County	.....	Unclassifiable/Attainment.
Kleberg County	.....	Unclassifiable/Attainment.
Lavaca County	.....	Unclassifiable/Attainment.
Live Oak County	.....	Unclassifiable/Attainment.
McMullen County	.....	Unclassifiable/Attainment.
Refugio County	.....	Unclassifiable/Attainment.
San Patricio County	.....	Unclassifiable/Attainment.
AQCR 215 Metro Dallas-Fort Worth Intrastate (remainder of):		
Cooke County	.....	Unclassifiable/Attainment.
Erath County	.....	Unclassifiable/Attainment.
Fannin County	.....	Unclassifiable/Attainment.
Grayson County	.....	Unclassifiable/Attainment.
Henderson County	.....	Unclassifiable/Attainment.
Hood County	.....	Unclassifiable/Attainment.
Hunt County	.....	Unclassifiable/Attainment.
Navarro County	.....	Unclassifiable/Attainment.
Palo Pinto County	.....	Unclassifiable/Attainment.
Somervell County	.....	Unclassifiable/Attainment.
Wise County	.....	Unclassifiable/Attainment.
AQCR 216 Metro Houston-Galveston Intrastate (remainder of):		
Austin County	.....	Unclassifiable/Attainment.
Colorado County	.....	Unclassifiable/Attainment.
Matagorda County	.....	Unclassifiable/Attainment.
Walker County	.....	Unclassifiable/Attainment.
Wharton County	.....	Unclassifiable/Attainment.
AQCR 217 Metro San Antonio Intrastate (remainder of):		
Atascosa County	.....	Unclassifiable/Attainment.
Bandera County	.....	Unclassifiable/Attainment.
Dimmit County	.....	Unclassifiable/Attainment.
Edwards County	.....	Unclassifiable/Attainment.
Frio County	.....	Unclassifiable/Attainment.
Gillespie County	.....	Unclassifiable/Attainment.
Karnes County	.....	Unclassifiable/Attainment.
Kendall County	.....	Unclassifiable/Attainment.
Kerr County	.....	Unclassifiable/Attainment.
Kinney County	.....	Unclassifiable/Attainment.
La Salle County	.....	Unclassifiable/Attainment.
Maverick County	.....	Unclassifiable/Attainment.
Medina County	.....	Unclassifiable/Attainment.
Real County	.....	Unclassifiable/Attainment.
Uvalde County	.....	Unclassifiable/Attainment.
Val Verde County	.....	Unclassifiable/Attainment.
Wilson County	.....	Unclassifiable/Attainment.
Zavala County	.....	Unclassifiable/Attainment.
AQCR 218 Midland-Odessa-San Angelo Intrastate (part):		
Ector County	.....	Unclassifiable/Attainment.
AQCR 218 Midland-Odessa-San Angelo Intrastate (remainder of):		
Andrews County	.....	Unclassifiable/Attainment.

TEXAS.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Borden County	.....	Unclassifiable/Attainment.
Coke County	.....	Unclassifiable/Attainment.
Concho County	.....	Unclassifiable/Attainment.
Crane County	.....	Unclassifiable/Attainment.
Crockett County	.....	Unclassifiable/Attainment.
Dawson County	.....	Unclassifiable/Attainment.
Gaines County	.....	Unclassifiable/Attainment.
Glasscock County	.....	Unclassifiable/Attainment.
Howard County	.....	Unclassifiable/Attainment.
Irion County	.....	Unclassifiable/Attainment.
Kimble County	.....	Unclassifiable/Attainment.
Loving County	.....	Unclassifiable/Attainment.
McCulloch County	.....	Unclassifiable/Attainment.
Martin County	.....	Unclassifiable/Attainment.
Mason County	.....	Unclassifiable/Attainment.
Menard County	.....	Unclassifiable/Attainment.
Midland County	.....	Unclassifiable/Attainment.
Pecos County	.....	Unclassifiable/Attainment.
Reagan County	.....	Unclassifiable/Attainment.
Reeves County	.....	Unclassifiable/Attainment.
Schleicher County	.....	Unclassifiable/Attainment.
Sterling County	.....	Unclassifiable/Attainment.
Sutton County	.....	Unclassifiable/Attainment.
Terrell County	.....	Unclassifiable/Attainment.
Tom Green County	.....	Unclassifiable/Attainment.
Upton County	.....	Unclassifiable/Attainment.
Ward County	.....	Unclassifiable/Attainment.
Winkler County	.....	Unclassifiable/Attainment.
Beaumont/Port Arthur, TX:		
Hardin County	.....	Unclassifiable/Attainment.
Jefferson County	.....	Unclassifiable/Attainment.
Orange County	.....	Unclassifiable/Attainment.
Dallas-Fort Worth, TX:		
Collin County	.....	Unclassifiable/Attainment.
Dallas County	.....	Unclassifiable/Attainment.
Denton County	.....	Unclassifiable/Attainment.
Ellis County	.....	Unclassifiable/Attainment.
Johnson County	.....	Unclassifiable/Attainment.
Kaufman County	.....	Unclassifiable/Attainment.
Parker County	.....	Unclassifiable/Attainment.
Rockwall County	.....	Unclassifiable/Attainment.
Tarrant County	.....	Unclassifiable/Attainment.
Houston-Galveston-Brazoria, TX:		
Brazoria County	.....	Unclassifiable/Attainment.
Chambers County	.....	Unclassifiable/Attainment.
Fort Bend County	.....	Unclassifiable/Attainment.
Galveston County	.....	Unclassifiable/Attainment.
Harris County	.....	Unclassifiable/Attainment.
Liberty County	.....	Unclassifiable/Attainment.
Montgomery County	.....	Unclassifiable/Attainment.
Waller County	.....	Unclassifiable/Attainment.
San Antonio, TX:		
Bexar County	.....	Unclassifiable/Attainment.
Comal County	.....	Unclassifiable/Attainment.
Guadalupe County	.....	Unclassifiable/Attainment.
Victoria Area:		
Victoria County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 46. In § 81.345, the table entitled "Utah.—PM2.5" is added to the end of the section to read as follows:

§ 81.345 Utah.

* * * * *

UTAH.—PM2.5

Designated area	Designation[a]	
	Date[1]	Type
Box Elder County, UT (part):		
Box Elder County (except Brigham City)	.....	Unclassifiable/Attainment.
Brigham City, UT:		
Box Elder County (part)	.....	Unclassifiable/Attainment.
The area surrounding Brigham City, as described by the following Townships or the portions of the following Townships in Box Elder County: T9N 2W, T9N R1W, T8N 2W		
Cache County, UT (part):		
Cache County (except Lower Cache Valley)	.....	Unclassifiable/Attainment.
Davis County, UT (part):		
Davis County (except Wasatch Front)	.....	Unclassifiable/Attainment.
Grantsville, UT:		
Tooele County (part)	.....	Unclassifiable/Attainment.
The area surrounding Grantsville, as described by the following Townships or the portions of the following Townships in Tooele County: T2S R6W, T2S R5W, T2S R4W, T3S R6W, T3S R5W, T3S R4W, T4S R6W, T4S R5W, T4S R4W		
Lower Cache Valley, UT:		
Cache County (part)	.....	Unclassifiable/Attainment.
The Cache Valley, below 6500 ft. msl. This area is described by the following list of Townships or the portions of the following Townships in Cache County: T15N R1E, T15N R2W, T15N R1W, T14N R2W, T14N R1W, T14N R1E, T13N R2W, T13N R1W, T13N R1E, T12N R2W, T12N R1W, T12N R1E, T11N R1W, T11N R1E, T10N R1W, T10N R1E, T9N R1E		
Salt Lake County, UT (part)		
Salt Lake County (except Wasatch Front)	.....	Unclassifiable/Attainment.
Tooele County, UT (part):		
Tooele County (remainder)	.....	Unclassifiable/Attainment.
Utah County, UT (part):		
Utah County (except Wasatch Front)	.....	Unclassifiable/Attainment.
Wasatch Front, UT:		
Davis County (part)	.....	Unclassifiable/Attainment.
The portion of the Wasatch Front residing in Davis County, as described by the following Townships or the portions of the following Townships in Davis County: T5N R3W, T5N R2W, T5N R1W, T4N R2W, T4N R1W, T3N R1W, T3N R1E, T2N R1W, T2N R1E, T1N R1W, T1N R1E.		
Salt Lake County (part)	.....	Unclassifiable/Attainment.
The portion of the Wasatch Front residing in Salt Lake County, as described by the following Townships or the portions of the following Townships in Salt Lake County: T1N R2W, T1N R1W, T1N R1E, T1S R3W, T1S R2W, T1S R1W, T1S R1E, T2S R3W, T2S R2W, T2S R1W, T2S R1E, T3S R3W, T3S R2W, T3S R1W, T3S R1E, T4S R3W, T4S R2W, T4S R1W, T4S R1E.		
Utah County (part)	.....	Unclassifiable/Attainment.
The portion of the Wasatch Front residing in Utah County, as described by the following Townships or the portions of the following Townships in Utah County: T4S R2W, T4S R1W, T4S R1E, T4S R2E, T5S R2W, T5S R1W, T5S R1E, T5S R2E, T6S R3W, T6S R2W, T6S R1W, T6S R2E, T6S R3E, T6S R1E, T7S R3W, T7S R2W, T7S R1W, T7S R1E, T7S R2E, T7S R3E, T8S R3W, T8S R2W, T8S R1W, T8S R3E, T8S R2E, T8S R1E, T9S R3W, T9S R2W, T9S R1E, T9S R3E, T9S R2E, T9S R1W, T10S 2W, T10S R2E, T10S R1E, T10S R1W, T1S R2W, T11S R1W, T12S R2W.		
Weber County (part)	.....	Unclassifiable/Attainment.
The portion of the Wasatch Front residing in Weber County, as described by the following Townships or the portions of the following Townships in Weber County: T7N R2W, T7N R1W, T7N R3W, T6N R3W, T6N R2W, T6N R1W, T5N R3W, T5N R2W, T5N R1W		
Weber County, UT (part):		
Weber County (except Wasatch Front)	.....	Unclassifiable/Attainment.
Rest of State:		
Beaver County	.....	Unclassifiable/Attainment.
Carbon County	.....	Unclassifiable/Attainment.
Daggett County	.....	Unclassifiable/Attainment.
Duchesne County	.....	Unclassifiable/Attainment.
Emery County	.....	Unclassifiable/Attainment.
Garfield County	.....	Unclassifiable/Attainment.
Grand County	.....	Unclassifiable/Attainment.
Iron County	.....	Unclassifiable/Attainment.
Juab County	.....	Unclassifiable/Attainment.
Kane County	.....	Unclassifiable/Attainment.
Millard County	.....	Unclassifiable/Attainment.
Morgan County	.....	Unclassifiable/Attainment.
Piute County	.....	Unclassifiable/Attainment.
Rich County	.....	Unclassifiable/Attainment.

UTAH.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
San Juan County	.....	Unclassifiable/Attainment.
Sanpete County	.....	Unclassifiable/Attainment.
Sevier County	.....	Unclassifiable/Attainment.
Summit County	.....	Unclassifiable/Attainment.
Uintah County	.....	Unclassifiable/Attainment.
Wasatch County	.....	Unclassifiable/Attainment.
Washington County	.....	Unclassifiable/Attainment.
Wayne County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 47. In § 81.346, the table entitled "Vermont.—PM2.5" is added to the end of the section to read as follows:

§ 81.346 Vermont.

* * * * *

VERMONT.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
Statewide:		
Addison County	.....	Unclassifiable/Attainment.
Bennington County	.....	Unclassifiable/Attainment.
Caledonia County	.....	Unclassifiable/Attainment.
Chittenden County	.....	Unclassifiable/Attainment.
Essex County	.....	Unclassifiable/Attainment.
Franklin County	.....	Unclassifiable/Attainment.
Grand Isle County	.....	Unclassifiable/Attainment.
Lamoille County	.....	Unclassifiable/Attainment.
Orange County	.....	Unclassifiable/Attainment.
Orleans County	.....	Unclassifiable/Attainment.
Rutland County	.....	Unclassifiable/Attainment.
Washington County	.....	Unclassifiable/Attainment.
Windham County	.....	Unclassifiable/Attainment.
Windsor County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 48. In § 81.347, the table entitled "Virginia.—PM2.5" is added to the end of the section to read as follows:

§ 81.347 Virginia.

* * * * *

VIRGINIA.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
Washington, DC-MD-VA:		
Arlington County	.....	Nonattainment.
Fairfax County	.....	Nonattainment.
Loudoun County	.....	Nonattainment.
Prince William County	.....	Nonattainment.
Alexandria City	.....	Nonattainment.
Fairfax City	.....	Nonattainment.
Falls Church City	.....	Nonattainment.
Manassas City	.....	Nonattainment.
Manassas Park City	.....	Nonattainment.
AQCR 207 Eastern Tennessee-SW Virginia Interstate (remainder of):		
Bland County	.....	Unclassifiable/Attainment.
Buchanan County	.....	Unclassifiable/Attainment.
Carroll County	.....	Unclassifiable/Attainment.
Dickenson County	.....	Unclassifiable/Attainment.
Grayson County	.....	Unclassifiable/Attainment.
Lee County	.....	Unclassifiable/Attainment.

VIRGINIA.—PM2.5—Continued

Designated area	Designation[a]	
	Date[1]	Type
Russell County	.....	Unclassifiable/Attainment.
Scott County	.....	Unclassifiable/Attainment.
Smyth County	.....	Unclassifiable/Attainment.
Tazewell County	.....	Unclassifiable/Attainment.
Washington County	.....	Unclassifiable/Attainment.
Wise County	.....	Unclassifiable/Attainment.
Wythe County	.....	Unclassifiable/Attainment.
Bristol City	.....	Unclassifiable/Attainment.
Galax City	.....	Unclassifiable/Attainment.
Norton City	.....	Unclassifiable/Attainment.
AQCR 222 Central Virginia Intrastate:		
Amelia County	.....	Unclassifiable/Attainment.
Amherst County	.....	Unclassifiable/Attainment.
Appomattox County	.....	Unclassifiable/Attainment.
Bedford County	.....	Unclassifiable/Attainment.
Brunswick County	.....	Unclassifiable/Attainment.
Buckingham County	.....	Unclassifiable/Attainment.
Campbell County	.....	Unclassifiable/Attainment.
Charlotte County	.....	Unclassifiable/Attainment.
Cumberland County	.....	Unclassifiable/Attainment.
Franklin County	.....	Unclassifiable/Attainment.
Halifax County	.....	Unclassifiable/Attainment.
Henry County	.....	Unclassifiable/Attainment.
Lunenburg County	.....	Unclassifiable/Attainment.
Mecklenburg County	.....	Unclassifiable/Attainment.
Nottoway County	.....	Unclassifiable/Attainment.
Patrick County	.....	Unclassifiable/Attainment.
Pittsylvania County	.....	Unclassifiable/Attainment.
Prince Edward County	.....	Unclassifiable/Attainment.
Bedford City	.....	Unclassifiable/Attainment.
Danville City	.....	Unclassifiable/Attainment.
Lynchburg City	.....	Unclassifiable/Attainment.
Martinsville City	.....	Unclassifiable/Attainment.
AQCR 223 Hampton Roads Intrastate (remainder of):		
Southampton County	.....	Unclassifiable/Attainment.
Franklin City	.....	Unclassifiable/Attainment.
AQCR 224 NE Virginia Intrastate (remainder of):		
Accomack County	.....	Unclassifiable/Attainment.
Albemarle County	.....	Unclassifiable/Attainment.
Caroline County	.....	Unclassifiable/Attainment.
Culpeper County	.....	Unclassifiable/Attainment.
Essex County	.....	Unclassifiable/Attainment.
Fauquier County	.....	Unclassifiable/Attainment.
Fluvanna County	.....	Unclassifiable/Attainment.
Greene County	.....	Unclassifiable/Attainment.
King and Queen County	.....	Unclassifiable/Attainment.
King George County	.....	Unclassifiable/Attainment.
King William County	.....	Unclassifiable/Attainment.
Lancaster County	.....	Unclassifiable/Attainment.
Louisa County	.....	Unclassifiable/Attainment.
Madison County	.....	Unclassifiable/Attainment.
Mathews County	.....	Unclassifiable/Attainment.
Middlesex County	.....	Unclassifiable/Attainment.
Nelson County	.....	Unclassifiable/Attainment.
Northampton County	.....	Unclassifiable/Attainment.
Northumberland County	.....	Unclassifiable/Attainment.
Orange County	.....	Unclassifiable/Attainment.
Rappahannock County	.....	Unclassifiable/Attainment.
Richmond County	.....	Unclassifiable/Attainment.
Westmoreland County	.....	Unclassifiable/Attainment.
Charlottesville City	.....	Unclassifiable/Attainment.
AQCR 225 State Capital Intrastate (remainder of):		
Dinwiddie County	.....	Unclassifiable/Attainment.
Goochland County	.....	Unclassifiable/Attainment.
Greensville County	.....	Unclassifiable/Attainment.
New Kent County	.....	Unclassifiable/Attainment.
Powhatan County	.....	Unclassifiable/Attainment.
Surry County	.....	Unclassifiable/Attainment.
Sussex County	.....	Unclassifiable/Attainment.
Emporia City	.....	Unclassifiable/Attainment.

VIRGINIA.—PM2.5—Continued

Designated area	Designation[a]	
	Date[1]	Type
Petersburg City	.....	Unclassifiable/Attainment.
AQCR 226 Valley of Virginia Intrastate:		
Alleghany County	.....	Unclassifiable/Attainment.
Augusta County	.....	Unclassifiable/Attainment.
Bath County	.....	Unclassifiable/Attainment.
Clarke County	.....	Unclassifiable/Attainment.
Craig County	.....	Unclassifiable/Attainment.
Floyd County	.....	Unclassifiable/Attainment.
Giles County	.....	Unclassifiable/Attainment.
Highland County	.....	Unclassifiable/Attainment.
Montgomery County	.....	Unclassifiable/Attainment.
Page County	.....	Unclassifiable/Attainment.
Pulaski County	.....	Unclassifiable/Attainment.
Rockbridge County	.....	Unclassifiable/Attainment.
Rockingham County	.....	Unclassifiable/Attainment.
Shenandoah County	.....	Unclassifiable/Attainment.
Warren County	.....	Unclassifiable/Attainment.
Buena Vista City	.....	Unclassifiable/Attainment.
Covington City	.....	Unclassifiable/Attainment.
Harrisonburg City	.....	Unclassifiable/Attainment.
Lexington City	.....	Unclassifiable/Attainment.
Radford City	.....	Unclassifiable/Attainment.
Staunton City	.....	Unclassifiable/Attainment.
Waynesboro City	.....	Unclassifiable/Attainment.
Frederick Co., VA:		
Frederick County	.....	Unclassifiable/Attainment.
Winchester City	.....	Unclassifiable/Attainment.
Fredericksburg, VA:		
Spotsylvania County	.....	Unclassifiable/Attainment.
Stafford County	.....	Unclassifiable/Attainment.
City of Fredericksburg	.....	Unclassifiable/Attainment.
Norfolk-Virginia-Beach Newport News (Hampton Roads), VA:		
Gloucester County	.....	Unclassifiable/Attainment.
Isle of Wight County	.....	Unclassifiable/Attainment.
James City County	.....	Unclassifiable/Attainment.
York County	.....	Unclassifiable/Attainment.
Chesapeake City	.....	Unclassifiable/Attainment.
Hampton City	.....	Unclassifiable/Attainment.
Newport News City	.....	Unclassifiable/Attainment.
Norfolk City	.....	Unclassifiable/Attainment.
Poquoson City	.....	Unclassifiable/Attainment.
Portsmouth City	.....	Unclassifiable/Attainment.
Suffolk City	.....	Unclassifiable/Attainment.
Virginia Beach City	.....	Unclassifiable/Attainment.
Williamsburg City	.....	Unclassifiable/Attainment.
Richmond-Petersburg, VA:		
Charles City County	.....	Unclassifiable/Attainment.
Chesterfield County	.....	Unclassifiable/Attainment.
Hanover County	.....	Unclassifiable/Attainment.
Henrico County	.....	Unclassifiable/Attainment.
Prince George County	.....	Unclassifiable/Attainment.
Colonial Heights City	.....	Unclassifiable/Attainment.
Hopewell City	.....	Unclassifiable/Attainment.
Richmond City	.....	Unclassifiable/Attainment.
Roanoke, VA:		
Botetourt County	.....	Unclassifiable/Attainment.
Roanoke County	.....	Unclassifiable/Attainment.
Roanoke City	.....	Unclassifiable/Attainment.
Salem City	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 49. In § 81.348, the table entitled "Washington.—PM2.5" is added to the end of the section to read as follows:

§ 81.348 Washington.

* * * * *

WASHINGTON.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
Portland—Vancouver AQMA:		
Clark County (part)		Unclassifiable/Attainment.
Air quality maintenance area		
Seattle—Tacoma Area		Unclassifiable/Attainment.
The following boundary includes all of Pierce County, and all of King County except a small portion on the north-east corner and the western portion of Snohomish County: Starting at the mouth of the Nisqually river extend northwesterly along the Pierce County line to the southernmost point of the west county line of King County; thence northerly along the county line to the southernmost point of the west county line of Snohomish County; thence northerly along the county line to the intersection with SR 532; thence easterly along the north line of SR 532 to the intersection of I–5, continuing east along the same road now identified as Henning Rd., to the intersection with SR 9 at Bryant; thence continuing easterly on Bryant East Rd. and Rock Creek Rd., also identified as Grandview Rd., approximately 3 miles to the point at which it is crossed by the existing BPA electrical transmission line; thence southeasterly along the BPA transmission line approximately 8 miles to point of the crossing of the south fork of the Stillaguamish River; thence continuing in a southeasterly direction in a meander line following the bed of the River to Jordan Road; southerly along Jordan Road to the north city limits of Granite Falls; thence following the north and east city limits to 92nd St. N.E. and Menzel Lake Rd.; thence south-southeasterly along the Menzel Lake Rd. and the Lake Roesiger Rd. a distance of approximately 6 miles to the northernmost point of Lake Roesiger; thence southerly along a meander line following the middle of the Lake and Roesiger Creek to Woods Creek; thence southerly along a meander line following the bed of the Creek approximately 6 miles to the point the Creek is crossed by the existing BPA electrical transmission line; thence easterly along the BPA transmission line approximately 0.2 miles; thence southerly along the BPA Chief Joseph-Covington electrical transmission line approximately 3 miles to the north line of SR 2; thence southeasterly along SR 2 to the intersection with the east county line of King County; thence south along the county line to the northernmost point of the east county line of Pierce County; thence along the county line to the point of beginning at the mouth of the Nisqually River.		
AQCR 062 E Washington-N Idaho Interstate (part):		
Spokane County		Unclassifiable/Attainment.
AQCR 062 E Washington-N Idaho Interstate (remainder of):		
Adams County		Unclassifiable/Attainment.
Asotin County		Unclassifiable/Attainment.
Columbia County		Unclassifiable/Attainment.
Garfield County		Unclassifiable/Attainment.
Grant County		Unclassifiable/Attainment.
Lincoln County		Unclassifiable/Attainment.
Whitman County		Unclassifiable/Attainment.
AQCR 193 Portland Interstate (remainder of):		
Clark County (remainder)		Unclassifiable/Attainment.
Cowlitz County		Unclassifiable/Attainment.
Lewis County		Unclassifiable/Attainment.
Skamania County		Unclassifiable/Attainment.
Wahkiakum County		Unclassifiable/Attainment.
AQCR 227 Northern Washington Intrastate:		
Chelan County		Unclassifiable/Attainment.
Douglas County		Unclassifiable/Attainment.
Ferry County		Unclassifiable/Attainment.
Okanogan County		Unclassifiable/Attainment.
Pend Oreille County		Unclassifiable/Attainment.
Stevens County		Unclassifiable/Attainment.
AQCR 228 Olympic-Northwest Washington Intrastate:		
Clallam County		Unclassifiable/Attainment.
Grays Harbor County		Unclassifiable/Attainment.
Island County		Unclassifiable/Attainment.
Jefferson County		Unclassifiable/Attainment.
Mason County		Unclassifiable/Attainment.
Pacific County		Unclassifiable/Attainment.
San Juan County		Unclassifiable/Attainment.
Skagit County		Unclassifiable/Attainment.
Thurston County		Unclassifiable/Attainment.
Whatcom County		Unclassifiable/Attainment.
AQCR 229 Puget Sound Intrastate (remainder of):		
King County (remainder)		Unclassifiable/Attainment.
Kitsap County		Unclassifiable/Attainment.
Snohomish County (remainder)		Unclassifiable/Attainment.
AQCR 230 South Central Washington Intrastate:		
Benton County		Unclassifiable/Attainment.

WASHINGTON.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Franklin County	.....	Unclassifiable/Attainment.
Kittitas County	.....	Unclassifiable/Attainment.
Klickitat County	.....	Unclassifiable/Attainment.
Walla Walla County	.....	Unclassifiable/Attainment.
Yakima County	.....	Unclassifiable/Attainment.
Seattle-Tacoma Area:		
Pierce County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 50. In § 81.349, the table entitled "West Virginia.—PM2.5" is added to the end of the section to read as follows:

§ 81.349 West Virginia.

* * * * *

WEST VIRGINIA.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
Charleston, WV:		
Kanawha County	.....	Nonattainment.
Putnam County	.....	Nonattainment.
Huntington-Ashland, WV-KY-OH:		
Cabell County	.....	Nonattainment.
Mason County (part)	.....	Nonattainment.
Graham Tax District		
Wayne County	.....	Nonattainment.
Marion County, WV (aka Fairmont CBSA):		
Harrison County (part)	.....	Nonattainment.
Tax District of Clay		
Marion County	.....	Nonattainment.
Monongalia County (part)	.....	Nonattainment.
Tax District of Cass		
Martinsburg, WV-Hagerstown, MD:		
Berkeley County	.....	Nonattainment.
Parkersburg-Marietta, WV-OH:		
Pleasants County (part)	.....	Nonattainment.
Tax District of Grant		
Wood County	.....	Nonattainment.
Steubenville-Weirton, OH-WV:		
Brooke County	.....	Nonattainment.
Hancock County	.....	Nonattainment.
Wheeling, WV-OH:		
Marshall County	.....	Nonattainment.
Ohio County	.....	Nonattainment.
Rest of State:		
Barbour County	.....	Unclassifiable/Attainment.
Boone County	.....	Unclassifiable/Attainment.
Braxton County	.....	Unclassifiable/Attainment.
Calhoun County	.....	Unclassifiable/Attainment.
Clay County	.....	Unclassifiable/Attainment.
Doddridge County	.....	Unclassifiable/Attainment.
Fayette County	.....	Unclassifiable/Attainment.
Gilmer County	.....	Unclassifiable/Attainment.
Grant County	.....	Unclassifiable/Attainment.
Greenbrier County	.....	Unclassifiable/Attainment.
Hampshire County	.....	Unclassifiable/Attainment.
Hardy County	.....	Unclassifiable/Attainment.
Harrison County (remainder)	.....	Unclassifiable/Attainment.
Jackson County	.....	Unclassifiable/Attainment.
Jefferson County	.....	Unclassifiable/Attainment.
Lewis County	.....	Unclassifiable/Attainment.
Lincoln County	.....	Unclassifiable/Attainment.
Logan County	.....	Unclassifiable/Attainment.
McDowell County	.....	Unclassifiable/Attainment.
Mason County (remainder)	.....	Unclassifiable/Attainment.
Mercer County	.....	Unclassifiable/Attainment.
Mineral County	.....	Unclassifiable/Attainment.

WEST VIRGINIA.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Mingo County	.....	Unclassifiable/Attainment.
Monongalia County (remainder)	.....	Unclassifiable/Attainment.
Monroe County	.....	Unclassifiable/Attainment.
Morgan County	.....	Unclassifiable/Attainment.
Nicholas County	.....	Unclassifiable/Attainment.
Pendleton County	.....	Unclassifiable/Attainment.
Pleasants County (remainder)	.....	Unclassifiable/Attainment.
Pocahontas County	.....	Unclassifiable/Attainment.
Preston County	.....	Unclassifiable/Attainment.
Raleigh County	.....	Unclassifiable/Attainment.
Randolph County	.....	Unclassifiable/Attainment.
Ritchie County	.....	Unclassifiable/Attainment.
Roane County	.....	Unclassifiable/Attainment.
Summers County	.....	Unclassifiable/Attainment.
Taylor County	.....	Unclassifiable/Attainment.
Tucker County	.....	Unclassifiable/Attainment.
Tyler County	.....	Unclassifiable/Attainment.
Upshur County	.....	Unclassifiable/Attainment.
Webster County	.....	Unclassifiable/Attainment.
Wetzel County	.....	Unclassifiable/Attainment.
Wirt County	.....	Unclassifiable/Attainment.
Wyoming County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 51. In § 81.350, the table entitled "Wisconsin.—PM2.5" is added to the end of the section to read as follows:

§ 81.350 Wisconsin.

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WISCONSIN.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
Statewide:		
Adams County	.....	Unclassifiable/Attainment.
Ashland County	.....	Unclassifiable/Attainment.
Barron County	.....	Unclassifiable/Attainment.
Bayfield County	.....	Unclassifiable/Attainment.
Brown County	.....	Unclassifiable/Attainment.
Buffalo County	.....	Unclassifiable/Attainment.
Burnett County	.....	Unclassifiable/Attainment.
Calumet County	.....	Unclassifiable/Attainment.
Chippewa County	.....	Unclassifiable/Attainment.
Clark County	.....	Unclassifiable/Attainment.
Columbia County	.....	Unclassifiable/Attainment.
Crawford County	.....	Unclassifiable/Attainment.
Dane County	.....	Unclassifiable/Attainment.
Dodge County	.....	Unclassifiable/Attainment.
Door County	.....	Unclassifiable/Attainment.
Douglas County	.....	Unclassifiable/Attainment.
Dunn County	.....	Unclassifiable/Attainment.
Eau Claire County	.....	Unclassifiable/Attainment.
Florence County	.....	Unclassifiable/Attainment.
Fond du Lac County	.....	Unclassifiable/Attainment.
Forest County	.....	Unclassifiable/Attainment.
Grant County	.....	Unclassifiable/Attainment.
Green County	.....	Unclassifiable/Attainment.
Green Lake County	.....	Unclassifiable/Attainment.
Iowa County	.....	Unclassifiable/Attainment.
Iron County	.....	Unclassifiable/Attainment.
Jackson County	.....	Unclassifiable/Attainment.
Jefferson County	.....	Unclassifiable/Attainment.
Juneau County	.....	Unclassifiable/Attainment.
Kenosha County	.....	Unclassifiable/Attainment.
Kewaunee County	.....	Unclassifiable/Attainment.
La Crosse County	.....	Unclassifiable/Attainment.

WISCONSIN.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Lafayette County	.....	Unclassifiable/Attainment.
Langlade County	.....	Unclassifiable/Attainment.
Lincoln County	.....	Unclassifiable/Attainment.
Manitowoc County	.....	Unclassifiable/Attainment.
Marathon County	.....	Unclassifiable/Attainment.
Marinette County	.....	Unclassifiable/Attainment.
Marquette County	.....	Unclassifiable/Attainment.
Menominee County	.....	Unclassifiable/Attainment.
Milwaukee County	.....	Unclassifiable/Attainment.
Monroe County	.....	Unclassifiable/Attainment.
Oconto County	.....	Unclassifiable/Attainment.
Oneida County	.....	Unclassifiable/Attainment.
Outagamie County	.....	Unclassifiable/Attainment.
Ozaukee County	.....	Unclassifiable/Attainment.
Pepin County	.....	Unclassifiable/Attainment.
Pierce County	.....	Unclassifiable/Attainment.
Polk County	.....	Unclassifiable/Attainment.
Portage County	.....	Unclassifiable/Attainment.
Price County	.....	Unclassifiable/Attainment.
Racine County	.....	Unclassifiable/Attainment.
Richland County	.....	Unclassifiable/Attainment.
Rock County	.....	Unclassifiable/Attainment.
Rusk County	.....	Unclassifiable/Attainment.
St. Croix County	.....	Unclassifiable/Attainment.
Sauk County	.....	Unclassifiable/Attainment.
Sawyer County	.....	Unclassifiable/Attainment.
Shawano County	.....	Unclassifiable/Attainment.
Sheboygan County	.....	Unclassifiable/Attainment.
Taylor County	.....	Unclassifiable/Attainment.
Trempealeau County	.....	Unclassifiable/Attainment.
Vernon County	.....	Unclassifiable/Attainment.
Vilas County	.....	Unclassifiable/Attainment.
Walworth County	.....	Unclassifiable/Attainment.
Washburn County	.....	Unclassifiable/Attainment.
Washington County	.....	Unclassifiable/Attainment.
Waukesha County	.....	Unclassifiable/Attainment.
Waupaca County	.....	Unclassifiable/Attainment.
Waushara County	.....	Unclassifiable/Attainment.
Winnebago County	.....	Unclassifiable/Attainment.
Wood County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 52. In § 81.351, the table entitled "Wyoming.—PM2.5" is added to the end of the section to read as follows:

§ 81.351 Wyoming.

* * * * *

WYOMING.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
Casper, WY:		
Natrona County (part)	.....	Unclassifiable/Attainment.
The portion within the City of Casper		
Cheyenne, WY:		
Laramie County (part)	.....	Unclassifiable/Attainment.
The portion within the City of Cheyenne		
Evanston, WY:		
Uinta County (part)	.....	Unclassifiable/Attainment.
The portion within the City of Evanston		
Gillette, WY:		
Campbell County (part)	.....	Unclassifiable/Attainment.
The portion within the City of Gillette		
Jackson, WY:		
Teton County (part)	.....	Unclassifiable/Attainment.
The portion within the City of Jackson		

WYOMING.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Lander, WY:		
Fremont County (part)	.....	Unclassifiable/Attainment.
The portion within the City of Lander		
Laramie, WY:		
Albany County (part)	.....	Unclassifiable/Attainment.
The portion within the City of Laramie		
Riverton, WY:		
Fremont County (part)	.....	Unclassifiable/Attainment.
The portion within the City of Riverton		
Rock Springs, WY		
Sweetwater County (part)	.....	Unclassifiable/Attainment.
The portion within the City of Rock Springs		
Sheridan, WY:		
Sheridan County (part)	.....	Unclassifiable/Attainment.
The portion within the City of Sheridan		
Rest of State:		
Albany County (remainder)	.....	Unclassifiable/Attainment.
Big Horn County	.....	Unclassifiable/Attainment.
Campbell County	.....	Unclassifiable/Attainment.
Carbon County	.....	Unclassifiable/Attainment.
Converse County	.....	Unclassifiable/Attainment.
Crook County	.....	Unclassifiable/Attainment.
Fremont County (remainder)	.....	Unclassifiable/Attainment.
Goshen County	.....	Unclassifiable/Attainment.
Hot Springs County	.....	Unclassifiable/Attainment.
Johnson County	.....	Unclassifiable/Attainment.
Laramie County (remainder)	.....	Unclassifiable/Attainment.
Lincoln County	.....	Unclassifiable/Attainment.
Natrona County (remainder)	.....	Unclassifiable/Attainment.
Niobrara County	.....	Unclassifiable/Attainment.
Park County	.....	Unclassifiable/Attainment.
Platte County	.....	Unclassifiable/Attainment.
Sheridan County (remainder)	.....	Unclassifiable/Attainment.
Sublette County	.....	Unclassifiable/Attainment.
Sweetwater County	.....	Unclassifiable/Attainment.
Teton County (remainder)	.....	Unclassifiable/Attainment.
Uinta County (remainder)	.....	Unclassifiable/Attainment.
Washakie County	.....	Unclassifiable/Attainment.
Weston County	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ In § 81.352, the table entitled "American Samoa.—PM2.5" is added to the end of the section to read as follows:

§ 81.352 American Samoa.

* * * * *

AMERICAN SAMOA.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
Statewide:		
Eastern District	.....	Unclassifiable/Attainment.
Manu'a District	.....	Unclassifiable/Attainment.
Rose Island	.....	Unclassifiable/Attainment.
Swains Island	.....	Unclassifiable/Attainment.
Western District	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 54. In § 81.353, the table entitled "Guam.—PM2.5" is added to the end of the section to read as follows:

§ 81.353 Guam.

* * * * *

GUAM.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
Statewide:		
Guam	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 55. In § 81.354, the table entitled "Northern Mariana Islands.—PM2.5" is added to the end of the section to read as follows:

§ 81.354 Northern Mariana Islands.

* * * * *

NORTHERN MARIANA ISLANDS.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
Statewide:		
Northern Islands Municipality	.....	Unclassifiable/Attainment.
Rota Municipality	.....	Unclassifiable/Attainment.
Saipan Municipality	.....	Unclassifiable/Attainment.
Tinian Municipality	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 56. In § 81.355, the table entitled "Puerto Rico.—PM2.5" is added to the end of the section to read as follows:

§ 81.355 Puerto Rico.

* * * * *

PUERTO RICO.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
Statewide:		
Adjuntas Municipio	.....	Unclassifiable/Attainment.
Aguada Municipio	.....	Unclassifiable/Attainment.
Aguadilla Municipio	.....	Unclassifiable/Attainment.
Aguas Buenas Municipio	.....	Unclassifiable/Attainment.
Aibonito Municipio	.....	Unclassifiable/Attainment.
Añasco Municipio	.....	Unclassifiable/Attainment.
Arecibo Municipio	.....	Unclassifiable/Attainment.
Arroyo Municipio	.....	Unclassifiable/Attainment.
Barceloneta Municipio	.....	Unclassifiable/Attainment.
Barranquit'as Municipio	.....	Unclassifiable/Attainment.
Bayamón County	.....	Unclassifiable/Attainment.
Cabo Rojo Municipio	.....	Unclassifiable/Attainment.
Caguas Municipio	.....	Unclassifiable/Attainment.
Camuy Municipio	.....	Unclassifiable/Attainment.
Canóvanas Municipio	.....	Unclassifiable/Attainment.
Carolina Municipio	.....	Unclassifiable/Attainment.
Cataño County	.....	Unclassifiable/Attainment.
Cayey Municipio	.....	Unclassifiable/Attainment.
Ceiba Municipio	.....	Unclassifiable/Attainment.
Ciales Municipio	.....	Unclassifiable/Attainment.
Cidra Municipio	.....	Unclassifiable/Attainment.
Coamo Municipio	.....	Unclassifiable/Attainment.
Comerío Municipio	.....	Unclassifiable/Attainment.
Corozal Municipio	.....	Unclassifiable/Attainment.
Culebra Municipio	.....	Unclassifiable/Attainment.
Dorado Municipio	.....	Unclassifiable/Attainment.
Fajardo Municipio	.....	Unclassifiable/Attainment.
Florida Municipio	.....	Unclassifiable/Attainment.
Guánica Municipio	.....	Unclassifiable/Attainment.
Guayama Municipio	.....	Unclassifiable/Attainment.
Guayanilla Municipio	.....	Unclassifiable/Attainment.
Guaynabo County	.....	Unclassifiable/Attainment.
Gurabo Municipio	.....	Unclassifiable/Attainment.
Hatillo Municipio	.....	Unclassifiable/Attainment.

PUERTO RICO.—PM2.5—Continued

Designated area	Designation [a]	
	Date [1]	Type
Hormigueros Municipio	.....	Unclassifiable/Attainment.
Humacao Municipio	.....	Unclassifiable/Attainment.
Isabela Municipio	.....	Unclassifiable/Attainment.
Jayuya Municipio	.....	Unclassifiable/Attainment.
Juana Díaz Municipio	.....	Unclassifiable/Attainment.
Juncos Municipio	.....	Unclassifiable/Attainment.
Lajas Municipio	.....	Unclassifiable/Attainment.
Lares Municipio	.....	Unclassifiable/Attainment.
Las Marías Municipio	.....	Unclassifiable/Attainment.
Las Piedras Municipio	.....	Unclassifiable/Attainment.
Loíza Municipio	.....	Unclassifiable/Attainment.
Luquillo Municipio	.....	Unclassifiable/Attainment.
Manatí Municipio	.....	Unclassifiable/Attainment.
Maricao Municipio	.....	Unclassifiable/Attainment.
Maunabo Municipio	.....	Unclassifiable/Attainment.
Mayagnez Municipio	.....	Unclassifiable/Attainment.
Moca Municipio	.....	Unclassifiable/Attainment.
Morovis Municipio	.....	Unclassifiable/Attainment.
Naguabo Municipio	.....	Unclassifiable/Attainment.
Naranjito Municipio	.....	Unclassifiable/Attainment.
Orocovis Municipio	.....	Unclassifiable/Attainment.
Patillas Municipio	.....	Unclassifiable/Attainment.
Peñuelas Municipio	.....	Unclassifiable/Attainment.
Ponce Municipio	.....	Unclassifiable/Attainment.
Quebradillas Municipio	.....	Unclassifiable/Attainment.
Rincón Municipio	.....	Unclassifiable/Attainment.
Río Grande Municipio	.....	Unclassifiable/Attainment.
Sabana Grande Municipio	.....	Unclassifiable/Attainment.
Salinas Municipio	.....	Unclassifiable/Attainment.
San Germán Municipio	.....	Unclassifiable/Attainment.
San Juan Municipio	.....	Unclassifiable/Attainment.
San Lorenzo Municipio	.....	Unclassifiable/Attainment.
San Sebastián Municipio	.....	Unclassifiable/Attainment.
Santa Isabel Municipio	.....	Unclassifiable/Attainment.
Toa Alta Municipio	.....	Unclassifiable/Attainment.
Toa Baja County	.....	Unclassifiable/Attainment.
Trujillo Alto Municipio	.....	Unclassifiable/Attainment.
Utuado Municipio	.....	Unclassifiable/Attainment.
Vega Alta Municipio	.....	Unclassifiable/Attainment.
Vega Baja Municipio	.....	Unclassifiable/Attainment.
Vieques Municipio	.....	Unclassifiable/Attainment.
Villalba Municipio	.....	Unclassifiable/Attainment.
Yabucoa Municipio	.....	Unclassifiable/Attainment.
Yauco Municipio	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

■ 57. In § 81.356, the table entitled "Virgin Islands.—PM2.5" is added to the end of the section to read as follows:

§ 81.356 Virgin Islands.

* * * * *

VIRGIN ISLANDS.—PM2.5

Designated area	Designation [a]	
	Date [1]	Type
Statewide:		
St. Croix	.....	Unclassifiable/Attainment.
St. John	.....	Unclassifiable/Attainment.
St. Thomas	.....	Unclassifiable/Attainment.

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.

[FR Doc. 05–1 Filed 1–4–05; 8:45 am]
BILLING CODE 6560–50–P

Federal Register

Wednesday,
January 5, 2005

Part III

Department of Agriculture

Forest Service

36 CFR Part 219

National Forest System Land and Resource Management Planning; Removal of 2000 Planning Rule; National Environmental Policy Act Documentation Needed for Developing, Revising, or Amending Land Management Plans; Categorical Exclusion; Final Rules and Notice

DEPARTMENT OF AGRICULTURE

Forest Service

36 CFR Part 219

RIN 0596–AB86

National Forest System Land and Resource Management Planning; Removal of 2000 Planning Rule

AGENCY: Forest Service, USDA.

ACTION: Final rule.

SUMMARY: The Department of Agriculture is issuing a final rule to remove the November 9, 2000, National Forest System Land and Resource Management Planning regulations at Title 36, Code of Federal Regulations, part 219, subpart A, in their entirety. Subsequent to the publication of the 2000 planning rule, several amendments were published to revise certain sections of the rule and to provide for transition to the 2000 rule. This action to remove the 2000 rule is being taken before the adoption of the new 2004 planning rule to clarify and avoid any confusion about which planning regulations the Department intends to be used to implement the National Forest Management Act of 1976. Elsewhere in this part of today's **Federal Register**, the Department is simultaneously publishing another final rule to add the new (2004) planning regulations at 36 CFR part 219, subpart A.

EFFECTIVE DATE: This rule is effective January 5, 2005.

FOR FURTHER INFORMATION CONTACT: Dave Barone, Planning Specialist, Ecosystem Management Coordination Staff, Forest Service, USDA at (202) 205–1019.

SUPPLEMENTARY INFORMATION:

Background

On November 9, 2000 (65 FR 67514), the Department adopted planning regulations for the National Forest System at 36 CFR part 219, subpart A (65 FR 67514). Despite the positive aspects of the 2000 rule, however, the number of very detailed analytical requirements, the lack of clarity regarding many of the requirements, the lack of flexibility, and the lack of recognition of the limits of agency budgets and personnel led to a reconsideration of this rule in the spring of 2001. After careful review of concerns expressed internally and externally about this 2000 planning rule, the Department requested the Forest Service to develop a proposed planning rule to revise the 2000 rule. A proposed planning rule was published for public notice and comment on December 6, 2002 (67 FR 72770).

Transition language at § 219.35(b) of the 2000 rule was revised on May 17, 2001 (66 FR 27552), and again on May 20, 2002 (67 FR 35431), to allow a responsible official to elect to continue or to initiate new plan amendments or revisions under the planning regulations in effect prior to November 9, 2000 (*see* 36 CFR parts 200 to 299, revised as of July 1, 2000), or to conduct the amendment or revision process in conformance with the provisions of the 2000 rule. To date, no unit of the National Forest System has elected to use the 2000 planning rule for plan amendments or revisions. All plan amendments and revisions have been made under the provisions of the planning regulations in effect prior to November 9, 2000.

Transition language at § 219.35(d) of the 2000 rule was revised by the interim final rule published on September 10, 2003 (68 FR 53294) to extend the date by which site-specific decisions made by the responsible official must conform with provisions of the 2000 planning rule from November 9, 2003, until the Department promulgates the final planning regulations published as proposed on December 6, 2002 (67 FR 72770). The Department is promulgating these final planning regulations in the final rule to 36 CFR part 219, subpart A, published simultaneously elsewhere in this part of today's **Federal Register**.

The final planning rule added today at 36 CFR part 219, subpart A, and published elsewhere in this part of today's **Federal Register**, has new transition language that clearly describes the Department's intent on when the new 2004 planning regulations must be used and when regulations published previously at 36 CFR part 219, subpart A, may be used. Furthermore, in order to avoid any possible confusion within the Forest Service, other agencies, and the public regarding which revision of the planning regulations should be followed, the Department has determined that removing the November 2000 planning regulations in their entirety is necessary.

Regulatory Certifications

Regulatory Impact

This final rule has been reviewed under USDA procedures and Executive Order (E.O.) 12866, Regulatory Planning and Review. It has been determined that this is not an economically significant rule. This rule would not have an annual effect of $100 million or more on the economy nor adversely affect productivity, competition, jobs, the environment, public health or safety, nor State or local governments. This final rule would not interfere with an action taken or planned by another agency nor raise new legal or policy issues. Finally, this rule would not alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients of such programs.

Moreover, this final rule has been considered in light of Executive Order 13272 regarding proper consideration of small entities and the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), which amended the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). No direct or indirect financial impact on small businesses or other entities has been identified. Therefore, it is hereby certified that this final rule will not have a significant economic impact on a substantial number of small entities as defined by the act.

Environmental Impact

This final rule has no direct or indirect effect on the environment and is merely procedural in nature to clarify that the planning rule adopted by the Department on November 9, 2000, and all of its requirements and provisions, is being removed in its entirety from 36 CFR part 219, subpart A, prior to the adoption of the new 2004 final planning rule at 36 CFR part 219, subpart A, which is published simultaneously elsewhere in this part of today's **Federal Register**. Section 31.1b of Forest Service Handbook 1909.15 (57 FR 43168; September 18, 1992) excludes from documentation in an environmental assessment or environmental impact statement "rules, regulations, or policies to establish Service-wide administrative procedures, program processes, or instruction." Based upon the scope of this rulemaking and its procedural nature, the Department has determined that this final rule falls within this category of actions and that no extraordinary circumstances exist which would require preparation of an environmental assessment or an environmental impact statement.

No Takings Implications

This final rule has been analyzed in accordance with the principles and criteria contained in Executive Order 12360, and it has been determined that it would not pose the risk of a taking of private property, as this final rule is limited to the establishment of administrative procedures.

Energy Effects

This final rule has been analyzed under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. It has been determined that this rule does not constitute a significant energy action as defined in the Executive order.

Civil Justice Reform

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. The Department has not identified any State or local laws or regulations that are in conflict with or that would impede full implementation of this rule.

Unfunded Mandates

Pursuant to Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538), which the President signed into law on March 22, 1995, the Department has assessed the effects of this final rule on State, local, and Tribal governments and on the private sector. This rule does not compel the expenditure of $100 million or more by any State, local, or Tribal government, or anyone in the private sector. Therefore, a statement under section 202 of the act is not required.

Federalism

The Department has considered this final rule under the requirements of Executive Order 13132, Federalism. The Department has made an assessment that this rule conforms with the federalism principles set out in this Executive order; would not impose any significant compliance costs on the States; and would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, the Department concludes that this rule does not have federalism implications.

Consultation and Coordination with Indian Tribal Governments

This final rule does not have Tribal implications as defined by Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, and, therefore, advance consultation with Tribes is not required.

Controlling Paperwork Burdens on the Public

This final rule does not contain any record keeping or reporting requirements or other information collection requirements as defined in 5 CFR part 1320 and, therefore, imposes no paperwork burden on the public. Accordingly, the review provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*) and implementing regulations at 5 CFR part 1320 do not apply.

Government Paperwork Elimination Act Compliance

The Department is committed to compliance with the Government Paperwork Elimination Act (44 U.S.C. 3504), which requires Government agencies to provide the public the option of submitting information or transacting business electronically to the maximum extent possible.

List of Subjects in 36 CFR 219

Administrative practice and procedure, Environmental impact statements, Indians, Intergovernmental relations, Forest and forest products, National forests, Natural resources, Reporting and recordkeeping requirements, Science and technology.

■ Therefore, for the reasons set forth in the preamble, amend chapter II of title 36 of the Code of Federal Regulations as follows:

PART 219—PLANNING

Subpart A—[Removed and Reserved]

■ 1. In part 219, remove and reserve subpart A.

Dated: December 22, 2004.

Mark Rey,

Under Secretary, Natural Resources and Environment.

[FR Doc. 05–20 Filed 1–4–05; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Forest Service

36 CFR Part 219

RIN 0596–AB86

National Forest System Land Management Planning

AGENCY: Forest Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule describes the National Forest System land management planning framework; establishes requirements for sustainability of social, economic, and ecological systems and developing, amending, revising, and monitoring land management plans; and clarifies that land management plans under this final rule, absent extraordinary circumstances, are strategic in nature and are one stage in an adaptive cycle of planning for management of National Forest System lands. The intended effects of the final rule are to streamline and improve the planning process by making plans more adaptable to changes in social, economic, and environmental conditions; to strengthen the role of science in planning; to strengthen collaborative relationships with the public and other governmental entities; and to reaffirm the principle of sustainable management consistent with the Multiple-Use Sustained-Yield Act and other authorities.

Elsewhere in this part of today's **Federal Register**, the Department of Agriculture is simultaneously publishing another final rule to remove the planning regulations adopted on November 9, 2000.

DATES: *Effective Date:* This rule is effective January 5, 2005.

ADDRESSES: The following information is posted on the World Wide Web/Internet at *http://www.fs.fed.us/emc/nfma/*: (1) This final rule; (2) supplemental responses to substantive public comments and a description of the changes, if any, made in response to those comments and the reasons for those changes to the 2002 proposed rule; (3) the Civil Rights Impact Analysis for this final rule; (4) the cost-benefit analysis for this final rule; (5) the business model cost study done to estimate predicted costs to implement the 2000 planning rule and the 2002 proposed rule, and (6) the notice of proposed National Environmental Policy Act implementing procedures; request for comment. This information may also be obtained upon written request from the Director, Ecosystem Management Coordination Staff, Forest Service, USDA, Mail Stop 1104, 1400 Independence Avenue, SW., Washington, DC 20250–1104.

FOR FURTHER INFORMATION CONTACT: Dave Barone, Acting Assistant Director for Planning; Ecosystem Management Coordination Staff (202) 205–1019, or Regis Terney, Planning Specialist, Ecosystem Management Coordination Staff (202) 205–1552.

SUPPLEMENTARY INFORMATION:

Table of Contents

1. Forest Service Directives

The Forest Service is developing planning directives to set forth the legal authorities, objectives, policy, responsibilities, direction, and overall guidance needed by Forest Service line officers, agency employees, and others to use this planning rule. A request for public comment on the Forest Service directives will be published in the **Federal Register** as soon as possible after adoption of this final rule.

2. Events Since Publication of the 2002 Proposed Rule

The 2002 proposed rule was released for public review and comment in Volume 67 of the **Federal Register**, page 72770, December 6, 2002. Between February 18–20, 2003, during the comment period, scientists, experts in public land management issues, resource professionals, Tribal officials, State officials, local government officials, and the public participated in a diversity options workshop. In addition, the public comment period on the 2002 proposed rule was extended from March 6, 2003 to April 7, 2003 (68 FR 10420, Mar. 5, 2003). The agency received about 195,000 comments, of which approximately 7,000 were original letters. All of the substantive comments on the 2002 proposed rule were carefully considered and led to a number of changes in this final rule.

Also, interim final rules extending the transition from the 1982 planning rule to the 2000 planning rule were published in 2001 (66 FR 27552, May 17, 2001) and 2002 (67 FR 35431, May 20, 2002), the latter rule allowing Forest Service managers to elect to continue preparing plan amendments and revisions under the 1982 planning rule until a new final rule is adopted. Finally, an interim rule was published in 2003 (68 FR 53294, Sept. 10, 2003) extending the date by which site-specific project decisions must conform with provisions of the 2000 planning rule until replaced with a new rule. To date, Forest Service officials have elected to use the 1982 planning rule for all plan development, amendments, and revisions.

3. Overview of the Final 2004 Rule

This final rule embodies a paradigm shift in land management planning based, in part, on the Forest Service's 25 years of experience developing plans under the 1982 planning rule. Having assessed the current system's flaws and benefits during this extended period, the Forest Service believes it is time to think differently about National Forest System (NFS) planning and management. Thus, based on the agency's expertise and experience, the Forest Service created this final rule to enable a better way to protect the environment and to facilitate working with the public. The final rule prioritizes agency resources to monitoring and, when necessary, provides a process to change plans to ensure that clean air, clean water, and abundant wildlife are available for future generations. This final rule allows the Forest Service to rapidly respond to changing conditions like hazardous fuels, new science, and many other dynamics that affect NFS management. Protection and management of the NFS should be based on sound science, which is fundamental to this final rule.

This final rule assures the public an effective voice in the entire planning process from beginning to end. Finally, because this final rule provides for more efficient planning, more resources will be shifted to the public's expressed priorities, that is, improved conservation of the forests and grasslands and better responses to the real threats the forests and grasslands face, such as critical wildfire danger and invasive species which degrade ecological systems.

To achieve these important goals, plans under this final rule will be more strategic and less prescriptive in nature than under the 1982 planning rule. Emphasizing the strategic nature of plans under this rule is the most effective means of guiding NFS management in light of changing conditions, science and technology. Specifically, plans under this final rule will not contain final decisions that approve projects or activities except under extraordinary circumstances. Rather, as described further below, plans under this final rule will contain five components, which set forth broad policies to help guide future decisions on the ground: The plan components are desired conditions, objectives, guidelines, suitability of areas, and special areas.

Major Themes and Areas of Public Comment in the Final Rule

The major themes of the final rule discussed in this preamble reflect the public comments received on the 2002 proposed rule. This final rule sets forth the process for NFS land management planning, including the requirements for complying with the National Forest Management Act (NFMA) of 1976 (16 U.S.C. 1600 *et seq.*) during development, amendment, and revision of land management plans (plans) for NFS units, including the national forests, grasslands, prairie, or other comparable administrative units. The Forest Service has prepared and revised plans more than 150 times since enactment of NFMA and expects to complete more than 100 additional plans and revisions during the next decade. The Forest Service has also been amending plans during the last 25 years. Based on the experience gained and public comments on the 2002 proposed rule, the U.S. Department of Agriculture (Department) has concluded that this final rule should be based on the following principles and practical considerations:

- *Plans should be strategic in nature.* The purpose of plans should be to establish goals for forests, grasslands, and prairies and set forth the guidance to follow in pursuit of those goals. Such goals can be expressed by describing: desired conditions, objectives, guidelines, suitability or areas, and

special areas. Typically, a plan does not include final decisions approving projects or activities.

• *Plans must be adaptive and based on current information and science.*

During the 15-year life expectancy of a plan, information, science, and unforeseen circumstances evolve. It must be possible to adjust plans and the plan-monitoring program and to react to new information and science swiftly and efficiently. An environmental management system (EMS) approach will enhance adaptive planning and should be part of the land management framework.

• *Land management planning must involve the public.*

Plans are prepared for public lands. Public participation and collaboration needs to be welcomed and encouraged as a part of planning. To the extent possible, Responsible Officials need to work collaboratively with the public to help balance conflicting needs, to evaluate management under the plans, and to consider the need to adjust plans.

• *Plans must guide sustainable management of NFS lands.*

The Multiple-Use Sustained-Yield Act (MUSYA) of 1960 (16 U.S.C. 528–531) requires that NFS lands be managed to provide a continuous flow of goods and services to the nation. To meet this requirement, plans must focus on providing a sustainable framework—based on social, economic, and ecological systems—that guides on-the-ground management of projects and activities, which provide these goods and services.

• *Planning must comply with all applicable laws, regulations, and policies.*

Planning must comply with all applicable laws, regulations, and policies, although all these requirements do not need to be restated in a plan. For example, the Clean Water Act includes requirements for nonpoint source management programs, to be administered by the States. The States or the Forest Service then develops Best Management Practices (BMPs) for use in design of projects or activities on NFS lands. BMPs are designed to meet State water quality standards and are intended to result in prevention of adverse consequences. Specific BMPs do not have to be repeated in the plan to be in effect and applicable to National Forest System projects and activities.

The Strategic Nature of Land Management Plans

Land management plans are strategic in nature. A plan establishes a long-term management framework for NFS units. Within that framework, specific projects and activities will be proposed, approved, and implemented depending on specific conditions and circumstances at the time of implementation. The U.S. Supreme Court described the nature of NFS plans in *Ohio Forestry Ass'n* v. *Sierra Club,* (523 U.S. 726, 737 (1998)) explaining that plans are "tools for agency planning and management." The Court recognized that the provisions of such plans "do not command anyone to do anything or to refrain from doing anything; they do not grant, withhold, or modify any formal legal license, power, or authority; they do not subject anyone to any civil or criminal liability; they create no legal rights or obligations" (523 U.S. 733 (1998)).

The Supreme Court also recently recognized the similar nature of land management plans for public lands under the jurisdiction of the Bureau of Land Management (BLM) in *Norton* v. *Southern Utah Wilderness Alliance, 124 S.Ct. 2373 (2004).* The Supreme Court again observed that "land use plans are a preliminary step in the overall process of managing public lands—'designed to guide and control future management actions and the development of subsequent, more detailed and limited scope plans for resources and uses.'" In addition, "a land use plan is not ordinarily the medium for affirmative decisions that implement the agency's 'project[ion]s.'" Like a NFS land management plan, a BLM plan typically "'is not a final implementation decision on actions which require further specific plans, process steps, or decisions under specific provisions of law and regulations.'" "The BLM's * * * land use plans are normally not used to make site-specific implementation decisions." The Supreme Court acknowledged that plans are "tools by which 'present and future use is *projected*' [and] * * * generally a statement of priorities," *124 S.Ct. 2373 (2004).*

Under the Final Rule, plans will continue to be strategic in nature, as described by the Supreme Court in *Ohio Forestry* and *SUWA.* As described below, the five components of a plan under the Final Rule do not authorize project and activity decisions, but rather characterize general future conditions and guidance for such decisions. Only in extraordinary circumstances will project and activity decisions be implemented at the time of a plan development, revision, or amendment.

• *Planning documentation.*

The final rule requires a Plan Document or Set of Documents to contain all information relevant to the planning and EMS processes. A Plan Document or Set of Documents includes: (1) Evaluation reports that, among other things, document the public involvement process in planning; (2) the plan, including applicable maps; (3) the plan approval document; (4) National Environmental Policy Act of 1969 (NEPA) documents; (5) the monitoring program for the plan area; (6) documents relating to the environmental management system (EMS) established for the unit; and (7) documentation of how science was taken into account in the planning process.

• *Plan components.*

The 2002 proposed rule used the term "management direction" to describe the parts of a plan. This final rule uses the term "plan components" to describe the elements of the plan pursuant to the final rule. How plans are characterized and plan components operate has evolved over the years. This evolution has occurred through an ongoing evaluation of the role plans play, how plans guide projects, how plans by themselves do or do not have impacts on the ground, how current plans enable or restrict decisions to respond to changing circumstances and science, and how more active and structured monitoring provides better information to amend or revise plans as needed. Proposals for action to accomplish plan goals and desired conditions, with effects that can be meaningfully evaluated and which may be significant, generally are made at the project and activity stage.

Through this evaluation, the agency has concluded that plans are more effective if they include more detailed descriptions of desired conditions, rather than long lists of prohibitive standards or guidelines or absolute suitability determinations developed in an attempt to anticipate and address every possible future project or activity and the potential effects they could cause. Under this final rule, plans have five principal components (§ 219.7(a)(2)): desired conditions, objectives, guidelines, suitability of areas, and special areas.

• *Desired Conditions.*

Desired conditions are the social, economic, and ecological attributes toward which management of the land and resources of the plan area is to be directed. Desired conditions are long-term in nature and aspirational, but are neither commitments nor final decisions approving projects and activities. Desired conditions may be achievable only over a period longer than the 15 years covered by the plan.

The increased attention to fire regimes provides an example of the role of

"desired conditions." The Forest Service is challenged with unnatural fuel levels throughout the NFS. Much of the western United States is currently in a severe drought cycle, and fuel reduction is needed. To facilitate moving toward a healthier and more natural condition on the land, a plan could contain, for example, desired conditions that include a description of desired fuel loading, along with a description of desired tree species, structure, distribution, and density closer to what would have occurred under natural fire regimes.

The agency, working with the public, also may seek to achieve or maintain desired conditions for attributes, such as quietness, or a sense of remoteness, or attributes of our cultural heritage. Desired conditions also have a key role to play for wildlife habitat management. During plan development, it is difficult to envision all the site-specific factors that can influence wildlife. For example, in the past plans might have included standards precluding vegetation treatment during certain months or for a buffer for activities near the nest sites of birds sensitive to disturbance during nesting. However, topography, vegetation density, or other factors may render such prohibitions inadequate or unduly restrictive in specific situations. A thorough desired condition description of what a species needs is often more useful than a long list of prohibitions. Thorough desired condition descriptions are more useful because they provide a better starting point for project or activity design, when the site-specific conditions are better understood and when species conservation measures can be most meaningfully evaluated and effectively applied. Again, a description of what the agency, working with the public, wants to achieve is key.

• *Objectives.*

Objectives are concise projections of intended outcomes of projects and activities to contribute to maintenance or achievement of desired conditions. Objectives are measurable and time-specific and, like desired conditions, are aspirational, but are neither commitments nor final decisions approving projects and activities. Application of objectives is the same as applied under the 1982 planning rule.

• *Guidelines.*

Guidelines provide information and guidance for the design of projects and activities to help achieve objectives and desired conditions. Guidelines are not commitments or final decisions approving projects and activities. Guidelines should provide the recommended technical and scientific specifications to be used in the design of projects and activities to contribute to the achievement of desired conditions and objectives. They are the guidance that a project or activity would normally apply unless there is a reason for deviation. If deviation from plan guidelines is appropriate in specific circumstances, the rationale for deviation should be based on project or activity analysis and explained fully in the project decision document. However, deviation does not require an amendment to the plan.

In the National Forest Management Act (NFMA) of 1976 (16 U.S.C. 1600 *et seq.*), the terms "standards" and "guidelines" are both used, with no apparent distinction between them with respect to their force and effect. In the 1982 planning rule and the first round of plans, the two terms were usually written together as "standards and guidelines." Some plan revisions have designed mandatory provisions as "standards" and general direction with latitude for implementation as "guidelines." The 2000 planning rule did not use the term "guidelines." In the 2000 planning rule, a provision that is labeled as a standard could be either mandatory or discretionary depending upon its wording and the scope of its requirements.

The 2002 proposed rule, consistent with the approach in the 2000 planning rule, continued to use only the term "standards" and did not use the term "guidelines." However, in line with and to clarify the strategic nature of plans, this final rule instead adopts the term "guidelines" and has removed the term "standards" as a plan component. The Department decided to employ the term "guideline" to reflect a more flexible menu of choices consistent with the nature of plans set forth in this rule.

In this final rule, guidelines are described as "information and guidance for project and activity decisionmaking." Guidelines will not contain final decisions approving activities and uses. A Responsible Official has the discretion to act within the range of guidelines, as well as the latitude to depart from guidelines when circumstances warrant it. In the latter case, the Responsible Official should document the rationale for taking such exception to guidelines.

• *Suitability of areas.*

Suitability of areas is the identification of the general suitability of an area in an NFS unit for a variety of uses. Areas may be identified as generally suitable for uses that are compatible with desired conditions and objectives for that area. The identification of an area as generally suitable for a use or uses is neither a commitment nor a decision approving activities and uses. The suitability of an area for a specific use or activity is authorized through project and activity decisionmaking.

Suitable use identification has evolved over time. Suitable use identification has often been characterized in plans prepared under the 1982 planning rule as permanent restrictions on uses or permanent determinations that certain uses would be suitable in particular areas of the unit over the life of the plan. However, even under the 1982 planning rule, these identifications were never truly permanent, unless they were statutory designations by Congress. It became apparent early in implementation of the 1982 planning rule that plan suitability identifications, like environmental analysis itself, always necessitated site-specific reviews when projects or activities were proposed.

For example, on lands identified as generally suitable for timber production, site-specific analysis of a proposal could identify a portion of that area as having poor soil or unstable slopes. The project design would then exclude such portions of the project area from timber harvest. Thus, the final determination of suitability was never made until the project or activity analysis and decision process was completed. This final rule better characterizes the nature and purpose of suitability identification.

An illustration of the effect of suitability identifications in the final rule may be helpful. Under this final rule, a plan may identify certain portions of an NFS unit as suitable for some uses. For example, some areas of an NFS unit may be suitable for transportation development or motorized use. Identification of an area in a plan as suitable for transportation development or motorized use does not mean that construction of a road is immediately approved or is even inevitable. Rather, the identification merely provides guidance for where road construction may be considered suitable. Proposed projects for construction of a road or roads would be approved after appropriate project-specific National Environmental Policy Act (NEPA) analysis and public involvement.

This final rule, as discussed next in this preamble, also includes specific provisions for identification of lands generally suitable for timber harvest and identification of lands not suitable for timber production as required by NFMA. However, under this final rule, other generally suitable uses may be identified in a variety of ways. A land

management plan may identify all uses that are generally suitable for a particular area, may identify the major or most prominent generally suitable uses, and/or may identify criteria to be used to determine whether a use is compatible with the desired condition of the area.

• *Special areas.*

Special areas are areas within the NFS designated for their unique or special characteristics. These areas include wilderness, wild and scenic river corridors, and research natural areas. Some of these areas are statutorily designated. Other areas may be designated through plan development, amendment, revision, or through a separate administrative process with an appropriate NEPA process.

• *Monitoring.*

The monitoring program is a central element of adaptive management planning in this final rule because monitoring is the key to discovering how to make project specific decisions consistent with objectives and to discovering what ultimately may need to be changed in a plan. Experience has shown that while some monitoring programs and specific monitoring techniques have been adequate to assess need for changes in plans of national forests, grasslands, prairie, or other comparable administrative units over time, some have not. New uses, such as mountain biking, were not contemplated 25 years ago. Noxious weeds can infest a previously pristine landscape. New methods of measuring water quality or wildlife habitat can be developed. Therefore, a unit's monitoring program must be readily adaptable too. Most plans revised under the 1982 planning rule, in fact, have removed most monitoring operational details from the plans themselves to allow for quicker changes to monitoring when needed.

The final rule allows the plan's monitoring program to be changed with administrative corrections, instead of amendments, to more quickly reflect the best available science and account for unanticipated changes in conditions. Changes in monitoring programs will be reported annually, and the Responsible Official has flexibility to involve the public in a variety of ways to develop program changes.

• *Streamlining the planning rule and use of the Forest Service Directive System.*

Part of the strategic and adaptive nature of planning is to make the planning rule itself more strategic and adaptive. Therefore, procedural and technical details are being moved to the Forest Service Directive System (Forest Service directives). Forest Service directives are the primary basis for the Forest Service's internal management of all its programs and the primary source of administrative direction to Forest Service employees. The Forest Service Manual (FSM) contains legal authorities, objectives, policies, responsibilities, instructions, and guidance needed on a continuing basis by Forest Service line officers and primary staff to plan and execute programs and activities. The Forest Service Handbook (FSH) is the principal source of specialized guidance and instruction for carrying out the policies, objectives, and responsibilities contained in the FSM.

The public will have an opportunity to comment on both the FSM and FSH provisions to implement this final rule. The FSH and FSM provisions will be issued as soon as possible after release of this final rule. Thereafter, the agency will provide the public an opportunity to comment on future changes to the adopted provisions where there is substantial public interest or controversy concerning the future changes.

Role of Science in Planning

The 2002 proposed rule would have required that Forest Service decisions be consistent with the best available science. The final rule requires that the Responsible Official take into account the best available science (§ 219.11). The actual process for taking into account science in planning has not changed from the 2002 proposed rule. Under the final rule, science, while only one aspect of decisionmaking, is a significant source of information for the Responsible Official. When making decisions, the Responsible Official also considers public input, competing use demands, budget projections, and many other factors as well as science.

The final rule, like the 2002 proposed rule, states that the Responsible Official may use independent peer reviews, science advisory boards, or other appropriate review methods to evaluate the application of science used in the planning process. Specific procedures for conducting science reviews will be provided in the Forest Service directives.

The Responsible Official must take into account the best available science, and document in the plan that science was considered, correctly interpreted, appropriately applied, and evaluate and disclose incomplete or unavailable information, scientific uncertainty, and risk. This evaluation and disclosure of uncertainty and risk provide a crosscheck for appropriate interpretation of science and helps clarify the limitations of the information base for the plan.

Public Involvement

The final rule is similar to the 2002 proposed rule regarding public involvement requirements, but the final rule more clearly expresses the Department's emphasis on public involvement and collaboration. The final rule clarifies requirements regarding public involvement in the 2002 proposed rule by consolidating these requirements contained in several sections of the 2002 proposed rule into § 219.9, which requires consultation with interested individuals and organizations, State and local governments, Federal agencies, and federally recognized Indian Tribes.

The Department expects that, compared with prior planning rules, this final rule will allow more members of the public to be more effectively engaged because development of a plan, plan amendment, or plan revision will be simpler, more transparent, and faster. The public will have the opportunity to be engaged collaboratively in the development, amendment, or revision of a plan, in monitoring and in the unit's environmental management system (EMS). In addition, the public will have an opportunity to comment on a plan, plan amendment, or plan revision, and to object prior to approval if concerns remain.

The final rule requires opportunities for public involvement in the unit's land management planning process (§ 219.9) and in monitoring (§ 219.6(b)(3)). In response to public comments on the 2002 proposed rule, the final rule eliminates the prohibition on the use of duplicative materials, such as form letters, when filing an objection to a plan, thus removing a perceived barrier to wider public participation (§ 219.13).

One of the more important changes in public involvement is how the Forest Service will work with the public to collaboratively develop, amend, or revise a plan. The Forest Service has found that the traditional way of developing plan alternatives under the 1982 planning rule was not very useful. The traditional approach of developing and choosing among discrete alternatives that were carried throughout the entire planning process often proved divisive, because it often maintained adversarial positions, rather than helping people seek common ground.

To overcome this tendency, the final rule allows an iterative approach to planning. The Department recognizes

that people have many different ideas about how NFS lands should be managed. Furthermore, a plan could potentially include a variety of different desired conditions, objectives, identification of potential suitable uses, guidelines, and special area designations. The Department also recognizes that the public should be involved in determining what plan components should be. Therefore, the final rule provides for participation and collaboration with the public at all stages of plan development, plan amendment, or plan revision.

The Responsible Official and the public will review the various options to respond to the need to change the plan, and together they will successively narrow potential options until a proposed plan is developed. However, the final rule also recognizes that it is not always possible or desirable to present only one proposed plan for public comment and, therefore, options to the proposed plan can be provided for public comment when appropriate.

The process for plan development will be transparent to the public. Key steps in development of the proposed plan will be documented in the Plan Document or Set of Documents, which will be available to the public. While the final rule requires the Responsible Official to collaborate with the public and that a record of that collaboration be kept, it does not require in-depth social, economic, or ecological analysis of every potential option for a plan. In-depth analysis, documented in an evaluation report, is required only for the proposed plan and the options that remain after public collaboration.

The plan approved by the Responsible Official will be a result of public participation and collaboration that will have included consideration of a variety of different ways to manage a national forest, grassland, prairie, or other comparable administrative unit. Although the Responsible Official will continue to have the responsibility and the authority to make the final decision, the proposed plans that the Forest Service will present for public comment will be plans jointly and collaboratively developed with the public. The Department hopes this approach to plan development will serve to encourage people to work together to understand each other and find common solutions to the important and critical planning issues the agency faces. In summary, the final rule emphasizes collaboration and provides for effective public involvement.

Sustainability

This final rule retains the concept of the interdependent social, economic, and ecological elements of sustainability (§ 219.10) in the 2002 proposed rule. However, the final rule does not include many of the specific analytical processes and requirements set out in the 2002 proposed rule. Appropriate processes will be included in the Forest Service directives. The Department believes it is more appropriate to put specific procedural analytical requirements in the Forest Service directives rather than in the rule itself so that the analytical procedures can be changed more rapidly if new and better techniques emerge. As for other portions of the Forest Service directives, public notice and comment is required where there is substantial public interest or controversy.

As did the 2000 planning rule and the 2002 proposed rule, the final rule makes sustainability the overall goal for NFS planning. Managing NFS lands for sustainability of their renewable resources meets the MUSYA mandate that the Secretary develop and administer the renewable surface resources of the National Forests for multiple use and sustained yield (16 U.S.C. 529). Managing for sustainability will provide for management of the various renewable resources without impairment of the productivity of the land, as required by the MUSYA. Sustaining the productivity of the land and its renewable resources means meeting present needs without compromising the ability of those lands and resources to meet the needs of future generations. The final rule is similar to the 2002 proposed rule for social and economic sustainability requirements. However, as stated, there are changes from the 2002 proposed rule for ecological sustainability.

NFMA requires guidelines for land management plans which provide for diversity of plant and animal communities (16 U.S.C. 1604 (g)(3)(B)) based on the suitability and capability of the land area to meet overall multiple-use objectives. Almost 30 years after passage of the NFMA, the concepts of biological diversity at different spatial and temporal scales, including genetic diversity, species diversity, structural diversity, and functional diversity have been substantially refined and developed. Today, the agency has a vast array of methods available to provide for diversity. The complexity of biological diversity often results in a corresponding complicated array of concepts, measures, and values from several scientific disciplines.

The Department developed the final rule based on the following concepts related to diversity. First, maintenance of the diversity of plant and animal communities starts with an ecosystem approach. In an ecosystem approach, the plan will provide a framework for maintaining and restoring ecosystem conditions necessary to conserve most species.

Second, where the Responsible Official determines that the ecosystem approach does not provide an adequate framework for maintaining and restoring conditions to support specific federally listed threatened or endangered species, species-of-concern, and species-of-interest, then the plan must include additional provisions for these species. This final rule defines species-of-concern as those species for which the Responsible Official determine that continued existence is a concern and listing under the Endangered Species Act (ESA) may become necessary. This final rule defines species-of-interest as those species for which the Responsible Official determines that management actions may be necessary or desirable to achieve ecological or other multiple-use objectives. Forest Service directives will identify lists of species developed by an objective and scientifically credible third party, such as the U.S. Fish and Wildlife Service or NatureServe (*http://www.natureserve.org/*).

Third, agency managers should concentrate their efforts on contributing to the persistence of species where Forest Service management activities may affect species rather than on species management where the cause of species decline is outside the limits of agency authority or the capability of the plan area.

Fourth, the presence of all native and desired non-native species in a plan area is important. However, the Responsible Official should have the flexibility to determine the degree of conservation to be provided for the species that are not in danger of ESA listing, to better balance the various multiple uses, including the often-competing needs of different species themselves.

Fifth, the planning framework should provide measures for accounting for progress toward ecosystem and species diversity goals. The final rule and the Forest Service directives provide a framework within which efforts to maintain and restore species will be monitored. Progress toward desired conditions and objectives will be monitored and the results made available to the public. The adaptive monitoring and feedback process will help maintain and improve diversity.

The 2002 proposed rule included two different approaches to the NFMA diversity requirement labeled "Option 1" and "Option 2" and asked for comments on both options. The agency also hosted a workshop to provide an opportunity for public discussion of these options and for identification of other ideas on how to best meet the statutory diversity requirement. An extremely wide range of opinions was expressed, both in public comments and during the workshop. The Department found these comments useful in developing a scientifically credible and realistic approach for this final rule and the Forest Service directives to meet legal requirements and the agency's stewardship responsibilities.

The final rule incorporates features of both Options 1 and 2. In common with both options, the final rule approaches diversity at two levels of ecological organization: the ecosystem level and the species level. This concept has considerable support among scientists, has already been tested by a number of NFS administrative units developing or revising plans under the 1982 planning rule, and was included in the planning rule adopted in 2000.

The final rule is less detailed than either Options 1 or 2 with respect to specific ecosystem analysis requirements. After reviewing public comments, and after consideration of the Forest Service's experience with planning over the past 25 years, the Department concluded that such detail regarding analysis is more properly included in the Forest Service directives. These directives can be more extensive and can be more easily changed as the agency learns how to improve its analytic processes and as new scientific concepts and new technological capabilities become available.

In common with Options 1 and 2, the final rule focuses on ecosystem diversity as the primary means of providing for the diversity of plant and animal communities. The final rule differs from Option 2 in not explicitly requiring analysis of ecosystem diversity at multiple temporal and spatial scales, analysis of disturbance regimes, or analysis of the landscape context. Guidance on appropriate analysis will be included in the Forest Service directives. The agency will seek public comment on this guidance.

Another point in common between this final rule and Options 1 and 2 is the concept that the more effective the ecosystem management guidance is in sustaining species habitat, the less need there is for analysis and planning at the species level of ecological organization. Option 1, Option 2, and this final rule all recognize that some additional analysis and additional plan provisions may be needed for some species. However, the final rule differs from Option 1 in that it does not include a requirement to provide for viable populations of plant and animal species. Such a requirement had previously been included in both the 1982 planning rule and the 2000 planning rule.

The species viability requirement was not adopted for several reasons. First, the experience of the Forest Service under the 1982 planning rule has been that ensuring species viability is not always possible. For example, viability of some species on NFS lands may not be achievable because of species-specific distribution patterns (such as a species on the extreme and fluctuating edge of its natural range), or when the reasons for species decline are due to factors outside the control of the agency (such as habitat alteration in South America causing decline of some Neotropical birds), or when the land lacks the capability to support species (such as a drought affecting fish habitat).

Second, the number of recognized species present on the units of the NFS is very large. It is clearly impractical to analyze all species, and previous attempts to analyze the full suite of species via groups, surrogates, and representatives have had mixed success in practice.

Third, focus on the viability requirement has often diverted attention and resources away from an ecosystem approach to land management that, in the Department's view, is the most efficient and effective way to manage for the broadest range of species with the limited resources available for the task.

Requirements for species population monitoring are not included in this final rule. Population data are difficult to obtain and evaluate because there are so many factors outside the control of the Forest Service that affect populations. The Department believes that it is best to focus the agency's monitoring program on habitat on NFS land where the agency can adjust management to meet the needs of certain species. Desired conditions are often a focus of the monitoring program. The agency will identify species-of-concern and species-of-interest (§ 219.16). Where ecological conditions for these species are identified as desired conditions, the habitat could be monitored to assist in avoiding future listing of these species. However, the final rule does not preclude population monitoring. Plans may include population monitoring as appropriate.

In summary, in compliance with NFMA, the ecological sustainability provisions in the final rule provide the foundation for the plan to provide for diversity of plant and animal communities. The final rule provides a complementary ecosystem and species diversity approach for ecological sustainability. The final rule at § 219.7(a)(2) establishes requirements for developing plan components to guide projects and activities. All parts of the land management framework, including plan components, monitoring, and plan adjustment, are designed to work together to contribute to sustainability.

Environmental Management Systems and Adaptive Management

• *Adaptive management and land management planning.*

Plans must adapt to ever-changing conditions. Agency policy may change, new laws may be enacted, or court decisions can change interpretation of existing laws. Fires, invasive species, or outbreaks of insects or disease can substantially change environmental conditions. Changes in market conditions or public values may shift the demand for specific goods and services. Scientific findings can change our understanding of the environment and of the effects of specific management activities. Better monitoring techniques or ways to achieve objectives may be found. Land management plans must reflect the fact that change and uncertainty are inevitable. Consequently, plans must allow for quick response to these ever-changing conditions.

The National Association of Professional Forestry Schools and Colleges and others commented on the 2002 proposed rule regarding the importance, from the scientific perspective, of using adaptive management when dealing with complex ecosystems. In 1999, the Committee of Scientists developed recommendations that strongly encouraged the use of adaptive management. The Committee of Scientists recommended setting a high priority on developing ongoing analyses that are based on monitoring to continually adjust or change land management planning decisions. In response to these comments and recommendations for a greater emphasis on and commitment to adaptive management, the Department has chosen to include environmental management systems (EMS) in the land management framework.

The adaptive management approach includes land management plans along

with comprehensive evaluations, an environmental management system, monitoring, evaluation, and research. Adaptive management requires careful coordination of the work performed through these programs. It does not require equal emphases among these various programs, but rather requires organizational learning, an active pursuit of best available scientific information, evaluation and disclosure of uncertainties and risks about scientific information, and a response to change.

A land management plan starts the adaptive management cycle. Managers then pursue ways to achieve desired conditions and objectives described in the plan. The comprehensive evaluation may describe the risks and uncertainties associated with implementing the plan. Managers prioritize risks and develop strategies to control them.

Monitoring and evaluations check for status and change across the administrative unit. Monitoring results may show that the desired conditions are not being achieved through projects. This may trigger future project changes to reach desired conditions. Alternatively, monitoring results may lead to conclusions that the land management plan should be changed through a plan amendment.

Research is an important part of adaptive management. Through experimentation, researchers investigate cause and effect relationships of management practices on the environment. Experiments test hypotheses and researchers develop reliable knowledge about effects of management practices. The new information may be used to amend plans, change project level work, or update an environmental management system.

• *Land management plans, adaptive management, and environmental management systems.*

This final rule requires each national forest, grassland, prairie, or other comparable administrative unit to develop and implement an EMS based on the international consensus standard published by the International Organization for Standardization as "ISO 14001: Environmental Management Systems—Specification With Guidance For Use" (ISO 14001). Each unit's EMS should be designed and implemented to more efficiently meet legal obligations, including supporting the creation of effective land management plans, ensuring public participation in the process, and providing a framework for adaptive management.

The administrative units' EMS will be a systematic approach to identify and manage environmental conditions and obligations to achieve improved performance and environmental protection. Each unit's EMS will identify and prioritize environmental conditions; set objectives in light of Congressional, agency, and public goals; document procedures and practices to achieve those objectives; and monitor and measure environmental conditions to track performance and verify that objectives are being met. Agency management personnel will regularly review performance, and information about environmental conditions will be regularly updated to continually improve land management and environmental performance.

By systematically collecting and updating information about environmental conditions and practices (for example, through monitoring, measurement, research, and public input), the units' EMS will provide a foundation for effective adaptive management, plan amendments, or even changing specific project or work practices. The agency expects that, whenever possible, EMS and land management plan documentation will be coordinated and integrated to avoid unnecessary duplication.

The units' EMS will more efficiently meet legal obligations, will improve public participation in the land management planning process, and enhance the agency's ability to identify and respond to public input. Creating a transparent and consistent framework that describes how units are managed will improve the public's ability to effectively participate in land management. The units' EMS will not replace any legal obligations that the agency has under NFMA, MUSYA, NEPA, or any other statute, nor will the EMS diminish the public's ability to participate in the land management process or its rights under any law. To the contrary, EMS will significantly improve the public's ability to effectively participate in the process.

The agency chose ISO 14001 as the EMS model for several reasons. First, it is the most commonly used EMS model in the United States and around the world. This will make it easier to implement and understand (internally and externally) because there is a significant knowledge base about ISO 14001. Second, the National Technology and Advancement Act of 1995 (NTAA) (Pub. L. 104–113) requires that Federal agencies use or adopt applicable national or international consensus standards wherever possible, in lieu of creating proprietary or unique standards. The NTAA's policy of encouraging Federal agencies to adopt tested and well-accepted standards, rather than reinventing-the-wheel, clearly applies to this situation where there is a ready-made international and national EMS consensus standard (through the American National Standards Institute) that has already been successfully implemented in the field for almost a decade. Third, it has been a long-standing policy that Federal agencies implement EMS to improve environmental performance (Executive Order 13148 issued April 21, 2000 (E.O. 13148), titled "Greening the Government Through Leadership in Environmental Management" and an April 1, 2002, Memorandum from the Chair of the Council on Environmental Quality and the Director of the Office of Management and Budget to the heads of all Federal agencies). Federal agencies that have been implementing EMS in response to the E.O. 13148 have typically been using ISO 14001 as their model.

The implementation of ISO 14001 in NFS administrative units will have to reflect the legal and public obligations of the agency, as well as the environmental conditions and issues relevant to land management, such as sustainability and long-term issues, including cumulative effects. For example, while ISO 14001 requires implementing organizations to identify their "environmental aspects," administrative units implementing their EMS under this rule will include the concept of environmental conditions in land management planning in this step. Another example reflecting the legal and public obligations of the agency is that the units' EMS must include the public participation requirements of this rule, which are much stronger than the public communication provisions of ISO 14001. Therefore, the agency will interpret and implement ISO 14001 in a manner consistent with the agency's legal obligations, its duty to the public, and the unique circumstances of land management.

National Environmental Policy Act and National Forest Management Act Planning

The application of NEPA to the planning process as identified in this final rule is the next iterative step in an evolution that began with the promulgation of the 1979 planning rule, revised in 1982. In developing the NEPA provisions of this final rule, the Department took into account the nature of the five plan components under this final rule, experience the agency has gained over the past 25 years from

developing, amending, and revising land management plans; the requirements of NEPA and NFMA, the Council on Environmental Quality (CEQ) regulations, and the comments by the Supreme Court in *Ohio Forestry Ass'n* v. *Sierra Club* and *Norton* v. *Southern Utah Wilderness Alliance* regarding the nature of plans themselves.

The 1979 planning rule required an environmental impact statement (EIS) for development of plans, significant amendments, and revisions. This requirement continued in the revised rule adopted in 1982. At the time, the Forest Service believed that the NEPA document prepared for a plan would suffice for making most project-level decisions. However, the agency came to understand that this approach to complying with NEPA was impractical, inefficient, and sometimes inaccurate. Over the course of implementing NFMA during the past 25 years, the agency has learned that environmental effects of projects and activities cannot be meaningfully evaluated without knowledge of the specific timing and location of the projects and activities.

At the time of plan approval, the Forest Service does not have detailed information about what projects and activities will be proposed over the 15-year life of a plan, how many projects will be approved, where they will be located, or how they will be designed. At the point of plan approval, the Forest Service can only speculate about the projects that may be proposed and budgeted and the natural events, such as fire, flood, insects, and disease that may occur that will make uncontemplated projects necessary or force changes in the projects and the effects of projects that were contemplated. Indeed, the Forest Service has learned that over the 15-year life of a plan it can only expect the unexpected.

In the course of completing NEPA analysis on the first generation of NFMA plans, the Forest Service also became more aware of the difficulties of scale created by the size of the national forests and grasslands. The National Forest System includes 192 million acres, and individual planning units, such as the Tongass National Forest, may be as large as 17 million acres. These vast landscapes contain an enormous variety of different ecosystems, which will respond differently to the same management practices. As the Committee of Scientists said on page 26 of the Committee of Scientists Report:

> Because of the wide variation in site-specific practices and local environmental conditions (*e.g.*, vegetation type, topography, geology, and soils) across a given national forest or rangeland, the direct and indirect effects of management practices may not always be well understood or easily predicted. (Committee of Scientists Report, March 15, 1999, U.S. Department of Agriculture, Washington, DC 193 p.)

The result is that it is usually infeasible to do environmental analysis for a national forest as a whole that is sufficiently site-specific to allow projects to be carried out without further detailed NEPA analysis after the plan has been approved.

The agency has found itself preparing much more extensive NEPA documentation for projects than it had anticipated when it adopted the 1979 and 1982 planning rules. Moreover, the extensive changes to conditions in the plan area that occurred during the 15-year life of each plan made it increasingly impractical to tier project-level NEPA documentation to the plan EIS. The requirements of the 1979 and 1982 planning rules created an inefficient and ineffective system for complying with NEPA.

The 2000 planning rule furthered the existing presumption of requiring an EIS for plan development or revision, notwithstanding concerns raised by the Committee of Scientists. Secretary Glickman named the Committee of Scientists (COS) on December 11, 1997. The charter for the COS stated that the Committee's purpose was to provide scientific and technical advice to the Secretary of Agriculture and the Chief of the Forest Service on improvements that can be made in the National Forest System Land and Resource Management Planning Process.

The Committee of Scientists said, on page 117 of the Committee of Scientists Report:

> Perhaps the most difficult problem is that the current EA/EIS process assumes a one-time decision. The very essence of small-landscape planning is an adaptive management approach, based upon monitoring and learning. Although small-landscape planning can more readily do real-time cumulative effects analysis * * *, this kind of analysis is difficult to integrate with a one-time decision approach. Developing a decision disclosure and review process that is ongoing and uses monitoring information to adjust or change treatments and activities will need to be a high priority * * *. (Committee of Scientists Report, March 15, 1999, U.S. Department of Agriculture, Washington, DC 193 p.)

In addition to concern about timely and accurate disclosure of environmental effects, the agency's experience with planning has demonstrated the need to clarify what plans, in fact, actually do. Neither the 1982 nor the 2000 planning rule clearly described or contrasted the differences between the effects of plans and the effects of projects and activities. This has been confusing to the public and agency employees. As discussed previously in the guidelines and the suitability discussions, plan components have not been applied or interpreted consistently throughout the agency and often have been characterized as the functional equivalent of final project-level decisions or actions, rather than guidance for projects and activities over time.

This final rule clarifies that plans will be strategic rather than prescriptive in nature absent extraordinary circumstances. Plans will describe the desired social, economic, and ecological conditions for a national forest, grassland, prairie, or other comparable administrative unit. Plan objectives, guidelines, suitable uses, and special area identifications will be designed to help achieve the desired conditions. While plans will identify the general suitability of lands for various uses, they typically will not approve projects or activities with accompanying environmental effects. Decisions approving projects or activities with environmental effects that can be meaningfully evaluated will typically be made subsequent to the plan. In essence, a plan simply is a description of a vision for the future that coupled, with evaluation, provides a starting point for project and activity NEPA analysis. Therefore, under this rule approval of a plan, plan amendment, or plan revision typically will not have environmental effects.

The formulation of plans under the final rule as being merely strategic rather than prescriptive is further evident in the five components of plans under the final rule. As described above, none of the five components is intended to directly dictate on the ground decisions which have impacts on the environment. Rather, they state general guidance and goals to be considered in project and activity decisions. These five components thus do not have any significant effect on the environment.

Notwithstanding their strategic nature, approval of a plan, plan amendment, or plan revision is a final action under the CEQ regulations. Further, such actions may have environmental effects in some extraordinary circumstances, such as when a plan amendment or revision includes final decisions approving projects or activities. For example, an amendment or revision including a decision approving a project to thin

certain trees to reduce fire hazards may have environmental affects that could be significant.

NFMA requires the Secretary of Agriculture to determine how to comply with NEPA during the course of NFMA planning. Section 106(g)(1) of NFMA directs the Secretary to specify in land management regulations procedures to insure that plans are prepared in accordance with NEPA, including direction on when and for what plans an EIS is required (16 U.S.C. 1604(g)(1)). The CEQ regulations direct Federal agencies to adopt procedures that designate major decision points for the agency's principal programs likely to have a significant effect on the human environment and ensuring that the NEPA process corresponds with them (40 CFR 1505.1(b)).

Under NEPA and the CEQ regulations, an EIS is required for every report or recommendation on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment (16 U.S.C. 4321 *et seq.*, 40 CFR 1502.3). CEQ regulations define "major Federal action" as including "actions with effects that may be major." The regulations explain that "Federal actions" generally tend to fall within several categories. Although these categories include adoption of formal agency plans within the definition of "federal action," not all federal actions are major federal actions. As applied to the final rule, land management plans under this final rule, as evidenced by their five components, are strategic and aspirational in nature and generally will not include decisions with on-the-ground effects that can be meaningfully evaluated and that may be major. During plan development, amendment, or revision, the agency generally is not at the stage in National Forest planning of proposing actions to accomplish the goals in land management plans. CEQ regulations define "proposals" that can trigger the requirement for an EIS as "that stage in development of an action when an agency subject to the Act has a goal and is actively preparing to make a decision on one or more alternative means of accomplishing that goal and the effects can be meaningfully evaluated (40 CFR 1508.23). Proposals for action to accomplish plan goals and desired conditions, with effects that can be meaningfully evaluated and which may be significant, generally are made at the project and activity stage. While a plan includes desired conditions, goals, and objectives, the Forest Service does not actively prepare to make a decision on an action aimed at achieving desired conditions, goals, or objectives until the agency proposes projects and activities. Thus, the decision to adopt, amend, or revise a plan, therefore, is typically not the point in the decisionmaking process at which the agency is proposing an action likely to have a significant effect on the human environment.

The approach in this final rule is consistent with the nature of Forest Service land management plans acknowledged in *Ohio Forestry Ass'n* v. *Sierra Club*, 523 U.S. 726 (1998). As described above, in *Ohio Forestry*, the Supreme Court held that the timber management provisions of land management plans are tools for further agency planning and guide, but do not direct future management. When considering the role of land management plans with respect to timber harvesting, the Supreme Court explained that:

> Although the Plan sets logging goals, selects the areas of the forest that are suited to timber production, and determines which "probable methods of timber harvest" are appropriate, it does not itself authorize the cutting of any trees. Before the Forest Service can permit the logging, it must: (a) Propose a specific area in which logging will take place and the harvesting methods to be used; (b) ensure that the project is consistent with the Plan; (c) provide those affected by proposed logging notice and an opportunity to be heard; (d) conduct an environmental analysis pursuant to the National Environmental Policy Act of 1969, to evaluate the effects of the specific project and to contemplate alternatives; and (e) subsequently make a final decision to permit logging, which affected persons may challenge in an administrative appeals process and in court.

The Supreme Court repeated its description of plans as merely strategic without any immediate on the ground impact in the recent SUWA decision described above. Both cases reinforce the observations of the FS in reflecting on 25 years of completing EISs for plans, and buttress the approach to planning and NEPA compliance described in the final rule.

In accordance with NFMA, NEPA, and the CEQ regulations, this final rule will ensure that Forest Service NEPA analysis will be timed to coincide with those stages in agency planning and decisionmaking likely to have a significant effect on the human environment. The final rule emphasizes the clear distinction between the mere adoption, revision or amendment of a plan and projects and activities having on-the-ground environmental effects. In this final rule, the Department is clarifying the nature of National Forest land management plans, and based on the nature of plans, specifying that plans, plan amendments, and plan revisions may be categorically excluded from NEPA documentation as provided in agency NEPA procedures.

The CEQ regulations (40 CFR 1500) require that each agency establish specific criteria for and identification of three types of actions: (1) Those that normally require preparation of an environmental impact statement (EIS); (2) those that normally require the preparation of an environmental assessment (EA); and (3) those that normally do not require either an EA or EIS. Actions qualifying for this third type of action are defined as categorical exclusions because they do not individually or cumulatively have a significant impact on the human environment; therefore, neither an environmental assessment nor an environmental impact statement is required (40 CFR 1508.4).

A categorical exclusion is not an exemption from the requirements of NEPA. Categorical exclusions are an essential part of NEPA that provide a categorical determination that certain actions do not result in significant impacts, eliminating the need for individual analyses and lengthier documentation for those actions. CEQ regulations at 40 CFR 1500.4(p), 1507.3 and 1508.4 direct agencies to use categorical exclusions to define categories of actions which do not individually or cumulatively have a significant effect on the human environment and do not require the preparation of an environmental assessment or an environmental impact statement, thereby reducing excessive paperwork. Current Forest Service procedures for complying with and implementing NEPA are set out in Forest Service Handbook (FSH) 1909.15.

Simultaneously with this rulemaking, the Forest Service is proposing to revise its NEPA procedures to provide a new categorical exclusion for plan development, amendment, and revision. The proposed categorical exclusion describes the extraordinary circumstances that may require preparation of an EIS or an EA. The Forest Service is seeking comment on the proposed categorical exclusion.

The Forest Service presented and sought public comment on this approach to NEPA and NFMA planning in the 2002 proposed rule. The 2002 proposed rule at § 219.6(b) provided that if the Responsible Official determines that a new plan, plan amendment, or plan revision, or a component thereof, would be an action significantly affecting the quality of the human environment, or authorizes an action that commits funding or

resources that could have a significant effect on the quality of the human environment, then an EIS would be required. Otherwise, a new plan, plan amendment, or plan revision may be categorically excluded from documentation in an EA or EIS as provided in agency NEPA procedures. The categorical exclusion proposed in connection with this final rule clarifies that plan development, plan amendment or plan revisions in accordance with this final rule do not significantly affect the environment, and thus are categorically excluded from further NEPA analysis, unless extraordinary circumstances are present. Of course, the FS will comply with all applicable NEPA requirements, including preparation of an EA or an EIS where appropriate, when considering specific projects or making other project-specific decisions affecting the environment.

The public identified three key concerns related to the proposal to categorically exclude plans from documentation. First, many people commented that they were unsure about how they would be involved in planning if an EIS process were not used. Second, they questioned how planning analysis would be documented in the absence of an EIS. Third, some asked how cumulative effects would be accounted for if a Categorical Exclusion (CE) were relied upon. The Department has fully considered the concerns raised by the public and believes the final rule addresses the concerns as follows:

• Public participation.

This final rule provides extensive opportunity for public participation that exceeds requirements for public participation under NEPA and improves the clarity of the process for public notification (§ 219.9).

• Evaluations and documentation.

This final rule requires comprehensive and other evaluations in § 219.6. Evaluation reports will document existing social, economic, and ecological conditions and trends; and will be available to the public and included in the Plan Document or Set of Documents. Evaluations are prepared for plan development, plan amendment, and plan revision (§ 219.6); use a systematic and interdisciplinary approach (§ 219.7(a)); and consider environmental amenities and values along with economic and technical considerations (§ 219.10).

The Plan Document or Set of Documents will be supplemented with annual evaluation reports and with other information as appropriate to form a continually refreshed and current analytical base of information. Because of this more current information base, evaluations will provide a much stronger and more robust source of information for projects and activities than an EIS prepared under the 1982 planning rule.

• Cumulative effects.

To account for cumulative effects of management and natural events, this final rule requires (§ 219.6(a)): (1) A comprehensive evaluation for the development of a new plan or plan revision; (2) annual plan monitoring and evaluation; and (3) review of the comprehensive evaluations at least every 5 years. These evaluations, as opposed to predictive EIS's that grow increasingly stale over time, will provide more timely and informed consideration of cumulative effects. The Plan Document or Set of Documents provides for a robust information base for the consideration of cumulative effects of management in NEPA documents prepared for projects or activities.

• The relationship between EMS and NEPA.

Implementing EMS will improve the quality of agency NEPA analysis for projects and activities. In a September 2003 report, titled "Modernizing NEPA Implementation," the CEQ NEPA Task Force stated at page 54, "Federal agencies, having made the connection between EMS and adaptive management, would be integrating NEPA-related adaptive management actions into their developing EMSs." The task force also said that NEPA and EMS provide "a synergy that can encourage a robust analysis when the EMS information is extensive, current, and available for use in the NEPA analy[sis]." The Department agrees with the task force's conclusions and believes that requiring each unit to implement an EMS will improve environmental performance and effective land management in addition to enhancing NEPA analysis and documentation.

Under the existing process, information about environmental conditions is collected for the purposes of preparing detailed NEPA analysis and documentation for plan development, plan amendment, or plan revision. There is no effective system for keeping this information current, because the collection and analysis of information often typically ceases when the NEPA analysis and documentation is completed. Therefore, the information collected for the environmental documents for 126 NFS units can grow stale as environmental, social, and economic conditions change. Further, the focus of the information collection and analysis process is on NEPA analysis and documentation, rather than for use in the ongoing management of the administrative unit. Therefore, the large volume of information and analysis that is so expensively created over a long period is often used as a snapshot for purposes of making a single decision, instead of being integrated into a dynamic, ongoing system to effectively manage units.

This rule will improve this situation by requiring each administrative unit to implement an EMS that includes defined procedures for identifying environmental conditions, keeps that information current, and includes monitoring and measurement procedures for continually evaluating conditions in the unit. The EMS requirement is separate from any obligations to develop EISs, EAs, or CEs. Therefore, the obligation to keep this information current and make it available for public review is separate from the obligation to create any particular NEPA document. This information will be used in formulating the land management plans that are subject of this rule, managing administrative units on an ongoing basis, as well as for specific project and activity proposals that trigger the need for EISs, EAs, or CEs. Therefore, through the implementation of EMS, administrative units will be continually collecting and evaluating the data necessary to create any documents that may be required by NEPA. This will make the creation of accurate and relevant NEPA documents more efficient. More importantly, it will make available to administrative unit managers and the public a "library" of current information, analyses, and research that, through EMS, will be used to manage the administrative unit on an ongoing basis, and better adapt management practices to avoid unwanted environmental effects.

Summary

This final rule represents a paradigm shift in planning. It emphasizes the strategic nature of NFMA land management plans and will permit more flexibility in implementing projects in response to evolving scientific doctrines and changing conditions on the ground, such as unforeseen natural disasters. It requires that each NFS unit develop an EMS that will be used to continually improve environmental performance and conditions. It requires that Responsible Officials take into account the best available scientific information. It requires public involvement and collaboration throughout the entire cycle of planning, plan development, plan amendment, plan revision, project

and activity decisionmaking, and monitoring of environmental performance. The final rule requires plans to focus on the social, economic, and ecological sustainability of the management of the NFS, and it has specific provisions for biological diversity at both the ecosystem and species level. It clarifies the nature of plans and explains how the planning process complies fully with the requirements of NEPA. Plans developed and maintained using the EMS and other processes required by this final rule will improve the performance, accountability, and transparency of NFS land management planning.

4. Department Response to Comments on the 2002 Proposed Rule

The Forest Service received approximately 7,000 original letters and 195,000 total comments from a wide variety of respondents on the 2002 proposed rule. Each comment received consideration in the development of the final rule. The following is a summary of comments and response to issues raised by these comments. A response to less substantive issues may be found in the supplemental response to comments located on the World Wide Web/ internet (*see* **ADDRESSES**).

General Issues

The Department received the following comments not specifically tied to a particular section of the 2002 proposed rule.

Comment: Compliance with NFMA. Some respondents thought the 2002 proposed rule would allow more timber harvest and road construction than currently exists and therefore would violate the National Forest Management Act (NFMA) of 1976 (16 U.S.C. 1600 *et seq.*). Other respondents believed the timber industry, other commercial interests, or Forest Service employees unduly influenced the 2002 proposed rule; moreover, they perceived that the 2002 proposed rule would degrade the environment. Some contended the 2002 proposed rule was influenced by campaign contributions.

Response: The final rule is not intended to, and will not, determine the choices among the multiple uses. The NFMA requires the Secretary of Agriculture to develop regulations under the principles of the Multiple-Use Sustained-Yield Act (MUSYA) of 1960 (16 U.S.C. 528–531). Congress gave the Secretary broad discretion in interpreting how these principles are applied. This final rule affirms the overall goal of MUSYA and provides a framework for plans to reflect contemporary priorities and values. Pursuant to MUSYA, this final rule adopts social, economic, and ecological sustainability as the goal of National Forest System (NFS) management. Furthermore, timber production from NFS lands has been reduced dramatically since NFMA was written. The sale of timber has fallen from an annual level of 10 to 12 billion board feet in the 1970s and 1980s to three billion board feet in the early 1990s and below three billion board feet since then. Finally, the final rule does not promote or discourage other uses of NFS lands, such as outdoor recreation, range, wildlife and fisheries, and so forth. The planning process itself will determine the desired conditions and objectives for each NFS unit.

Comment: Plan oversight and resource conservation. Some respondents commented that the 2002 proposed rule would prevent court oversight of plans, eliminate restrictive plan requirements, inappropriately increase Forest Service discretion, and result in decreased conservation of resources such as wildlife. Several respondents wanted the 2002 planning rule to be stricter, attributing the collapse of Enron to inadequate regulatory oversight. Other respondents were concerned about the possibility of increased litigation and thought streamlined planning would shift more of the analysis burden to projects, thus slowing project completion.

Response: The final rule establishes a planning process that complies with NFMA and provides a broad planning framework within which issues specific to a plan area can be resolved in an efficient and reasonable manner informed by the latest data and scientific assessments and public participation and collaboration.

With respect to concerns that Forest Service discretion may be unchecked, there has always been a tension between providing needed detailed direction in the planning rule and discretion of the Responsible Official. However, the decisions of the Responsible Official are constrained and guided by a large body of law, regulation, and policy, as well as public participation and oversight. Because every issue cannot be identified and dealt with in advance for every situation, the Forest Service must rely on the judgment of the Responsible Official to make decisions based on laws, regulation, policy, sound science, public participation, and oversight.

The Department of Agriculture (Department) believes that the final rule is fully compatible with the nature of forest planning as described by the U.S. Supreme Court in *Ohio Forestry Ass'n* v. *Sierra Club* 523 U.S. 726 (1998) (A discussion of this case is found in the "Overview of the Final 2004 Rule" section of the preamble.) The Department expects public oversight and legal review of planning, as well as an assessment of the environmental impacts of specific projects under NEPA, to occur under the final rule in accordance with *Ohio Forestry*. As a general matter, and consistent with the Ohio Forestry Ass'n decision, a plan by itself is not expected to be reviewable by the courts at the time the plan is developed, revised or amended; but when the agency decides on a specific action, an aggrieved party will be able to challenge that action and, if appropriate, seek review of that part of the plan that is relevant to that action.

After years of experience with previous planning rules, the Department is ready to embrace the latest thinking in management techniques and believes this final rule provides the proper balance of regulatory requirements and flexibility needed to resolve issues on the ground. By streamlining the planning process, requiring environmental management systems (EMS), and emphasizing collaboration and public involvement, the final rule will result in plans that are more up to date, and should have broader public support. Similarly, the continual updating of the evaluations and analyses associated with plans is expected to reduce the amount of analysis needed at the project level. These concepts of collaboration, EMS, evaluations, and public involvement are described in detail in the "Overview of the Final 2004 Final Rule" section of the preamble.

Comment: Consultation with a committee of scientists. Several respondents were concerned that there was no consultation with a committee of scientists in developing the 2002 proposed rule. Several felt that an independent review was necessary. Some respondents also felt that the 2002 proposed rule should reflect current scientific knowledge.

Response: The NFMA does not require a committee of scientists for revision of the planning rule. Nonetheless, the Department based the 2002 proposed rule on the major recommendations from the 1999 Committee of Scientists report. Sustainability, public participation, adaptive management, monitoring and evaluation, the role of science, and the objection process, all concepts in the proposed and final rule, were recommendations of that report. The Department realizes that scientific knowledge will continue to expand. Therefore, the Responsible Official must

take into account the best available science when plans are developed, revised, or amended (§ 219.11).

Comment: Environmental conservation. Several respondents commented that the 2002 planning rule should conserve wildlife, wilderness, historic and cultural sites, special habitat, watersheds, genetic material, and reduce fragmentation. One person commented that planning should be done on whole ecosystems.

Response: The final rule provides the processes through which Responsible Officials conserve and manage resources with regard to the issues relevant in the plan area. Those communities, groups, or persons interested in these important resource issues can influence plan components and monitoring programs by becoming involved in planning efforts throughout the process, including the development and monitoring of the plan, as well as the development and implementation of proposed projects and activities.

The Department agrees that better quality planning is often accomplished when the appropriate scale is used. For species or watersheds, evaluation often needs to be completed at a broader scale than for an individual unit. The Department anticipates that the Forest Service, in its plan evaluations, will continue to look at issues at the appropriate scale.

Comment: The 2000 planning rule was never adequately tested. Some respondents disagreed with the 2002 proposed rule discussion of the difficulty of implementing the 2000 planning rule, since the 2000 planning rule was never used.

Response: The costing study, "A Business Evaluation of the 2000 planning rule and the Proposed NFMA Planning Rules," analyzed each of the work activities of the 2000 planning rule and used experienced planners and resource professionals to estimate how those work activities would be carried out. The Department believes that this analysis on the 2000 planning rule was adequate to determine how well that rule could be implemented.

Comment: Costing study of the 2000 Planning Rule. Several respondents said the report on cost and ability to implement the 2000 planning rule was not available.

Response: The **Federal Register** notice for the 2002 proposed rule explained how all associated studies were available for review. These studies have been, and still are, available on the Forest Service's World Wide Web/ Internet site (*see* **ADDRESSES**) and available from the Director, Ecosystem Management Coordination Staff, Forest Service, USDA, Mail Stop 1104, 1400 Independence Avenue, SW., Washington, DC 20250–1104, as described in the **ADDRESSES** section.

Comment: Inability to complete revisions. Several respondents said that the inability of the Forest Service to comply with a statutorily mandated revision timeline was due to reasons other than the requirements of the 1982 or 2000 planning rules.

Response: The Forest Service experience showed that the cost and unnecessary complexity of the planning process for the 1982 planning rule were the major causes of plan delays; this experience and the costing study indicated that the 2000 planning rule would exacerbate these concerns.

Comment: Cost study and the cost-benefit analysis for 1982 planning rule. Some respondents said the cost study of the 2000 planning rule and the 2002 proposed rule should also have considered the 1982 planning rule and that the cost-benefit analysis should have considered the costs of the 1982 planning rule, which is the rule that was actually being implemented at the time of the study.

Response: When the 2000 planning rule was developed, the costs to the Forest Service to implement it were unknown, while the costs associated with the 1982 planning rule were known. The cost-benefit analysis considered the costs of implementing the 1982 planning rule, the anticipated cost of implementing the 2000 planning rule, and the anticipated cost of implementing the 2002 proposed rule. The cost-benefit analysis used information from a business evaluation and costing study for the 2000 planning rule and the 2002 proposed rule. Although the 1982 planning rule was not included in the business evaluation, 1982 planning rule costs were included in the cost-benefit analysis using applicable costs from the business evaluation and historical cost information.

Comment: Biological assessment. Some respondents commented that the rule should consider the "degree to which the action [the rule] may adversely affect an endangered or threatened species or their habitat that has been determined to be critical under the Endangered Species Act (ESA) of 1973." They assert that a biological assessment of the 2002 proposed rule is needed to analyze its impacts on threatened and endangered species and that the agency must also consult on the 2002 proposed rule with the agencies responsible for implementing the ESA.

Response: The ESA, as amended (16 U.S.C. 1531 *et seq.*), requires consultation for actions authorized, funded, or carried out by a Federal agency. This final rule simply establishes a process for planning. The final rule is not an action having a direct effect on threatened or endangered species. The agency's obligations for conservation of threatened, endangered, and proposed species remains unchanged by this final rule; no consultation is required as part of the final rule's development.

Comment: Planning certification. One organization commented that a nationally recognized third party should certify sustainability of National Forests.

Response: The Department believes that the body of laws that govern management of NFS lands, the Forest Service Strategic Plan (Strategic Plan) required under the Government Performance and Results Act, the planning process itself, the expertise of career professionals, and the opportunity for public participation are adequate to ensure sustainability. Recognizing the point made by the respondent of the value of using recognized standards for forest management, this final rule requires units to develop and implement an EMS that conforms to ISO 14001 to manage natural resources and further the adaptive management approach advocated by other respondents. ISO 14001 is the internationally and nationally recognized standard for EMSs. The Forest Service understands that ISO 14001 is not itself a program for forest sustainability certification and does not contain specific natural resource provisions or requirements. Natural resource management requirements and priorities are properly set by Congress and open public participation, rather than by non-governmental standards setting bodies that are not directly answerable to the citizens of the United States.

ISO 14001 provides a well-accepted management process that will improve the Forest Service's ability to identify and meet the natural resource goals that are set by Congress in the NFMA and MUSYA and the Forest Service's commitments to sustainability, good science, and public involvement in a disciplined, systematic, and transparent manner.

Comment: Benchmarks in the 1982 planning rule were useful. Several respondents said that benchmarks, such as those required in the 1982 planning rule, are useful and should still be required.

Response: The agency's experience with the 1982 planning rule is that benchmarks have not been useful. In theory, benchmarks define the range of

production possibilities and ecosystem limits. In practice, however, they are difficult to develop due to limited data and uncertainty at the time plans are developed. However, the final rule does not prohibit benchmark analysis when it would provide meaningful information.

Comment: Fix the 1982 planning rule. Several respondents thought the agency should consider analyzing and correcting the 1982 planning rule instead of developing an entirely new rule.

Response: In many ways, the final rule reflects the 1982 planning rule. However, it makes improvements based on over 25 years of experience. The final rule includes the basic plan components set out in the 1982 planning rule, includes the provisions required by NFMA, and expands the public involvement requirements in the 1982 planning rule by requiring additional public involvement opportunities and emphasizing collaboration.

Comment: The final rule should be subject to NEPA. Some respondents commented that adoption of the final rule is itself subject to the National Environmental Policy Act (NEPA) of 1969, as amended (42 U.S.C. 4321–4346), and this rulemaking is a major Federal action having a significant effect on the human environment. Others questioned why previous rulemaking efforts were accompanied by environmental assessments and why this rulemaking was not.

Response: The Department disagrees that this rulemaking is a major Federal action that has significant effects on the environment because the final rule, which sets out a process for developing plans, plan amendments, and plan revisions, does not have environmental effects. The Forest Service Handbook (FSH) 1909.15, section 31.12, paragraph 2, specifically provides that procedures for amending or revising land management plans may be categorically excluded from NEPA documentation.

The Forest Service produced an environmental assessment for the 2000 planning rulemaking efforts, but asserted at the time that it was going beyond the requirements of the law or policy. In the spirit of efficiency and streamlining inherent in this rulemaking effort, it seemed inconsistent to produce a NEPA document that was not required or useful. In summary, this final rule does not significantly affect the quality of the human environment and does not trigger NEPA obligations.

Comment: Integration of planning process requirements. One respondent commented that the 2002 proposed rule listed many requirements and was unclear how these requirements were to be integrated into a plan.

Response: The Department agrees that it was difficult to track the planning process steps in the 2002 proposed rule. This difficulty is one of the primary reasons the Department substantially reorganized the final rule.

Comment: Research. One professional organization felt that the final rule should support "bold and imaginative" research on NFS lands.

Response: The Department believes that the final rule does support research. The strong emphasis on monitoring, evaluation, and the Department's recognition of the value of environmental management systems produce an adaptable process where scientific experimentation is encouraged. Topics to be researched, however, are properly not set out in the final rule.

Comment: Forest Service directives. Several respondents expressed concern about placing management direction in the Forest Service Directive System (Forest Service directives) and said that the Forest Service directives have not been subject to rulemaking procedures and do not have the full force and effect of law. They said that NFMA requires direction to be in the planning rule and they are concerned that use of directives will foster distrust and a confusing system of malleable and unenforceable guidelines.

Some respondents were concerned that placing direction in the Forest Service directives instead of in the final rule would reduce meaningful public participation. Others endorsed the idea of using the Forest Service directives for technical details rather than burden the final rule with these "how to" requirements. Some said that the Forest Service should retain greater flexibility and should be able to make decisions more cost effectively. Finally, some respondents said that they would like the Forest Service directives to be updated and published for public review concurrent with the planning rule development.

Response: The Forest Service directives are the primary basis for the internal management and control of all programs and the primary source of administrative direction to Forest Service employees. The Forest Service Manual (FSM) contains legal authorities, objectives, policies, responsibilities, instructions, and guidance needed on a continuing basis by Forest Service line officers and primary staff to plan and execute assigned programs and activities. The Forest Service Handbook (FSH) is the principal source of specialized guidance and instruction for carrying out the direction issued in the FSM. Because the Forest Service directives are easier to change and more easily adopt the latest technology and science, they are the appropriate place for specific technical guidance.

As stated in the "Forest Service Directives" section in the preamble, the Forest Service is developing planning directives to provide overall guidance needed to use this final rule for Forest Service line officers, agency employees, and others. The Forest Service will provide the public with the opportunity to comment on planning directives as soon as they are prepared through notice in the **Federal Register**.

Comment: Other issues. Some respondents commented on a variety of important issues such as roads, recreation, timber harvest, taxes, recycling, access, travel management, public safety, effects on spiritual values, land exchanges and purchases, fire protection, paying for restoration, job creation, certain kinds of motorized use, and roadless areas and they wanted those issues addressed in the final rule.

Response: The Department agrees that the issues raised are important. However, the final rule is intended to guide how plans are developed, revised, and amended. The final rule provides the overall direction for planning. The final rule does not provide direction that is properly found in the plans themselves, or in the subsequent decisions regarding projects and activities on a particular national forest, grassland, prairie, or other comparable administrative unit.

Issues in Response to Specific Sections

Following are discussions and responses to public comments received on specific sections in 36 CFR part 219 during the Department's comment period on the 2002 proposed rule, including discussion on the differences between the 2002 proposed rule and the final rule and why these changes were made. The Department reorganized the final rule. As a result, some sections have new titles and/or a new designation as shown in the following table 1. In addition, the heading for subpart A in the 2002 proposed rule, "National Forest System Planning for Land and Resource Management Plans," has been shortened and simplified in the final rule to "National Forest System Land Management Planning," which is a term also used in the National Forest Management Act of 1976.

TABLE 1.—SECTION-BY-SECTION COMPARISON OF THE 2002 PROPOSED RULE WITH THE FINAL RULE

[2002 Proposed Rule]	[Final Rule]
Proposed section number and title	Final section number and title
§ 219.1 Purpose and applicability	§ 219.1 Purpose and Applicability.
§ 219.2 Nature and scope of a land and resource management plan	[some direction moved to §§ 219.2 and 219.3] [redesignated at § 219.3; planning process requirements incorporated in § 219.7]
§ 219.3 Levels of planning and planning authority	§ 219.2 Levels of planning and planning authority. [redesignated at § 219.2]
§ 219.4 Decisions embodied in plans	§ 219.3 Nature of land management planning. [incorporated in §§ 219.7 and 219.12]
§ 219.5 Indicators of need to amend or revise a plan	§ 219.4 National Environmental Policy Act compliance. [incorporated in § 219.6 or the Directive Systems.]
§ 219.6 Compliance with National Environmental Policy Act	§ 219.5 Environmental management systems. [redesignated at § 219.4]
§ 219.7 Amending a plan	§ 219.6 Evaluations and monitoring. [incorporated in §§ 219.2, 219.7 and 219.9]
§ 219.8 Revising a plan	§ 219.7 Developing, amending, or revising a plan. [incorporated in §§ 219.2, 219.7, 219.8 and 219.9]
§ 219.9 Developing a new plan	§ 219.8 Application of a new plan, plan amendment, or plan revision. [incorporated in §§ 219.2 and 219.7]
§ 219.10 Application of plan direction	§ 219.9 Public participation, collaboration, and notification. [incorporated in § 219.8]
§ 219.11 Monitoring and evaluation.	§ 219.10 Sustainability. [incorporated in § 219.6]
[2002 Proposed Rule]	§ 219.11 Role of science in planning. [Final Rule]
Proposed section number and title	Final section number and title
§ 219.12 Collaboration, cooperation, and consultation	[incorporated in § 219.9]
§ 219.13 Sustainability	§ 219.12 Suitable uses and provisions required by NFMA. [redesignated at § 219.10]
§ 219.14 The consideration of science in planning	[redesignated at § 219.11]
§ 219.15 Special designations	[incorporated in §§ 219.7]
§ 219.16 Determination of lands available for timber harvest and suitable for timber production.	[redesignated at § 219.12].
§ 219.17 Limitation on timber harvest	§ 219.13 Objections to plans, plan amendments, or plan revisions. [redesignated at § 219.12]
§ 219.18 Plan documentation, maintenance, and availability	§ 219.14 Effective dates and transition. [incorporated in §§ 219.6, 219.7, and 219.9]
	§ 219.15 Severability.
§ 219.19 Objections to amendments or revisions of plans	§ 219.16 Definitions. [redesignated at § 219.13]
§ 219.20 Appeals of plan amendments in site-specific project decisions.	[incorporated in § 219.13]
§ 219.21 Notice of plan decisions and effective dates	[incorporated in §§ 219.9 and 219.14]
§ 219.22 Transition	[incorporated in § 219.14]
§ 219.23 Definitions	[redesignated at § 219.16]

In this final rule, the Department reorganized sections of the 2002 proposed rule to improve clarity and reduce redundant material. The discussion of each section follows the numbering and titles adopted in the final rule, with references to where the text was located in the 2002 proposed rule. These new sections are ordered from general to specific. The first section introduces the reader to what is covered in the final rule and acknowledges the multiple-use and sustained yield productivity mandate of the Forest Service (remainder of § 219.1). Section 219.2 describes planning in general and the levels of planning in the agency. Then, the final rule contains a general description of plans (§§ 219.3 and 219.4), followed by the specific plan requirements (§§ 219.5–219.16).

Section 219.1—Purpose and Applicability

This section is coded the same in the final rule as it was in the 2002 proposed rule and introduces the reader to what is covered in the final rule, acknowledges the multiple-use and sustained-yield productivity mandate of the Forest Service, and directs the Chief of the Forest Service to establish planning procedures in the Forest Service directives. The 2002 proposed rule language is retained in the final rule, with some clarification regarding the overall goal to sustain the multiple uses of its renewable resources in perpetuity while maintaining the long-term productivity of the land.

Comment: Overall goals of planning. There were varied comments on the overall goal of National Forest System (NFS) planning. Some said that the purpose of planning should reflect sustainability priorities and values. Some respondents stated that the best approach to the purpose and applicability section is to state that ecological sustainability is the desired condition to be achieved through land management. Some requested that the Forest Service's vision statement be changed to reflect a philosophy of preservation and sustainability and that the Forest Service not make management decisions based on a productivity paradigm. They stated that good decisions that restore the forest will be approved quickly without controversy and lawsuits, while bad decisions should be stopped and the decisionmaker held accountable. Others requested that the Forest Service give attention to how plans affect tourism and recreation.

Response: The Department agrees that the mandate under the National Forest Management Act (NFMA) of 1976 and Multiple-Use Sustained Yield Act (MUSYA) of 1960 is not exclusively for production or for preservation because "multiple use and sustained yield" applies to all renewable resources, including outdoor recreation, range, timber, watershed, wildlife and fish, and wilderness. These laws direct the management of all the various renewable resources of the lands so that they are used in the combination that will best meet the needs of present and future generations of Americans. Planning for NFS lands is not simple, and often there is little agreement on how these lands should be managed. While relying on the expertise of the Forest Service and taking into account the best available science, this final rule also provides an open process for public collaboration and participation.

Finally, other overarching planning guidance, such as the intent of planning to produce responsible land management and how a plan aids the agency to fulfill its stewardship responsibilities, is discussed in § 219.3.

Comment: Multiple-Use Sustained-Yield Act (MUSYA). Some respondents pointed out that "multiple use" is part of the law and "ecosystem management" is not. Active forest management, they asserted, is necessary for forest health, maintaining biological diversity, and sustaining wildlife populations. These respondents requested that the final rule uphold what they believe are the active forest management principles mandated by the MUSYA. Further, they stated that timber harvesting is a goal of the MUSYA. They asked that the Forest Service provide a high-level sustained yield of renewable timber resources.

Some respondents requested that the Forest Service comply with MUSYA by managing lands according to what they call its "wood, water, wildlife, range, and recreation" formula. Others stated that the 2002 proposed rule violates the MUSYA requirement that NFS lands be used to best meet the needs of the American people. These respondents requested that emphasis be placed on recreation, aesthetics, air and water quality, species habitat, and ecosystem integrity, rather than natural resource development.

Response: The final rule is faithful to NFMA, which requires the use of the MUSYA to provide the substantive basis for forest planning. As used in the final rule, sustainability embodies these Congressional mandates. The interrelated and interdependent elements of sustainability are social, economic, and ecological as described in § 219.10. The final rule sets the stage for a planning process that can be responsive to the desires and needs of both present and future generations of the Americans for the multiple uses of NFS lands. The final rule does not make choices among the multiple uses; it describes the processes by which those choices will be made as a preliminary step during development of plans. Later, the plan provides guidance for projects and activities.

Comment: Forest planning versus project planning. Some respondents said that, unlike the 2000 planning rule, the 2002 proposed rule correctly focused only on the forest planning level and not on project planning.

Response: The final rule retains the focus of the 2002 proposed rule on land management plans, while at the same time explaining on how plans and projects or activities are linked. Inclusion of an EMS in the land management framework provides a current scientific and informational foundation for the effective development and implementation of projects and activities. This framework ensures the continued relevance of the entire cycle of planning while maintaining the distinction between strategic planning and projects and activities. As previously noted, there will be a comprehensive table in the Forest Service directives that includes guidance on what direction is appropriate for the plan level, what decisions are properly made at the project or activity level, and what scheduling, prioritization, or analysis may take place in between.

Section 219.2—Levels of Planning and Planning Authority

This section was located in the proposed rule at § 219.3, but has been re-designated at § 219.2 as part of the overall reorganization of the final rule. This section describes planning in general, the levels of planning in the agency, and provides the basic authorities and direction for developing, amending, or revising a plan.

Comment: Consistency of decisions across units and the Responsible Official. Some respondents were concerned that plans developed for individual units, each with a different Responsible Official, would not be consistent within larger areas. They said that the planning framework should be similar within each State or ecological region. Some said that without a regional context, the planning efforts of each forest or grassland would seem to take place in a vacuum. Some commented that plans needed to address species management plans and conservation agreements for wide ranging species in a consistent manner. Some commented that planning needed to use consistent consultation procedures with Tribes.

Several respondents commented on the provision that the Supervisor is usually the Responsible Official. Those in favor of this provision said that local Supervisors and staff are involved with actual hands-on project implementation and can better gauge success or failure of the planning process. Some said that Supervisors are close to the problem areas and are better able than Regional Foresters to seek solutions proactively and act upon them more quickly. These respondents felt that Supervisors are in a better position to facilitate citizen participation and negotiation between competing groups and to coordinate with local or State plans.

Those opposed to this provision were concerned that the local pressure for employment in forest products industry may outweigh the preservation of our national heritage if decisionmaking was left in local hands. They said that Supervisors are susceptible to political pressure or abuse of their authority. Still others said Supervisors sometimes do not have sufficient experience or expertise to make adequate plan decisions. Some said that local staff may not understand how to use inventory data, monitoring, or ecosystem or species evaluations and will simply copy what was done in other locations, causing endless escalation of planning efforts. Several respondents said that the current system has worked well with the Regional Forester as the Responsible Official.

Still others said that both national and local level staffs are necessary, because local staff cannot reasonably understand complex and overlapping policies, regulations, and laws, and national staff cannot efficiently study local conditions or gain local consensus. Finally, one respondent observed that if the planning process becomes so burdensome that local officials do nothing but plan, the system would once again break down. Some respondents wanted the final rule to clarify the conditions under which officials ranking higher than the Supervisor can act as the Responsible Official and to explain the types of decisions that these officials can make.

Response: Supervisors currently coordinate across unit and Regional boundaries and will continue to do so because the evaluations described in §§ 219.6, 219.7, and 219.10 will often cross boundaries of adjacent NFS units. In addition, the final rule provides the option for higher-level officials to act as

the Responsible Official for a plan, plan amendment, or plan revision across a number of plan areas when consistency is needed. Additional procedural guidance will be placed in the Forest Service directives to ensure consistency as needed for Tribal or public consultation or for social, economic, or ecological resource related issues.

The Department intends the final rule be flexible in addressing different issues that may arise at different levels. Therefore, the Department does not believe that the final rule should provide the specific criteria for when a higher-ranking official becomes the Responsible Official.

The final rule retains the provision in the 2002 proposed rule for the Supervisor to be the Responsible Official because the Department believes that the Supervisor is the person most familiar with the resources and the people on their unit and is usually the most appropriate person to make decisions affecting those lands. This provision has not changed from the 2000 planning rule. Together, environmental management systems, science, monitoring, evaluation, interdisciplinary teams, public participation, objection process, and other laws and direction all aid in providing relevant information for the decisionmaker.

However, the final rule retains the provision in the 2002 proposed rule to allow higher-level officials to serve as Responsible Officials. Also, the final rule retains the provision of the 2002 proposed rule for an objection process in which the Reviewing Officer, who is the supervisor of the Responsible Official, must respond to objections before approval of a plan, plan amendment, or plan revision (§§ 219.13 and 219.16).

Comment: Forest Service Strategic Plan. Some respondents observed that the 2002 proposed rule only acknowledges the existence of the Strategic Plan and does not provide guidance about using the Strategic Plan in new plans, plan amendments, or plan revisions.

Response: The Strategic Plan provides an overall vision for management of the NFS. Land management plans, projects, and activities contribute to the vision and Responsible Officials approve them within the context of the Strategic Plan. The Department believes that decisions regarding how plans should use the Strategic Plan are best made at the national forest, grassland, prairie, or other comparable administrative unit level.

Section 219.3—Nature of Planning and Land Management Plans

The direction found in § 219.2 of the 2002 proposed rule has been redesignated at § 219.3 as part of the reorganization of the final rule. The direction found in § 219.3 of the 2002 proposed rule has been moved to § 219.2 of the final rule. Section 219.3 describes the nature of planning, and the force and effect of plans.

Comment: Desired conditions as the purpose of planning. Some respondents believed that the final rule should establish desired conditions as the fundamental purpose of a plan and that this section of the final rule provides a clear statement of what a plan will do. Others said that the focus on desired conditions may be too narrow in light of the overall goals of multiple use and sustained yield. Others commented that the primary purpose should be to integrate human activities and ecological processes. Still others said that the term "desired conditions" was too susceptible to multiple interpretations and the purpose of a plan should be changed to "fulfill multiple-use objectives to ensure ecological sustainability."

Response: The Department concluded that, while "desired conditions" may drive how the other plan components are developed, "desired conditions" are not the "primary purpose" of a plan. The final rule has been changed at § 219.7(a) to clarify that plans also provide objectives, guidelines, suitability of areas, and special areas. There is further discussion of desired conditions in the preamble to the final rule in the section entitled "The strategic and adaptive nature of land management plans." Plans are developed in light of the overall goal of managing the NFS lands as described in § 219.1, which is to sustain the multiple uses of its renewable resources in perpetuity while maintaining the long-term productivity of the land.

Comment: Oil and gas leasing decisions. Some respondents felt that the 2002 proposed rule's emphasis on the programmatic nature of plans is contrary to the Federal Onshore Oil and Gas Leasing Reform Act (Oil and Gas Leasing Reform Act) of 1987 (Pub. L. 100–203, 101 Stat. 1330–256, 30 U.S.C. 181, 226, 226–3), Forest Service regulations, and the Mining and Minerals Policy Act of 1970 (30 U.S.C. 21a), which these respondents say, require project or activity decisions to be made in a plan.

Response: The Forest Service directives will include guidance on making an initial availability decision for oil and gas leasing where there is the geologic potential for the occurrence of such resources or where there has been an expression of interest in leasing. There is no irretrievable or irreversible commitment of resources unless and until the Department of the Interior decides to issue a lease, giving certain exclusive rights to the lessee. Ground-disturbing activity and the final irreversible and irretrievable commitment of resources occur only when a decision approves a surface use plan of operations. Exploration or development of a lease requires additional environmental analysis, public disclosure, and specific project decisions by the appropriate regulatory agencies.

Because plans include plan components that describe which lands are generally suitable for consideration for energy and mineral leasing, they meet the intent of the Oil and Gas Leasing Reform Act, the Forest Service regulations for oil and gas resources, and the Mining and Minerals Policy Act. Specific project decisions to explore or develop a lease or mining claim are properly deferred to the project or activity level.

Comment: Management zone authorities. Some respondents said that only counties have authority to create zoning ordinances. Others said that the zoning system creates a dominant or single use that is contrary to multiple-use.

Response: The Forest Service is responsible for managing the lands of the NFS under NFMA and other laws. The terms "zoning" or "zone" were not in the text of the 2002 proposed rule, nor are they in the text of the final rule. The Forest Service is not issuing zoning ordinances. The preamble to the 2002 proposed rule described plans as creating "zones" in the forest. The Department used the term as a metaphor to help describe how plans may identify suitability of areas.

Section 219.4—National Environmental Policy Act Compliance

Compliance with NEPA was addressed in § 219.6 in the 2002 proposed rule. This section has been redesignated at § 219.4 as part of the overall reorganization of the final rule. This section of the final rule describes how planning will comply with NEPA.

Comment: Applicability of NEPA, NEPA documentation, NEPA "significance," and the nature of forest plans. Some respondents said that NEPA is not applicable to planning, noting that a plan should provide a framework for future project and activity decisionmaking and that the

disclosure of effects in plan-level NEPA documents is necessarily speculative; some said that plans do not significantly affect the environment. Others said that it might be more advantageous to make as many project-level decisions during the forest planning process as possible, because one NEPA analysis document could be used to make numerous decisions. Another said that failure to make decisions at the plan level would delay implementation of projects.

Some respondents supported categorically excluding plans from NEPA documentation, while others suggested that the criteria for categorically excluding plans were unclear, or that extraordinary circumstances in the plan area would always preclude the use of a categorical exclusion (CE). Some respondents thought the criteria for determining whether a CE is appropriate gives the Responsible Official too much discretion; others thought the degree of discretion appropriate. Some respondents indicated that they did not see the relationship between categorically excluding plans from NEPA documentation and achieving a more streamlined, adaptive planning system and holding the Forest Service accountable for its plans. Some interpreted categorically excluding plans from NEPA documentation as not complying with NEPA, rather than application of a provision of the NEPA regulations.

Many questioned how certain procedures, such as plan analysis and public involvement, would occur if a CE is used. Many people questioned how cumulative effects would be considered if a CE was used, and how monitoring would occur. Some wanted clearer and stronger direction for when a plan might be categorically excluded and when an environmental impact statement (EIS) would be required. Some respondents asked the Forest Service to distinguish between effects to the environment and effects to the human environment.

Respondents stated a number of reasons in support of an EIS for plans. Some respondents commented that plans, by their very nature, are controversial and therefore should require an EIS. Some commented that the requirement of the 1982 and 2000 planning rules to prepare an EIS for plans and revisions was an acknowledgment that plans are major Federal actions having significant effects on the environment. Others suggested that a substantial change in the existing situation on the ground or a substantial change to an existing plan would trigger an EIS. Some respondents said that the 2002 proposed rule misconstrued the role of a plan and thus the applicability of NEPA, saying that a plan is not just a simple framework, but rather creates changes on-the-ground that have environmental consequences. Some said that if a plan acts as a zoning document and authorizes increased motorized recreational uses, detailed analysis would have to occur in the plan analysis for all affected sites. Some respondents thought that the 2002 proposed rule differentiated between whether an EIS would be required for plan revisions, as opposed to new plan development, arguing that existing plans must need "significant" changes because conditions had changed since the plans were originally adopted.

However, some said that a better approach, instead of focusing on "zones," would be to describe where in the plan area certain uses would have dominance over other uses. Others said that plans should set timber sale schedules; indicate what areas are available for logging, grazing, off-road vehicles use, and mineral extraction; and establish unique areas for protection, and that NEPA documentation would be necessary to make such decisions. They said that plans should establish measurable and enforceable standards and objectives. Others said that management activities must be analyzed on a site-by-site basis in a NEPA document for the plan.

Some respondents thought that in the absence of an EIS, the Forest Service would ignore information that would curb timber harvesting. Some thought that an EIS was needed to ensure ecological sustainability because adequate analysis needs a long-term view that considers science.

Some respondents commented that there is a history of case law that requires the Forest Service to follow not only NEPA, but also the Council on Environmental Quality (CEQ) regulations at 40 CFR parts 1500–1508. Some respondents raised a number of NEPA regulation requirements for "significance," including the uncertainty of effects; the potential for establishing a precedent for future actions with significant effects; connectivity of actions; potential violations of Federal, State, or local environmental laws; consideration of the 10 "significance" factors in the CEQ regulations; and various other factors.

Response: As described in the "Overview of the Final 2004 Rule," land management plans under this final rule will be strategic and aspirational in nature. They will include decisions with on-the-ground effects only in extraordinary circumstances. If a plan includes on-the-ground decisions, it will not fall within the categorical exclusion being proposed in connection with this final rule. Otherwise, it will be categorically excluded from NEPA documentation due to the fact that the adoption or amendment of plans containing the five plan components described above is not a major federal action significantly affecting the environment. Simultaneously with this rulemaking, the Forest Service is proposing to revise its NEPA procedures to provide a new categorical exclusion for plan development, amendment, and revision. The Forest Service is seeking comment on the proposed categorical exclusion. Information developed in plan monitoring and evaluation, including those required by § 219.6, may be incorporated by reference in applicable NEPA documents and used as basis for the analysis needed for specific project and activity decisions. The final rule establishes a planning process that complies with NEPA in a manner appropriate for NFMA planning. The final rule does not preclude Forest Service participation in development of an EA or EIS in a joint planning effort with another Federal agency.

The Department emphasizes that project or activity decisions are generally not appropriate for inclusion in a plan level document; experience has shown that including project and activity decisionmaking in planning has actually delayed the planning and project and activity processes without improving natural resource management or public participation. Thus, by sharpening the distinction between planning and project and activity decisions, the Department expects both better planning decisions and more useful and timely environmental analysis for project and activity decisionmaking. Experience has shown the futility of attempting detailed project and activity proposals at the time of plan approval: the NEPA documentation for the proposed projects and activities would be largely speculative and unwieldy and would not account for unforeseen circumstances. Most of the document would be out of date by the time most of the projects or activities would be ready for decisionmaking.

Paragraph (d) of § 219.4 specifies that nothing in this rule alters the application of NEPA to proposed projects and activities. For example, a decision to allow motorized recreational use within the plan area may be made contemporaneously with, but not as a part of, a plan, but such decision can only be made upon the completion of the appropriate level of NEPA analysis.

The Department believes that, in general, an EIS does not need to accompany planning decisions made pursuant to NFMA, particularly given that plans under the final rule will contain five components merely setting forth desired conditions, objectives, guidelines, suitability of areas, and special areas. Until now, the agency's practice under NEPA has been to require programmatic EISs for plan development and revision, and EISs or EAs for proposed plan amendments. Because a plan, in most cases, is a framework for future action, EISs prepared at the plan level had no proposed "action" on which to focus. Similarly, disclosure of effects of a plan included discussions of possible environmental impacts from an array of potential projects and activities whose dimensions and details were far from certain and ranged over a 15-year period for implementation without an ability to predict unforeseen natural events. To conduct a meaningful evaluation of environmental impacts, and to provide helpful information to decisionmakers, the agency must examine the details of proposed activities, the extent of those activities, the specific location of those activities, the environmental conditions at the site when the activities are proposed, past and reasonably foreseeable future actions that might relate to the cumulative impacts of the proposed activities, and reasonable mitigation measures, if appropriate. After 25 years of experience, the Department now knows this information is not generally available at the time of plan approval, and that to provide such specific information at the time of adopting or amending a plan is an inefficient use of resources.

Furthermore, between the time of plan evaluation and the design of projects, the possibilities change. A plan EIS disclosure of potential cumulative impacts and other unit-wide information are speculative to begin with, and therefore, quickly become outdated. The agency has found that a plan EIS typically does not provide useful, current information about potential cumulative impacts at the time of project or activity proposals; therefore, relying upon, or "tiering" to, a plan EIS has not proved to be effective over the long term.

Under the final rule, approval of a plan, plan amendment, or plan revision creates the framework that will lead to projects and activities for which EISs, EAs, or reliance on CEs will be necessary. Accordingly, the Department believes it is appropriate at the time of plan development, plan amendment, or plan revision to begin assembling appropriate data and other information to be used in those EISs, EAs, and CEs. Much of this information should come from the environmental management system processes described in the other parts of this rule. However, the assembling of data and other information that will be useful in making future project or activity decisions does not itself constitute a proposal for major Federal action. Thus, the process of implementing NEPA is a continuum that begins when the planning framework is established, and moves through scoping for specific project and activity decisions, culminating in a NEPA document for the project and activity proposals.

Moreover, the final rule does provide for extensive analysis, as set out in §§ 219.6 and 219.7. A comprehensive evaluation must be done for plan development and revisions and updated at least every five years (§ 219.6(a)). This evaluation will provide a broad overview of current conditions and trends relevant to the plan area. This overview, along with information from annual evaluations and other sources, will be part of the continually updated Plan Documents or Set of Documents that must be considered in project analysis. These Plan Documents or Set of Documents will provide a better context than had been provided in plan EISs for project cumulative effects disclosures; therefore, the Forest Service will make better informed management decisions at the time it decides to act. The Plan Documents or Set of Documents required by the final rule will make it easier to propose, approve, and carry out projects.

Conditions can and do change between the broad "cumulative effects" analysis the agency has done for plan EIS's and a later, actual project or activity decision. Fires can occur, adjacent landowners can do something that was not predicted, and the agency can be doing actions it had not anticipated at the time it developed the plan and not undertake projects or activities it thought it would. Under this final rule, the Forest Service uses monitoring and the results of the comprehensive evaluation with the most up-to-date site-specific information to provide a basis for the consideration of cumulative effects for projects and activities. Again, cumulative effects like project or activity specific impacts are best studied in the context of a concrete proposal.

The process outlined in the final rule retains and improves upon the important planning elements the public has come to expect, such as public involvement; taking into account the best available science; integrated analysis of social, economic, and ecological systems; monitoring and evaluation. An EIS is not necessary to ensure that the public is given an opportunity to participate in the planning process, or that the agency obtains high quality information, considers the best available science, and considers the long-term view. Under the final rule, the opportunities for the public will be greater than those opportunities required by regulation for an EIS, because the final rule mandates public involvement opportunities in developing and updating the comprehensive evaluation report, establishing the components of the plan, and designing the monitoring program. Additionally, by requiring an EMS, combined with the procedures in the Forest Service directives, the final rule provides for agency accountability through impartial and objective audits, management reviews, and public disclosure of the results of those reviews.

Plans under this final rule will not contain final decisions that approve projects and activities except under extraordinary circumstances. Guidelines, which are intended to provide some direction in how to implement decisions, have no influence until they are applied in a project or activity. The identification of an area as generally suitable for a use is not a commitment or decision approving projects and activities. Any proposed use in an area identified as suitable for that use must be separately considered under agency NEPA procedures at the time of a project decision. Desired conditions and objectives are not commitments or final decisions approving projects and activities in the plan area. Special areas may be designated by statute or through plan development, plan amendment, or plan revision or a separate administrative process under NEPA and other applicable laws. In summary, none of these component parts of a plan is permanent, or final, in that all are subject to reconsideration and change through plan amendment or plan revision at any time. Should a Responsible Official nevertheless choose to include projects or activities within the context of a plan, plan revision, or plan amendment, extraordinary circumstances may be present such that an EIS or an EA may be required.

From more than 25 years of NFMA planning experience, the Department concluded that it can most efficiently and appropriately evaluate and analyze the environmental consequences of an

array of potential projects and activities when those matters reach the status of a proposal. Making planning a more continuous process, not dependent on environmental impact statements that only give a prediction at one point in time, will actually make plans more relevant to projects by collecting, evaluating, and monitoring data on an ongoing basis, thereby maintaining a current base of information that Forest Service can use at the project or activity level.

Comment: Alternative or option development. Some respondents questioned how alternatives—when developing plans, amendments, or revisions—would be considered if plans were categorically excluded from NEPA documentation. Others emphasized the importance of forming effective partnerships with government, private landowners, industries, and others to promote consensus and reduce the need for numerous alternatives. Some expressed concern that the agency would consider only its proposed plan and not the comments on, or alternatives to, the plan. Others asserted that NEPA requires a full range of alternatives, while others said only two alternatives are needed.

Response: Requirements for how options may be considered while developing plans, amendments, or revisions are found in § 219.7(a)(6) of this final rule. The Department recognizes that people have many different ideas about how NFS lands should be managed and that the public should be involved in determining what the plan components should provide. Therefore, the final rule provides for participation and collaboration with the public at all stages of plan development, plan amendment, or plan revision. The Responsible Official shall work closely with the public to develop the proposed plan, plan amendment, or plan revision. Key steps in development of the proposed plan shall be documented in the plan set of documents, which will be available to the public. The proposed plans that the Forest Service presents for public comment shall be jointly and collaboratively developed with the public.

Section 219.5—Environmental Management Systems

This section has been added to the final rule to address public comments regarding how planning relates to adaptive management. Adaptive management was addressed in § 219.11, Monitoring and Evaluation, in the 2002 proposed rule. Both the proposed and final rule define adaptive management as an approach to natural resource management where actions are designed and executed, and effects are monitored for the purpose of learning and adjusting future management actions, which improves the efficiency and responsiveness of management. The "Overview of the Final 2004 Rule" section of the preamble provides a detailed description of the provisions of this section as developed through the response to public comments.

The Department has chosen to require each administrative unit to carry out an EMS based on standards developed by the International Organization for Standards (ISO). Each administrative unit's EMS will serve as a framework for land management planning, adaptive management and, at the project level, provide information for EISs, EAs, or CEs where required by NEPA. The EMS will provide a structured and documented process for evaluating each unit's environmental conditions, setting objectives to meet the unit's legal and public obligations, developing programs and procedures for managing the unit under the land management plan, monitoring and measurement procedures to collect and track information about environmental conditions, and corrective action and review processes to provide a "feedback loop" to push for continual improvement.

Section 219.6—Evaluations and Monitoring

This section has been organized to specify requirements for plan evaluation and plan monitoring. Monitoring and evaluation requirements were found in §§ 219.4(a)(6) and 219.11 of the 2002 proposed rule. The final rule allows the monitoring program to be changed with administrative corrections and public notification, instead of amendments, to more quickly reflect the best available science and account for unanticipated changes in conditions. Changes in a monitoring program will be reported annually, and the Responsible Official has flexibility to involve the public in a variety of ways in developing any changes to the program. Discussions of both evaluation and monitoring are found in the "Overview of the Final 2004 Rule" section of the preamble.

One clarification regarding the requirement at § 219.6(b)(2)(i) may be helpful. This paragraph requires that the plan monitoring program shall monitor to determine the effects of management on the productivity of the land. The term "productivity" refers to all of the multiple uses, such as outdoor recreation, range, timber, watershed, and wildlife and fish. Use of this term is broader than just commercial uses.

Comment: General. Several respondents supported the monitoring and evaluation provisions of the 2002 proposed rule, because they observed that the 2002 proposed rule provided the appropriate level of monitoring and evaluation. Others thought the 2002 proposed rule gave too much flexibility to the Responsible Official, weakening monitoring and evaluation requirements. Some respondents wanted the requirements from the 2000 planning rule retained because they felt the 2002 proposed rule did not have sufficient requirements to mandate adequate monitoring and evaluation.

Others thought the Responsible Official was given the appropriate level of flexibility to allow for alteration of monitoring and evaluation strategies and methods. Still others thought the 2002 proposed rule had burdensome requirements that needed to be relaxed. One person suggested the Forest Service establish an independent division to ensure monitoring compliance. Some suggested specific monitoring they believed was needed.

Several respondents submitted suggestions about how the Forest Service evaluates the information obtained from monitoring. One respondent stated that the use of evaluation is fuzzy and needs clarification. Others suggested that evaluation could be used to indicate the need for a new use of the NFS. Another cautioned that any evaluation of the information obtained from monitoring should include an estimate of error reliability of any apparent trend to preclude premature or ill-advised corrections.

Response: The Department believes that monitoring and evaluation are a critical and necessary part of the planning process. As the 2002 proposed rule provided, the final rule requires the Responsible Official to provide for monitoring of degree to which on-the-ground management is maintaining or making progress toward the desired conditions and objectives for the plan (§ 219.6(b)(2)). The Department has strengthened this section in the final rule by adding a requirement for comprehensive evaluation of the area of analysis (§ 219.6(a)(1)) at no longer than 5-year intervals and conducting an evaluation when amending a plan (§ 219.6(a)(2)). In addition, the use of an EMS with impartial and objective audits will address both the concerns expressed in the comments for local flexibility and those for agency accountability and compliance. The Department has also added a provision that the monitoring program take into account the best available science to

improve the evaluation process. These evaluations are an integral part of answering key planning questions such as the state of social, economic, and ecological conditions and trends, and the need for an amendment or revision.

Comment: Involvement of science. Several respondents wanted assurance that science would be involved in monitoring.

Response: The Department believes that the taking into account the best available science is important in monitoring and in evaluating results. The Department added the provision that the monitoring program shall take into account the best available science at § 219.6(b). In addition, the final rule at § 219.11 retains the intent of the 2002 proposed rule (§ 219.14) that requires the consideration of best available science during planning, including the development and implementation of monitoring program.

Section 219.7—Developing, Amending, or Revising a Plan

The provisions in §§ 219.4, 219.7, 219.8, 219.9, 219.15, and 219.18 of the 2002 proposed rule have been combined at § 219.7 of the final rule so that procedural requirements are located in one section. This section includes requirements for plan components; planning authorities; plan process, including review of areas with potential for wilderness recommendation; administrative corrections; Plan Document or Set of Documents; and the plan approval document. The detailed public participation, collaboration, and notification requirements found in §§ 219.7, 219.8, and 219.12 of the 2002 proposed rule have been moved, with additional detail, and consolidated at § 219.9 in the final rule to improve clarity and readability.

Section 219.7(b) provides for administrative corrections. The final rule, at § 219.7(b)(5), adds a new category for administrative corrections to include changes in the Plan Document or Set of Documents, except for changes in the plan components. The Department made this addition because, although an emphasis of the final rule is to allow for continual inclusion of new science and other information into the Plan Document or Set of Documents, the 2002 proposed rule included no specific vehicle for allowing this supplementation and change to occur. Changes to the Plan Document or Set of Documents may also occur when outdated documents are removed, for example, when a new inventory replaces an older one. The addition of this new administrative correction category fills this procedural gap.

Comment: Desired conditions. Some respondents said that it is unclear what the desired conditions for the plan area will be and who makes the decision on which desired conditions will be included in the plan. Some said specific substantive requirements should be established, such as requiring desired conditions to mimic natural conditions, or employment of a policy such as "limits of acceptable change."

Response: Desired conditions are one of the plan components (§ 219.7(a)) developed through public collaboration and participation. The Responsible Official is the decisionmaker for the plan. The Responsible Official will consider public participation, the comprehensive evaluation, monitoring information, legal requirements, and assessments in deciding on desired conditions for the plan area. The final rule at § 219.7(a) clarifies that desired conditions are the "social, economic, and ecological attributes" toward which the plan is to be directed.

Because desired conditions are a component of a plan, but not necessarily the primary focus of a plan, the final rule removes the words "primary focus of a plan." As it will for all plan components, the public will have an opportunity to comment on all aspects of the proposed plan, including desired conditions (§ 219.9), and may object to the plan in whole or in part (§ 219.13) if they have concerns. A discussion of plan components is found in the "Overview of the Final 2004 Rule" section of the preamble.

Comment: Objectives. Some respondents said that plan objectives must be clear and measurable. They said that plans should provide for a good faith commitment to accomplish a plan's multiple-use and sustained-yield objectives. Others said that it may be counterproductive to write simple objectives when many factors lead to complexity in their implementation. Some said that the 2002 proposed rule lacks policy direction concerning the extent to which investment in resource management activities may support different outputs. Others said the push for clear objectives, where there is no clear science, will lead to direction that is meaningless and simply become a tool of a political agenda. Others said the final rule should explicitly provide for forest plan objectives to be established in accordance with guidelines in the Forest Service directives.

Response: The final rule retains the provision of the 2002 proposed rule stating that objectives are measurable outcomes intended to guide management toward reaching desired conditions. Objectives can be thought of as a prospectus of outcomes, based on past performance and estimates of future trends. Objectives should be measurable so progress toward attainment of desired conditions can be determined. Variation should be expected due to changes in environmental conditions, available budgets, and other factors. In addition, the Department added the concept of maintenance of desired conditions to the description of objectives, because the desired conditions may already have been met and only need to be maintained.

Comment: Standards. One respondent commented that clear, measurable standards are important. One respondent identified the intent of the proposed regulations to simplify, clarify, and minimize the standards. Some said that only measurable standards allow the public to know what the Forest Service is doing. Some said that NFMA requires enforceable standards and that judicial review would be more difficult without measurable standards. Some said that standards should be defined as "requirements" instead of "limitations." Others wanted to make clear that standards can be forest-wide or area-specific.

Response: As explained in the "Overview of the Final 2004 Rule" section of the preamble, the Department has replaced the component of "standards" with "guidelines." The Department believes requiring mandatory standards are too restrictive; however, guidelines will be used and, in many cases, will be measurable. Policy contained in the Forest Service directives will provide the detailed direction for writing plan guidelines. The Forest Service directives will provide criteria for guidelines, requiring they be written clearly, so decision makers and the public know when a project is consistent with the guidelines.

While the final rule will not require standards, the public shall be kept informed about what the Forest Service is doing by procedures such as: (1) Providing opportunities for the public to collaborate and participate (§ 219.9(a)); (2) opportunities to object before approving plans, plan amendments, or plan revisions (§ 219.13(a)); and (3) public notice requirements for land management planning (§ 219.9(b)), NEPA procedures for projects and activities, and annual evaluation of monitoring results. The final rule also allows for forest-wide and area-specific guidelines.

Comment: Special designations. Some respondents suggested that the final rule should contain language that addresses presidential and congressionally designated areas. Respondents stated that the 2000 planning rule gives the Responsible Official too much discretion when evaluating roadless areas for special designation. Some said the final rule should provide standards for the Responsible Official to follow when evaluating and considering special designations of the roadless areas. Some said these standards should ensure that evaluations of roadless areas are completed, taking into account the best available science, and focus on ecological sustainability. One group wanted to ensure that special designations are not determined in a vacuum favoring only ecological values, and the group said that social and economic values must also be addressed. Others felt the effects of special designations should be considered for recreational access and mirror the increasing demand for recreation. Some said the final rule should require that plans set specific goals, such as an amount or a percentage of the forest for special area recommendations.

Response: Special area identification is an integral part of the planning process. The proposed and final rules provide for the identification of special areas in the plan. After reviewing comments, and consideration of the Forest Service's experience with planning over the past 25 years, the Department concluded that guidance about special area concerns, such as roadless area evaluations or social and economic values, are more properly included in the Forest Service directives. Provisions in directives can be more extensive and can be more easily changed as the agency learns how to improve its processes and as new scientific concepts become available.

Comment: Specific uses. Many respondents suggested that the final rule identify specific uses that should be included in plans. One person suggested that the final rule provide for large recreational gatherings. Another said that livestock grazing should be specifically discussed.

Response: Plans establish desired conditions, which include recognition of the type of societal benefits that the NFS provides. The final rule begins with a presumption that lands are available for multiple uses and that plans will identify suitable uses that best fit the local situation.

Comment: Need for amendment or revision. Several respondents were concerned about the discretion the 2002 proposed rule gives the Responsible Official in determining when a plan amendment or plan revision is needed. Some felt the final rule needs clear direction on when to propose a plan amendment or plan revision. Of equal concern was the discretion given to the Responsible Official to decide which issues would be considered in an amendment or revision. They felt that without specific requirements resources, such as flora and fauna, would not be analyzed for every plan amendment or plan revision. One respondent did not want plans to be revised or amended after disturbance events, such as wildfire, insect epidemics, and windstorms. Others supported limiting the analysis required in amending or revising a plan.

Response: The final rule provides the Responsible Official discretion about whether or not to initiate a plan amendment or plan revision (subject to the NFMA requirement that the plan be revised at least every 15 years) and what issues to consider (§ 219.7(a)(4)). The evaluations required by the final rule will document current conditions and trends for social, economic, and ecological systems within the area of analysis (§ 219.6(a)) and aid the Responsible Official in determining if a plan amendment or plan revision is needed and which issues need to be considered. The Responsible Official may amend or revise the plan based on monitoring and evaluation, as well as other factors. The Department believes that the efficiencies of the final rule would be reduced if the final rule identified specific issues that must be considered for every plan revision or plan amendment.

Comment: Interim amendments. Many respondents did not support interim amendments and suggested this provision be removed or at least have additional parameters added. Others supported this concept.

Response: The final rule allows for an efficient plan amendment process. Therefore, there is no need for interim amendments. Accordingly, the interim amendment provision has been removed from the final rule.

Comment: Significant plan amendments. Many respondents were concerned with how "significance" is determined for an amendment. Some wanted significance described, while others suggested certain factors to determine significance. Others wanted to understand the connection between an EIS and NFMA significance with respect to the 2002 proposed rule's provision that every amendment prepared with an EIS would be deemed a significant amendment.

Response: The Department decided not to distinguish between "significant" and "non-significant" amendments. The Department is not requiring an EIS with any plan amendment. The final rule treats all amendments as "significant," except when an amendment would relate only to a proposed project or activity. Plan amendments prepared under the procedures described in this final rule must have a 90-day comment period (required for significant amendments by NFMA) and must have an objection opportunity. Plan amendments associated with a proposed project or activity will follow the NEPA documentation required for the project or activity, as well as notice and comment requirements for the project or activity.

Comment: Roadless area evaluation. Some respondents felt that under the 2002 proposed rule, the requirements for evaluation and protection of the roadless areas' ecological values had been eliminated, allowing the Responsible Official to redefine roadless area boundaries upon a determination of circumstances deemed necessary and appropriate. Some felt this language was too broad, deferred too much authority to the Responsible Official, and would eliminate many lands from consideration for new wilderness, though they still met the physical requirements of a roadless area. Others supported the requirement that the Responsible Official review and validate the maps of inventoried roadless areas and then adjust them as necessary and appropriate.

Response: The Department has moved this provision from § 219.15(b)(3) in the 2002 proposed rule to § 219.7(a)(5)(ii) in the final rule. Because the 2002 proposed rule caused confusion concerning roadless area evaluation, the Department has changed the wording to describe these areas from "inventoried roadless areas" to "lands possessing wilderness characteristics." The final rule at 219.7(a)(5)(ii) directs Responsible Officials to ensure that, unless otherwise provided by law, all NFS lands possessing wilderness characteristics be considered for recommendation as potential wilderness areas during plan development or revision. Policy and guidance contained in the Forest Service directives will provide the detailed direction for the identification of these areas and the evaluation process to follow in carrying out this requirement.

Section 219.8—Application of a New Plan, Plan Amendment, or Plan Revision

This provision, found in § 219.10 in the 2002 proposed rule, has been redesignated at § 219.8 as part of the overall reorganization of the final rule. This section of the final rule describes how and when new plans, plan amendments, or plan revisions are applied to new or ongoing projects or activities. The general outline and intent of this section in the final rule is similar to the corresponding section of the 2002 proposed rule. However, § 219.10(e) of the proposed rule addressing testing and research projects was removed from the final rule because the acknowledgement that these projects are subject to all applicable laws is not necessary. While the 2002 proposed rule required project or activity consistency with standards, the final rule requires consistency with the applicable plan.

Comment: Valid existing rights. Respondents were both for and against the 2002 proposed rule provision that new plan direction is subject to valid existing rights. Those in favor supported respecting these rights. Those against said that protection of ecological conditions should take precedence.

Response: The final rule at § 219.8(a)(2) is consistent with NFMA (16 U.S.C. 1604(i)) which specifies that any revision in present or future permits, contracts, and other instruments made pursuant to the act shall be subject to valid existing rights.

Comment: Consistency with the desired conditions. Several respondents commented that under the 2002 proposed rule, projects do not need to be consistent with standards; they only have to disclose the project's relationship with desired conditions. Some said that NFMA requires all projects to be consistent with the plan and said that if desired conditions are in the plan, projects need to be consistent with them. They also said the public will be disappointed to find out that plans have no "teeth." Others were concerned that the 2002 proposed rule emphasizes desired conditions and objectives, which by definition may never be attained.

Response: NFMA (16 U.S.C. 1604(i)) requires that resource plans, permits, contracts, and other instruments for the use and occupancy of NFS lands be consistent with land management plans. In response to public comment, § 219.8(b) was added to the final rule to describe how projects or activities developed after approval of the plan must be consistent with applicable plan components. The Department removed two provisions: (1) the provision limiting consistency to standards and (2) the provision requiring disclosure of the project's relationship to desired conditions.

In the final rule, if an existing or proposed project or activity is not consistent with the applicable plan, the Responsible Official must take one of the following actions: (1) Modify the existing or proposed project; (2) reject the proposal or terminate the existing project; or (3) amend the plan. The Department changed the final rule so the wording conforms to 16 U.S.C. 1604(i).

Comment: Consistency with standards. Several respondents commented on the requirements that projects or activities not consistent with standards be either modified or rejected, or the plan be amended. Some said projects should not be exempted from standards, while others said that the final rule should specify that changes must be considered within the context of NEPA.

Response: The Department changed the final rule so that projects or activities must be consistent with the applicable plan. A project or activity-specific amendment does not "exempt" a project from the plan, but rather, the amendment changes the plan, for that project. If a plan amendment is necessary as part of a project or activity decision, that decision will be considered in accordance with project NEPA procedures.

Section 219.9—Public Participation, Collaboration, and Notification

This section of the final rule consolidates 2002 proposed rule provisions for public notifications and comment periods found in §§ 219.7, Amending a plan; 219.8, Revising a plan; 219.12, Collaboration, cooperation, and consultation; and 219.21, Notice of plan decisions and effective dates. A discussion of public involvement is found in the "Overview of the Final 2004 Rule" section of the preamble.

General comments: Some respondents expressed the belief that the 2002 proposed rule excludes the public from participation in the planning process, and they wanted clarification of what the public's role would be under the final rule. Some were concerned that the 2002 proposed rule no longer requires landscape goals be developed collaboratively. Additionally, some wanted a uniform process for public involvement. One person suggested the agency allow e-mail and other nontraditional forms of public participation and notification. One respondent said the Forest Service should not allow any public participation in planning. Many supported the 2002 proposed rule requirements for public involvement. Some respondents stressed the need for open and vigorous public participation. One Tribal group supported the requirement for consultation with federally recognized Indian Tribes. Others supported a broader range of media than is currently being used for public notification. Another felt the final rule should be specific about where plans are made available and about local public meetings. Some felt that a Notice of Intent should be placed in the **Federal Register** for all revisions.

Response: The Department strongly supports public involvement in planning. Public participation, collaboration, and notification requirements found in §§ 219.7, 219.8, and 219.12 of the 2002 proposed rule have been moved to § 219.9 in the final rule to improve clarity and readability. The final rule states that the Responsible Official shall use a collaborative and participatory approach to land management planning. The final rule does not exclude the public from participation in the planning process. There is a wide variety of methods for public involvement. For example, where practical, Responsible Officials may give extended notice of public meetings, including the use of unit Internet web sites. It is virtually impossible at the national level to specify details for each type of public involvement used during a planning process; however, the Forest Service is developing techniques that will improve public notification and participation in the planning process. Because planners are constantly improving these techniques, other forms of direction, such as the Forest Service directives, are more appropriate ways to prescribe the "how to" details of public notification.

Neither the 2002 proposed rule nor the final rule used the cooperative development of landscape goals, because this specific activity should not be a requirement of all planning efforts. It may not always be useful and may often be unachievable with participating groups. The Department also believes that one standard process for public involvement would not be effective for every unit in the NFS. The size and scope of issues, the interest level of the public, and the resources vary across the country. Therefore, the final rule requires the Responsible Official to involve the public, but allows discretion for the particular type of public involvement process used.

The final rule retains the requirement of the 2002 proposed rule that the Responsible Official provide opportunities for individuals and entities to participate, consult with federally recognized Indian Tribes, and provide for a 90-day public comment period. The final rule has added requirements that public involvement must occur in developing and updating the comprehensive evaluation report, establishing the components of the plan, and designing the monitoring program (§ 219.9(a)).

Other specific methods and timing for public participation and involvement outside of the formal public notice and comment process will be developed and implemented on a unit-specific basis so that they are tailored to the context and the stakeholders. The Department did not believe it appropriate to establish national "one-size-fits-all" requirements. In addition, the Department agrees with comments on the need for publication of a Notice of Intent to revise in the **Federal Register** for all plan revisions. The final rule adds the requirement that notification of new plans and plan revisions be published in both the **Federal Register** and the newspaper(s) of record.

Comment: Advisory Committees. One respondent suggested the use of an advisory committee as a means to improve public involvement. Another wanted a multi-agency review board. Another person wanted to know why the Department had not required advisory committees in the 2002 proposed rule. Several respondents supported the elimination of an advisory committee (required by the 2000 planning rule) as they felt the general public would be left out of the planning process. Two recreation organizations felt that this elimination was a vast improvement and would invigorate the public participation process.

Response: The Department believes that an advisory committee, or something similar, may be the most effective method to engage the public in some situations, but it may not be effective in other cases. As in the 2002 proposed rule, the final rule allows the Responsible Official the discretion to determine the methods of public involvement opportunities, which can include, but does not require, advisory committees.

Comment: Local involvement. Several respondents wanted local input to have priority over other input. Others were concerned that only special interests were being heard.

Response: The NFS lands belong to all citizens of the United States. The Department values involvement by all interested parties, and understands the particular importance of local citizens and governments in the planning process. Responsible Officials will address local social, economic, and environmental issues in the evaluations for plans, plan amendments, or plan revisions.

Comment: Public comment period. Some respondents suggested the establishment of a required comment period for plans, plan amendments, and plan revisions. Some said that all plans should have a 90-day comment period. Others wanted the public comment period to be longer than the NFMA requirement of 90 days (16 U.S.C. 1604(d)).

Response: The final rule includes a provision that requires a public comment period of 90 days for plans, plan amendments (except for a plan amendment that applies to project or activity decision), and plan revisions. The final rule consolidates the requirements for public notification and comment periods into this section so that it is easier for the public to understand and the agency to follow. Section 6(d) of NFMA requires a comment period "of at least three months." The final rule does not preclude the extension of the comment period beyond 90 days.

Section 219.10—Sustainability

The sustainability provisions found in § 219.13 in the 2002 proposed rule have been redesignated at § 219.10 as part of the overall reorganization of the final rule. This section of the final rule provides provisions for social, economic, and ecological sustainability. The final rule retains sustainability as the overall goal for NFS planning and retains the concept of the interdependent social, economic, and ecological elements of sustainability (§ 219.10) in the 2002 proposed rule. The final rule does not include many of the specific analytical processes and requirements set out in the 2002 proposed rule. These provisions will be placed in the Forest Service directives. A discussion of sustainability is found in the "Overview of the Final 2004 Rule" section of the preamble.

The agency also hosted a workshop to provide an opportunity for public discussion of these options and for identification of other ideas on how to best address the statutory diversity provision. Interested parties expressed an extremely wide range of opinions, both in public comments and in response to the workshop. The Department found these comments useful in developing a scientifically credible and realistic approach for this final rule to meet legal requirements and to meet the agency's stewardship responsibilities.

Comment: Sustainability definition. While some respondents focused their suggestions on clarification of the actual language of the sustainability section, other respondents suggested that a definition of the term "sustainability" would help clarify this topic. Some suggested using the 2000 planning rule's definition for sustainability, others suggested the Department should seek legislative clarification of definition, and others requested a definition that balances biological productivity, human use, and economically affordable management.

Response: The concept of sustainability is first addressed in this final rule at § 219.1, which provides that, consistent with MUSYA, the overall goal of managing the NFS is to sustain in perpetuity the productivity of the land and the multiple uses of its renewable resources in a manner that best meets the needs of the American people. Section 219.10 further clarifies that the relationship among, social, economic, and ecological sustainability is interrelated and interdependent.

Comment: Biological diversity and species considered. Some respondents requested that the Forest Service maintain biodiversity on NFS land. Similarly, there were a number of comments regarding what categories of species to consider in the final rule. Some respondents wanted to consider the full array of biodiversity as in Option 2 of the 2002 proposed rule and in the 2000 planning rule, and others agreed with the focus in Option 1 of the 2002 proposed rule, that identified only native and desired nonnative vertebrates and vascular plants. Others did not want to go beyond the specific focus in NFMA on plant and animal communities and tree species.

Response: The final rule affirms the commitment of the Forest Service to meet the NFMA requirement that plans provide for diversity of native plant and animal communities by providing for a plan framework for sustaining native ecological systems. The final rule at § 219.10(b)(1) requires that provisions in plan components establish a framework to provide characteristics of ecosystem diversity in the plan area. These characteristics are parameters that describe an ecosystem in terms of the composition (such as major vegetation types, rare communities, aquatic systems, and riparian systems); structure (such as successional stages, water quality, wetlands, and floodplains); principal ecological

processes (such as stream flows and historic and current disturbance regimes); and soil, water, and air resources. Providing characteristics of ecosystem diversity is the primary means by which a plan contributes to sustaining native ecological systems. Thus, plans provide for sustaining systems, the systems provide for diversity, and Forest Service meets NFMA requirements.

The final rule adopts the concept of plant and animal species consistent with terminology in NFMA, as well as ESA. While adoption of the concept of comprehensive biodiversity is a worthy goal, the Department did not deem this necessary to meet the requirements of NFMA. The concept of biodiversity includes the full variety of life and associated processes. The Department did not think it was reasonable or possible to include the full scope and complexity of biological diversity from microbes to processes such as photosynthesis.

Comment: Ecosystem and species sustainability. Respondents offered a variety of suggestions regarding the level at which to evaluate ecosystem sustainability. Some respondents requested that the Forest Service use a hierarchical approach to evaluate ecosystems, while others suggested a more iterative process is needed. Some respondents asked that analytical and evaluation requirements be spelled out in the final rule. Other respondents wanted ecosystem sustainability in the final rule to generate requirements for how ecosystems will be maintained and who will be responsible for their maintenance.

Some respondents commented on the level at which species management decisions should be made. Some respondents requested that species management decisions be mandated by the final rule, while others asked that decisionmaking be left at the level of individual plans. Other respondents said that special provisions to maintain species are unnecessary; they asserted that such provisions are not particularly effective.

Some respondents commented that species maintenance is important and is mandated by NFMA; they requested that the Forest Service retain the requirements from the 2000 planning rule. A number of respondents also requested that the Forest Service work to restore species that have been extirpated from the plan area.

Response: The final rule adopts an overall goal for the ecological element of sustainability to contribute to sustaining native ecological systems by sustaining healthy, diverse, and productive ecological systems as well as by providing ecological conditions to support diversity of native plant and animal species in the plan area. To carry out this goal, the final rule adopts a two-level approach to sustaining ecological systems: ecosystem diversity and species diversity. The overall goal demonstrates the Department's commitment to ecosystem diversity and species conservation. This two-level approach was part of both Options 1 and 2 of the 2002 proposed rule. The final rule clarifies the two-level approach and leaves the specific detail procedures for the Forest Service directives.

As part of the two-level approach, the plan area will be assessed for remaining species diversity needs after plan components are developed for ecosystem diversity. The Responsible Official would evaluate the framework established by the plan components for specific federally listed threatened and endangered species, species-of-concern, and selected species-of-interest. If needed, the Responsible Official would develop additional provisions for these species to maintain a framework for providing ecological conditions within the plan area that contributes to the conservation of these species. The Department selected federally listed threatened and endangered species, species-of-concern, and species-of-interest for evaluation and conservation because: (1) These species are not secure within their range (threatened, endangered, or species-of-concern), or (2) management actions may be necessary or desirable to achieve ecological or other multiple use objectives (species-of-interest). Species-of-interest may have two elements: (1) Species that may not be secure within the plan area and, therefore, in need of consideration for additional protection, or (2) additional species of public interest including hunted, fished, and other species identified cooperatively with State fish and wildlife agencies.

Comment: Accountability for ecological conditions. Citing a need for accountability for sustainability, a number of respondents requested the final rule require land management plans to "provide measurable progress toward maintenance or restoration of ecological conditions." A recommendation was made to retain the provision of the 2000 planning rule that requires the Responsible Official to be accountable for the long-term maintenance and restoration of ecosystems. A respondent suggested the Forest Service conduct research on validating a broad suite of indicators that can be used to evaluate the efficacy of planning in achieving the goal of ecological sustainability.

Response: The Department believes that the plan components adopted in the final rule provide accountability for ecological conditions in that: (1) The land management plan's desired condition component provides the overall vision; (2) the objectives component provides measurable intentions for attaining the desired conditions; (3) guidelines provide the recommended technical and scientific specifications so that projects and activities conserve species; and (4) that other provisions and monitoring ensure that the combined parts of the plan are effective. In addition, EMS will ensure that Responsible Officials conduct environmental improvement in a systematic and accountable manner.

Comment: Choosing Option 1 or 2. There were wide varieties of views on the ecological sustainability options in the 2002 proposed rule. In general, the response from the public can be grouped into two categories: those who did not support either option in the 2002 proposed rule and those who supported at least one of the options in the 2002 proposed rule. Many respondents suggested that neither option is adequate in the 2002 proposed rule, citing the lack of clarity, the lack of a Committee of Scientists to assist in the development of the options, and the lack of enforceability.

Other respondents considered either option to be sufficient and remarked that both options uphold the agency's NFMA diversity requirement. Alternative suggestions from respondents included creating a hybrid of Option 1 and 2; retaining the 1982 viability regulation; protecting species through monitoring; or adopting one of the new options presented by participants at the February 2003 diversity workshop.

Response: The final rule conceptually uses the principles of ecological sustainability from both Options 1 and 2 of the 2002 proposed rule. The final rule includes an ecosystem diversity provision that requires the development of plan components to establish a framework to provide the characteristics of ecosystem diversity. These characteristics are descriptions of ecosystem composition, structure, and processes. Responsible Officials may identify these characteristics for multiple spatial scales within the analysis area and characteristics may extend to the larger landscape adjacent to and beyond the plan area. This ecosystem diversity framework provides an essential ecological context and identifies the unique contributions that

NFS lands can make to the three elements of sustainability.

Option 2 required rigorous analysis of ecological conditions in relation to the range of characteristics of native ecosystems within the plan area, the range of natural variability. Forest Service directives will set out the analytical requirements for ecosystem diversity including abundance, distribution, and condition of selected characteristics of ecosystem diversity compared to their range of variation under historical disturbance regimes (or other ecological reference).

An important principle in the framework of this final rule is the concept that the more effective the ecosystem diversity provision is in sustaining species within the ecosystem, the less need there is for species-specific analysis.

Comment: Species-at-risk, management indicator species, or focal species. Some respondents asked that the final rule require species-at-risk and focal species to be identified and maintained. A number of respondents wanted a survey and monitoring requirement for management indicator species (MIS) or focal species in the final rule. There was a suggestion to use reliable historic information to analyze the population viability of focal species. There were comments in favor of requiring species surveys and reviews, as well as comments not to have mandatory survey and monitoring requirements for maintaining populations of wildlife. Other respondents requested that the Forest Service continue to use focal species as a means to analyze and provide for species viability and species diversity.

Response: The concept of MIS was not included in the 2002 proposed rule and is not in the final rule, except for transition provisions at § 219.14, because recent scientific evidence identified flaws in the MIS concept. The concept of MIS was that population trends for certain species that were monitored could represent trends for other species. Through time, this was found not to be the case.

The concept of focal species that was proposed by the Committee of Scientists and adopted in the 2000 planning rule is also not used in the final rule. The focal species concept is untested and it would not be prudent to potentially make the same mistake with focal species as was made with MIS in the 1982 planning rule. However, the concept of focal species as indicators of the ecological conditions may have merit and may be included in the Forest Service directives as a tool to identify monitoring approaches to assess progress towards achieving the desired condition articulated in a plan.

To focus management attention on the at-risk species, the concepts of "species-at-risk" and "species-of-concern" presented in the 2002 proposed rule were further developed in the final rule to make the provision for species-level analysis clearer and efficient in the planning process. However, the Department changed the terms used. "Species-of-concern" are those species for which their continued existence is a concern and listing under the ESA may occur (§ 219.16). "Species-of-interest" are species for which the Responsible Official determines that management actions may be necessary or desirable to achieve ecological or other multiple use objectives (§ 219.16). The Forest Service directives will describe a systematic, scientifically credible, and efficient approach, using existing information, to identify species-of-concern and species-of-interest.

Comment: Protection of water supply, water quality, wetlands, and riparian areas. Various respondents stated the need to protect the nation's water supply and require land management plans to address water quality restoration for those areas identified as water quality limited under the Clean Water Act. Other respondents believed the final rule should mandate the protection of wetland and riparian areas, which are essential for environmental quality and human health.

Response: The Department agrees that water quality is important, as is restoration of impaired watersheds. The final rule provides specific provisions at § 219.10(b)(1) for development of plan components that establish a framework to provide the characteristics of ecosystem diversity, which include water quality, wetlands, riparian areas, and floodplains. It is not necessary for the final rule to repeat direction in the Clean Water Act; in addition, water related issues are not the same on every unit of the NFS. Forest Service directives will provide additional provisions as needed.

Section 219.11—Role of Science in Planning

This provision was contained in § 219.14 in the 2002 proposed rule, and was redesignated as § 219.11 as part of the reorganization of the final rule. The final rule requires the Responsible Official to take into account the best available science. The final rule puts the burden on the Responsible Official rather than on the plan. The words "consistent with" has been replaced by "take into account" because this term better expresses that formal science is just one source of information for the Responsible Official and only one aspect of decisionmaking.

The final rule, like the 2002 proposed rule, states that the Responsible Official may use independent peer reviews, science advisory boards, or other review methods to evaluate science used in the planning process. Forest Service directives will provide specific procedures for conducting science reviews. The "Overview of the Final 2004 Rule" section of the preamble discusses the role of science in planning.

Comment: Role of science. Some respondents felt that the 2002 proposed rule should add emphasis to the role of science, while others felt that the 2002 proposed rule provided a welcome relief from the 2000 planning rule by eliminating excessive process requirements. Some felt that the 2002 proposed rule made the use of science and the review of science consistency optional. Others thought that the use of science in the 2002 proposed rule appeared to be budget driven. Several respondents suggested that public involvement should include science and scientists. They thought that the Responsible Official should not make a decision without the input of science and scientists. However, one respondent felt that there should be no consultation with a panel of scientists when drafting a plan.

Response: The Department is committed to taking into account the best available science in developing plans, plan amendments, and plan revisions as well as documenting the consideration of science information. The final rule retains the emphasis in the 2002 proposed rule on the consideration of science in planning, on documenting how science was interpreted and applied, and on evaluating the associated risks and uncertainties of using that science. In response to public comment regarding the Responsible Official's obligation to "demonstrate" consideration of science, the final rule requires the Responsible Official to "document" such consideration. The Department believes that this change gives clearer and stronger direction as to what is expected of the Responsible Official in developing the Plan Document or Set of Documents and in considering the best available science.

Under the final rule, the Responsible Official must: (1) Document how the best available science was considered in the planning process within the context of the issues being considered; (2) evaluate and disclose any substantial

uncertainties in that science; (3) evaluate and disclose substantial risks associated with plan components based on that science; and (4) document that the science was appropriately interpreted and applied. Additionally, the Responsible Official may use independent peer review, a science advisory board, or other review methods to evaluate the consideration of science in the planning process. Any interested scientists can be involved at any of the public involvement stages.

Section 219.12—Suitable Uses and Provisions Required by NFMA

This section (§ 219.12), which was not in the 2002 proposed rule, addresses the provisions found in §§ 219.4(a)(3), 219.4(a)(4), 219.16, and 219.17 of the 2002 proposed rule. The final rule requires the Chief of the Forest Service to include in the Forest Service directives procedures to address the provisions of NFMA that were addressed by §§ 219.4(a)(3), 219.16, and 219.17 of the 2002 proposed rule.

Guidance for suitable uses, located in paragraph (a) in the final rule, has been moved from § 219.4(a)(4) of the 2002 proposed rule. In addition, the Department reorganized this guidance to better describe the overall nature of identifying suitable land uses. Overall, NFS lands are generally suitable for a variety of multiple uses, including timber harvest and timber production, unless administratively withdrawn or prohibited by statute, Executive order, or regulation. On lands generally suitable for timber, the Forest Service may harvest timber for a variety of purposes, such as to create openings for wildlife or for fuels reduction and restoration. If timber production is not an objective for lands generally suitable for timber, the Responsible Official must identify these lands as not suitable for timber production. Provisions concerning not suitable for timber production have been moved with modifications from § 219.16 of the 2002 proposed rule to § 219.12(a)(2). Additional guidance for identification of lands not suitable for timber harvest and guidance for timber harvest that the proposed rule addressed at § 219.4(a)(3) will be placed in the Forest Service directives. A request for public comment on the Forest Service directives will be published in the **Federal Register** as soon as possible after adoption of the final rule.

In addition, Forest Service directives will address additional NFMA requirements. These requirements include limitations on timber harvest (§ 219.17 of proposed rule) and provisions for plans to determine forest management systems, restocking requirements, harvesting levels in light of the multiple uses, and the potential suitability of lands for resource management, as well as projections of proposed and possible actions, including the planned timber sale program. The Department made this change to provide a better balance between the specific procedures for timber and the provisions for other sections of the final rule.

Comment: Culmination of mean annual increment. Some respondents said that the culmination of mean annual increment (CMAI) requirement should not be limited to even-aged harvests and that the protection provided by a CMAI requirement on uneven-aged harvests would protect against over-zealous logging.

Response: CMAI is the age in the growth cycle of an even-aged stand where average annual growth is at its maximum. By definition, CMAI applies only to even-aged timber stands and not to uneven-aged stands. However, detailed guidance for CMAI is moved to the Forest Service directives because NFMA does not require this guidance to be in the rule itself. NFMA requires establishment of guidance so that stands of timber, not individual trees, generally have reached CMAI. The Forest Service directives will clarify the technical limits of the CMAI concept.

Comment: Restocking. A respondent said the rule is inconsistent with NFMA because it does not require restocking of lands within five years after final regeneration harvest.

Response: Section 219.16(a)(3) of the 2002 proposed rule has been removed in the final rule. Forest Service directives will address restocking requirements. Forest Service directives will meet the requirement of NFMA to ensure that timber will be harvested from NFS lands only where there is assurance that such lands can be adequately restocked within five years after harvest. Adequate restocking may vary depending on the purpose of a harvest and the objectives and desired conditions for the area. Restocking is not required for lands harvested to create openings for fuel breaks and vistas, to prevent encroaching conifers, and other similar purposes. This will apply to all timber harvest, including final regeneration harvest. Therefore, Responsible Officials will include in land management plans guidance for adequate restocking depending on the purpose of a harvest, the desired conditions, and objectives for the area.

Comment: Suitability. Respondents both agreed and disagreed with the presumption that lands are suitable for all uses unless identified and determined to be not suitable. Those who agreed liked this presumption. Those who disagreed stated that more lands are not suitable for all uses than are suitable, so the process would be easier to start with the presumption that lands are not suitable. Some said that this presumption places commercial uses ahead of other considerations like fish and wildlife.

One respondent stated that local planners should have the discretion to manage the range of opportunities offered by the forest and the flexibility to manage new uses unforeseen in the planning process.

Response: The Department agrees with the Committee of Scientists report, which holds the basic philosophy that these are the people's lands; and therefore, it is appropriate to have a presumption in the final rule that lands are suitable for a variety of uses. The Department removed the declaration that lands are suitable, unless identified and determined to be not suitable. Forest Service directives may use that analytical and philosophical assumption. The final rule removes the word "determine" and replaces it with "identify" to conform to the NFMA. In the overall adaptive management process, the starting point for identifying general suitability of land uses will likely be the existing suitable or not-suitable use identifications in current plans, and incremental changes will be based on public input, review of inventory, monitoring, evaluation, and assessment information. The final rule uses the expression "generally suitable" because identification of suitability is guidance and must be approved through project and activity decisionmaking. In response to public comment and to clarify the criteria for identifying suitability, the final rule has changed the resources to outdoor recreation, range, timber, watershed, and wildlife and fish purposes so that the resources listed agree with the Multiple-Use Sustained-Yield Act (MUSYA) of 1960 (16 U.S.C. 528–531). Energy resource development and mining activities were removed from § 219.12(a)(1) of the final rule because, even though allowable uses on many of the NFS lands, they are not renewable surface resources listed in MUSYA.

Comment: Suitable lands. Some respondents felt that social, economic, ecological, physical, and other factors should not be considered when determining suitability of land for timber production. Others felt that the Forest Service should analyze the effects on these factors when no logging is proposed, because they felt that the

fiscal support of their communities is not being adequately addressed due to the fact that there is no requirement to supply timber. One respondent felt that the 2002 proposed rule would allow "timber sales that are not justified by their social, economic, or ecological benefits."

Response: The 2002 proposed rule language is based on the NFMA that requires the Responsible Official to consider "physical, economic, and other pertinent factors to the extent feasible" when identifying lands which are not suited for timber production. However, the wording has been changed to "would not be compatible with the achievement of desired conditions and objectives," because desired conditions and objectives reflect the social, economic, and ecological attributes toward which management is to be directed. In addition, the NFMA does allow salvage sales and sales necessitated to protect other multiple-use values on lands identified as not suited for timber production.

Comment: Salvage logging. There were concerns expressed by some about salvage harvest and about timber harvest in general. While some respondents felt there should not be any salvage logging on any lands, others felt that salvage logging is important to improve the health of National Forest System lands.

Response: Salvage harvest of timber is a legitimate management practice, acknowledged by Congress in NFMA (16 U.S.C. 1604(k), 1611(b)). The Department believes that the language in this section of the final rule on suitability and salvage is an appropriate reflection of the intent of NFMA. The Department believes that specific decisions on the size of salvage units, and on where salvage logging would or would not occur, should be made at a project level and not at the national level.

Comment: Prohibitions for logging. Some suggested that the final rule should include more prohibitions for logging, including a prohibition on all commercial logging on NFS lands involving riparian areas, virgin forests, and old growth forests. Others suggested harvesting should be limited to selective logging, salvage harvest, or helicopter logging. One person suggested that the agency be required to justify logging for ecological reasons.

Response: The Department believes that broad-based prohibitions on timber harvest or timber harvest practices are not appropriate at the national level, given the range of ecological conditions that exist across the units of the NFS and the multiple-use mandates of MUSYA and NFMA. Such restrictions may be put in place at the plan or project level, but should not be part of the planning regulations.

Comment: Timber harvest. Many comments were made regarding logging. Many respondents felt that there should be more restrictions placed on logging and that social and economic analysis should eliminate areas from timber harvest if such harvests would produce below-cost sales. Conversely, some felt that profit was emphasized too much and there needed to be more emphasis placed on the effects to the environment. One person felt there should be a minimum mean annual increment threshold of timber growth, such as 50 cubic feet per acre per year, to determine if lands were suitable for timber. Some felt that there should be more requirements for evaluation of effects that timber harvests have on fish, woody debris, watershed, and wildlife habitat. Another felt that timber sales should be made affordable to local purchasers. Still others wanted analysis to consider the social and economic effects on timber-dependent communities.

Response: Consistent with NFMA (16 U.S.C. 1604(k)), the final rule (§ 219.12(a)(2)) requires the Responsible Official to identify lands as not suitable for timber production, if timber production would not be compatible with the achievement of desired conditions and objectives. These provisions give the Responsible Official the flexibility to develop criteria that are appropriate for the specific plan area. The Department feels that detailed national direction would not meet the social, economic, and ecological concerns of the individual NFS unit. The final rule establishes parameters that provide for conscientious decisions to be made at the local level.

Comment: Suitability for off-highway vehicle use. Many respondents were particularly concerned about management for off-highway vehicle (OHV) use, because of the presumption that lands are open for use unless determined to be closed. Others said that the travel management component of plans has been particularly challenging. They said that plans have often failed to regulate OHV as new technology has enabled expanded use. Other commentators wrote that land management plans need to clearly establish limits to OHV use while others said the Forest Service should inventory and evaluate lands declared unsuitable for OHV and other recreational uses to determine if restoration or mitigation measures could make them suitable.

Response: As a general matter, responsible and carefully managed OHV travel is an appropriate use of NFS lands. Under this final rule, travel management guidance will be expressed in desired conditions, objectives, guidelines, and identification of general suitability of areas for various uses. That guidance, in and of itself, would not close those lands to these uses; such a restriction would require a subsequent travel management decision and closure order pursuant to 36 CFR part 261, subpart B. Additionally, if a plan identifies an area as generally suitable for OHV travel where currently restricted, the plan would not open those lands to these uses; a subsequent project and activity NEPA analysis and decision would be necessary to effect the preliminary identification of the plan. Guidance for resource conservation is established in the plan and will be considered in the subsequent travel management decision. The final rule allows for levels and trends of OHV use to be monitored and changed as appropriate.

Comment: Fuels treatment. Several respondents, citing recent fire seasons, suggested that the final rule should allow for more timber harvest than is currently being harvested to reduce fuels, and they felt that the final rule would accomplish that goal. There was a concern that much of the dead and down material was being wasted and that this biomass could be used to meet energy and wood supply needs. Others, however, felt that logging of commercial-size trees was not necessary for fuels reduction and the final rule would do a disservice by allowing it. One respondent suggested that the fuels problem could be solved by using prescribed fire only. Others felt that fuels treatment should be allowed only in areas near urban centers to protect structures.

Response: The Department believes that the final rule, which is national in application, should not set out direction so specific that it cannot take into account the widely varying conditions found across the NFS. Such direction is better developed at the local level.

Comment: Allowable sale quantity. Some respondents request that the Forest Service retain the use of Allowable Sale Quantity (ASQ) to inform timber-purchasers, communities who support timber industry, and the public what the future timber production forecast will be.

Response: This concept has long caused confusion for those concerned with the management of the NFS lands. While under the 1982 rule, ASQ was the upper limit of timber that the Responsible Official may sell from the lands suitable for timber production,

ASQ has commonly been misinterpreted as an absolute commitment to a timber production target. Neither the 2002 proposed rule nor this final rule provide for ASQ. Forest Service directives will address the upper limit of timber and will likely use the concept of long-term sustained yield as proposed in the 2002 proposed rule as the upper limit of timber that the Forest Service may harvest during the planning period. The 2002 proposed rule used long-term sustained yield because this requirement is adequate, and removing the provision that planning establish an ASQ reduces the risk of misperception that ASQ is a target to be achieved, rather than a limit to harvest.

Comment: Sustained yield. Most respondents agreed that the concept of sustained yield is, in principle, a positive goal. However, some took exception to how this requirement will actually be implemented. They felt that salvage logging and other types of timber sales not undertaken for timber production purposes should be included in the sustained-yield calculations. Others felt that the use of "multiple-use objectives" gives too much flexibility in determining sustained yield, and there is actually no real limit. One person felt the harvest limits should mirror forest mortality rates.

Response: This provision for estimating the quantity of timber that can be removed annually in perpetuity is tied directly to NFMA (16 U.S.C. 1611(a)). The final rule moves detailed instructions on how sustained yield is calculated (found in the 2002 proposed rule at § 219.17) to the Forest Service directives.

Section 219.13—Objections to Plans, Plan Amendments, or Plan Revisions

This provision found in § 219.19 of the 2002 proposed rule has been redesignated at § 219.13 as part of the overall reorganization of the final rule. This section establishes the objection process by which the public can challenge plans, plan revisions, or plan amendments.

The Committee of Scientists, in their 1999 report, recommended that the Forest Service seek to harmonize its administrative appeal process with those of other Federal agencies. The Committee of Scientists said a pre-decisional process would encourage internal Forest Service discussion, encourage multi-agency collaboration, and encourage public interest groups to collaborate and work out differences. Therefore, to be more consistent with the Bureau of Land Management (BLM) and to improve public participation efforts, the Department is adopting the pre-decisional objection process (§ 219.13) to replace the appeals process. The objection process complements the public participation process because the objectors and the Reviewing Officer can collaboratively work through concerns before a Responsible Official approves a plan.

The 30-day objection period specified in this final rule is the same amount of time provided in the BLM protest process. The final rule does not specify a time limit for agency responses; the final rule has adopted the BLM requirement that the Reviewing Officer promptly render a decision on the objection. It is in the interest of the agency to render a decision promptly to move forward. Because Responsible Officials would not typically develop plans, plan amendments, or plan revisions using EISs, EAs, the Department removed unnecessary language in the final rule concerning NEPA documents. The final rule also eliminates details on responding to objections because this information is more appropriate in the Forest Service directives. The final rule also removes the requirement that objectors may only submit original substantive comments as objections. These changes make the final rule easier to read and follow.

References to appeals of plan amendments in site-specific decisions, previously at § 219.20 of the 2002 proposed rule, have been moved to § 219.13(a)(1) in the final rule to have requirements for objections and the reference to appeals in the same section. Specific requirements for administrative review of plan amendments approved contemporaneously with a project or activity decision are addressed in 36 CFR 215 and 218, subpart A.

Comment: Objection and appeals process. Some respondents felt that the final rule should include provisions to allow post-decisional appeals of plans. Some wanted both a pre-decisional objection process and a post-decisional appeals process. One person felt that the rule should require an objection process for plan amendments made in conjunction with site-specific project decisions and that the rule should require an appeals process for other plan amendments.

Some respondents were concerned that the objection process would reduce the influence that the current appeals process provides, and they claimed the 30-day objection period is insufficient time to identify issues and to prepare an objection. Although some respondents felt that the objection process is an inadequate protection of public interests, others supported the objection process and felt that requirements for standing to object should be much more stringent to prevent what they characterized as needless obstruction. Some respondents were concerned that there was no time limit for the agency to respond to objections.

Response: The objection process in the final rule retains the 2002 proposed rule's application of the objection process to plans, plan amendments, or plan revisions not associated with a project or activity decision (§ 219.13(a)). Unlike the provisions at 36 CFR, part 217, applicable to plan development, plan amendment, and plan revision under the 1982 planning rule, this final rule, like the 2002 proposed rule, integrates the objection process with public participation prior to plan approval. The objection process is expected to resolve many potential conflicts by encouraging resolution before a plan, plan amendment, or plan revision is approved.

Under the 36 CFR part 217 appeal process, the agency and the public expend significant human and financial resources in fulfillment of procedural requirements. Often an appeal leads to a polarized relationship where there is no real incentive to address natural resource issues and there is a squandering of human and financial capital, often without long-lasting solutions to problems.

Under this final rule, as in the 2002 proposed rule, the Responsible Official, the Reviewing Officer, and the objector have the opportunity to seek reasonable solutions to conflicting views of plan components before a Responsible Official approves a plan, plan amendment, or plan revision. The objection process allows discretion for joint problem solving to resolve issues.

Comment: Public participation. Several respondents expressed the opinion that the final rule should require participation in the planning process as a qualification for objection.

Response: The 2002 proposed rule did not require participation in the planning process to file an objection; however, the Department agrees that participation should be a prerequisite to submitting an objection. Therefore, the final rule at § 219.13(a) requires participation in the planning process through the submission of a written comment to have standing to submit an objection.

Comment: Consistency with law. Some respondents supported the requirement in the 2002 proposed rule that objectors must explain their position that the plan, plan amendment, or plan revision is inconsistent with law, regulation, or policy as well as provide any recommendation for

change. Others felt this requirement curtailed public input and required legal advice to object.

Response: The Department agrees that a person should be able to object to a plan, plan amendment, or plan revision even if the plan is consistent with law, regulation, or policy. Therefore, the final rule allows persons to object if they otherwise disagree with the decision. Accordingly, § 219.13(b)(3) of the final rule retains the main elements of this requirement from the 2002 proposed rule, so that the Reviewing Officer will know why an objector objects as well as what the objector recommends for change. The term "Executive order" has been removed from the final rule because Executive orders are already covered under the term "policy." The Forest Service directives will set forth the specific requirements of the Reviewing Officer working with the objector(s) to resolve their issue(s).

Section 219.14—Effective Dates and Transition

This direction found in §§ 219.21 and 219.22 of the 2002 proposed rule has been combined at § 219.14 to organize similar concepts in one location. This section specifies when a plan, plan amendment, or plan revision will take effect as well as how Responsible Officials may modify ongoing planning efforts to conform to the requirements of the final rule. The Department modified this section from the transition language in the 2002 proposed rule, primarily to account for integration of EMS into land management planning.

With this rule, the Department is simultaneously repealing the 2000 rule and including the transition provisions of the former rule. Recently, the Department clarified that projects were subject to the requirements of the former transition rule during the transition period until the completion of the plan revision process under the 2000 rule (69 FR 58055, September 29, 2004). The transition period of the former rule thus terminates with its repeal. This section defines, for purposes of pending or future plan documents, the applicable rules during the transition period. During the transition period, pending or proposed projects remain subject to the applicable forest plan.

This section also contains new direction on application of management indicator species (MIS) for units that will continue to use the 1982 planning rule for plans, plan amendments, and plan revisions during transition. There has been uncertainty regarding the application of provisions of the 1982 planning rule, particularly with respect to obligations regarding MIS (69 FR 58055, September 29, 2004). For those units with plans developed, amended, or revised under the 1982 planning rule, including those amended or revised during the transition period for the 2000 planning rule, § 219.14(f) provides that MIS obligations may be met by considering data and analysis relating to habitat unless the plan specifically requires population monitoring or population surveys. Other tools can often be useful and more appropriate in predicting the effects of projects that implement a land management plan (such as examining the effect of proposed activities on the habitat of specific species); using information identified, obtained, or developed through a variety of methods (such as assessments, analysis, and monitoring results); or using information obtained from other sources (such as State fish and wildlife agencies and organizations like The Nature Conservancy). The final rule also clarifies the appropriate scale for MIS monitoring which is the plan area.

Providing explicitly for MIS monitoring flexibility will allow for monitoring of habitat conditions as a surrogate for population trend data. It is appropriate for a range of methods to be available to estimate, or approximate, population trends for MIS. The Responsible Official will determine the which monitoring method or combination of monitoring methods to use for a given MIS.

Where Responsible Officials conduct actual population monitoring for MIS, population trend data are most efficiently collected using a sampling program rather than a total enumeration. In a sampling program, population data are collected at a selection of sites throughout the geographic range of the population. These sites might be systematically designated (for example, using a grid of specific dimension), established randomly, or selected in some other way. For species that use distinct seasonal ranges (for example, elk that use winter ranges distinct from their summer ranges), data may be collected primarily on the winter range.

The area over which sampling is conducted should relate to the geographic range occupied by the population, and will generally far exceed the area of a single management project. Because of using sampling procedures within the overall geographic area used by a population, individual project areas might or might not be part of a sampling program designed to estimate the overall population trend of a population. Based on the foregoing, for most species it would be technically and practically inappropriate to conduct population trend sampling at the scale of individual project areas. Consequently, where Responsible Officials conduct actual population monitoring for MIS, that monitoring should be carried out at the scale most appropriate to the species within the overall national forest, grassland, prairie, or other administrative comparable unit. Monitoring populations at the sites of individual projects is not part of this requirement. Therefore, the transition language at § 219.14 clarifies that MIS monitoring is appropriate at the times and places appropriate to the specific species, and is not required within individual project or activity areas.

Comment: Effective date. One respondent was concerned that there was a difference in the effective date of plan amendments depending on whether or not they were significant amendments and suggested the final rule should not differentiate between the types of amendments when determining an effective date.

Response: In the final rule, the only difference related to the effective date of plan amendments is dependent on if a plan amendment is approved contemporaneously with a project or activity decision and the plan amendment applies only to the project or activity; in which case, 36 CFR, part 215 or part 218, subpart A applies, not the planning regulations at part 219. All other amendments have a 30-day effective date.

Section 219.15—Severability

The Department has chosen to add a new section to address the issue of severability, in the event that portions of this rule are separately challenged in litigation. It is the Department's intent that the individual provisions of this rule be severable from each other.

Section 219.16—Definitions

This direction was found in § 219.23 in the 2002 proposed rule, but has been redesignated at § 219.16 as part of overall reorganization of the final rule. This section sets out and defines the special terms used in the final rule. A detailed discussion on definitions removed, added, or unchanged is found in the supplemental response to public comments located on the World Wide Web/Internet (see **ADDRESSES**).

Comment: Collaboration. A few respondents asked that collaboration be defined. They said that a "collaborative" process is generally a specific type of planning process involving shared power and total stakeholder involvement. One person

wanted the process of collaboration to be distinguished from processes authorized under the Federal Advisory Committee Act.

Response: The Forest Service cannot "share" its administrative authority over the NFS and must make the decisions for NFS management, including approval of plans, plan amendments, and plan revisions. The agency and the Department are committed to stakeholder involvement in planning; however, the Department does not believe it is necessary to set the boundaries of how this process may operate in planning through a definition of the process.

Comment: Silvicultural terminology. Some respondents said that the 2002 proposed rule (§ 219.4) confuses silvicultural objectives (for example, achieving an even-aged stand condition) with harvesting methods. They said that silvicultural definitions should be taken from the Society of American Foresters handbook.

Response: The Dictionary of Forestry reflects current professional acceptance and use of terms and definitions. Because the Dictionary of Forestry has wide acceptance, it was reviewed and the silvicultural definitions of the final rule at § 219.16, and other silvicultural terminology in the final rule are largely consistent with definitions found in the Dictionary of Forestry (Bethesda, MD, Society of American Foresters, 1998).

5. Regulatory Certifications

Regulatory Impact

This final rule has been reviewed under U.S. Department of Agriculture (Department) procedures and Executive Order 12866 issued September 30, 1993 (E.O. 12866) on Regulatory Planning and Review. It has been determined that this is not an economically significant rule. This final rule will not have an annual effect of $100 million or more on the economy nor adversely affect productivity, competition, jobs, the environment, public health or safety, nor State or local governments. This final rule will neither interfere with an action taken or planned by another agency nor raise new legal or policy issues. Finally, this final rule will not alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients of such programs. However, because of the extensive interest in National Forest System (NFS) planning and decisionmaking, this final rule has been designated as significant and, therefore, is subject to Office of Management and Budget review under E.O. 12866.

A cost-benefit analysis was conducted to compare the costs and benefits of implementing this final rule to the baseline, 1982 planning rule. This analysis is posted on the World Wide Web/Internet at *http://www.fs.fed.us/emc/nfma/,* along with other documents associated with this final rule. The 1982 planning rule was used as the baseline because all the land management plan revisions completed to date have used the requirements of the 1982 planning rule. Quantitative differences among the final rule, the 2000 rule, and the 2002 proposed rule were also estimated. Primary sources of data used to estimate the costs and benefits of the 2000 planning rule and the 2002 proposed rule are from the results of a 2002 report entitled "A Business Evaluation of the 2000 and Proposed NFMA Rules" produced by the Inventory and Monitoring Institutes of the Forest Service. The report is also identified as the "2002 NFMA Costing Study," or simply as the "Costing Study." The Costing Study used a business modeling process to identify and compare major costs for both the 2000 planning rule and the 2002 proposed rule. The main source of data used to approximate costs under the 1982 planning rule is from a recent report to Congress on planning costs, along with empirical data and inferences from the Costing Study.

The cost-benefit analysis focuses on key activities in land management planning for which costs can be estimated under the 1982 planning rule, the 2000 planning rule, the 2002 proposed rule, and this final rule. The key activities include regional guides, collaboration, consideration of science, evaluation of the sustainability of decisions and diversity requirements under the National Forest Management Act (NFMA) of 1976 (16 U.S.C. 1600 *et seq.*), monitoring, evaluation, and the resolution of disputes regarding the proposed plan decisions through the administrative processes of appeals and objections.

The final rule would reduce the cost of producing a plan or revision by shortening the length of the planning process and providing the Responsible Official with more flexibility to decide the scope and scale of the planning process. The final rule, by requiring inclusion of environmental management systems into the land management framework, requires a comprehensive evaluation during plan development and plan revision that will be updated at least every five years. Some upfront planning costs, such as analyzing and developing plan components, and documenting the land management planning process, are anticipated to shift to monitoring and evaluation to better document cumulative effects of management activities and natural events when preparing a comprehensive evaluation of the plan under the final rule.

Based on costs that can be quantified, implementation of this final rule is expected to have an estimated annual average cost savings of $4.6 million when compared to the 1982 planning rule, and an estimated annual average savings of $36.9 million when compared to estimates of implementation of the 2000 planning rule. When compared to the 2002 proposed rule, implementation of the final rule is estimated to cost $19 million less than the 2002 proposed rule with Option 1 and $24.9 million more than the 2002 proposed rule with Option 2. The higher cost over the 2002 proposed rule is due to increased monitoring and evaluation requirements in the final rule.

From this cost-benefit analysis, the estimated total costs for implementing the final rule are expected to be lower than the 2000 planning rule; however, the estimated cost savings are less than that predicted on the 2002 proposed rule because costs for monitoring and evaluation are expected to be higher. In other words, although the final rule is expected to be less costly than the 2000 planning rule, some of those saved costs are expected to be shifted to monitoring and evaluation.

This final rule has also been considered in light of the Regulatory Flexibility Act, as amended (5 U.S.C. 601 *et seq.*), and it has been determined that this action will not have a significant economic impact on a substantial number of small business entities as defined by the Regulatory Flexibility Act. Therefore, a regulatory flexibility analysis is not required for this final rule. The final rule imposes no requirements on either small or large entities. Rather, the final rule sets out the process the Forest Service will follow in land management planning for the NFS. The final rule should provide opportunities for small businesses to become involved in the national forest, grassland, prairie, or other comparable administrative unit plan approval. Moreover, by streamlining the land management planning process, the final rule should benefit small businesses through more timely decisions that affect outputs of products and services.

Environmental Impacts

This final rule establishes the administrative procedures to guide developing, amending, and revising NFS land management plans. This final rule, like earlier planning rules, does

not dictate how administrative units of the NFS are to be managed. The Department does not expect that this final rule will directly affect the mix of uses on any or all units of the NFS. Section 31.12 of FSH 1909.15 excludes from documentation in an EA or EIS "rules, regulations, or policies to establish Service-wide administrative procedures, program processes, or instruction." This final rule clearly falls within this category of actions and the Department has determined that no extraordinary circumstances exist that would require preparation of an EA or an EIS.

Energy Effects

This final rule has been reviewed under Executive Order 13211 issued May 18, 2001 (E.O. 13211), "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use." It has been determined that this final rule does not constitute a significant energy action as defined in E.O. 13211. Procedural in nature, this final rule would guide the development, amendment, and revision of NFS land management plans. These plans are strategic documents that provide the guidance for making future project or activity-level resource management decisions. As such, these plans will address access requirements associated with energy exploration and development within the framework of multiple-use, sustained-yield management of the surface resources of the NFS lands. These land management plans may identify major rights-of-way corridors for utility transmission lines, pipelines, and water canals. While these plans consider the need for such facilities, they do not authorize construction of them; therefore, the final rule and the plans developed under it do not have energy effects within the meaning of E.O. 13211. The effects of the construction of such lines, pipelines, and canals are, of necessity, considered on a case-by-case basis as specific construction proposals are made. Consistent with E.O. 13211, direction to incorporate consideration of energy supply, distribution, and use in the planning process is being included in the agency's administrative directives for implementing the final rule.

Controlling Paperwork Burdens on the Public

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or reporting requirements for the objection process were previously approved by the Office of Management and Budget (OMB) and assigned control number 0596–0158, expiring on October 31, 2003 for the 2000 planning rule.

The OMB has extended this approval through December 31, 2006 for this final planning rule, using the same control number. This extension was made after the Forest Service provided the public an opportunity to comment on the extension as required by the Paperwork Reduction Act (68 FR 50512, August 21, 2003). The Forest Service received no comments regarding extension.

The information required by 36 CFR 219.13 is needed for an objector to explain the nature of the objection being made to a proposed land management plan, plan amendment, or plan revision. This final rule retains but simplifies the objection process established in the 2000 planning rule. The final rule removes the requirements previously provided in the 2000 planning rule for interested parties, publication of objections, and formal requests for meetings (36 CFR 219.32). These changes will result in a minor reduction in the number of burden hours approved by OMB.

Federalism

The agency has considered this final rule under the requirements of Executive Order 13132 issued August 4, 1999 (E.O. 13132), "Federalism." The agency has made an assessment that the final rule conforms with the Federalism principles set out in this Executive order; would not impose any compliance costs on the States; and would not have substantial direct effects on the States, on the relationship between the national government and the States, nor on the distribution of power and responsibilities among the various levels of government. Therefore, the agency concludes that the final rule does not have Federalism implications. Moreover, § 219.9 of this final rule shows sensitivity to Federalism concerns by requiring the Responsible Official to meet with and provide opportunities for involvement of State and local governments in the planning process.

In the spirit of E.O. 13132, the agency consulted with State and local officials, including their national representatives, early in the process of developing the proposed regulation. The agency has consulted with the Western Governors' Association and the National Association of Counties to obtain their views on a preliminary draft of the 2002 proposed rule. The Western Governors' Association supported the general intent to create a regulation that works, and placed importance on the quality of collaboration to be provided when the agency implements the regulation. Agency representatives also contacted the International City and County Managers Association, National Conference of State Legislators, The Council of State Governments, Natural Resources Committee of the National Governors Association, U.S. Conference of Mayors, and the National League of Cities to share information about the 2002 proposed rule prior to its publication. Based on comments received on the 2002 proposed rule, the agency has determined that additional consultation was not needed with State and local governments.

Civil Rights Impact Analysis

A civil rights impact analysis was conducted for this final rule. This analysis is posted on the World Wide Web/Internet at *http://www.fs.fed.us/emc/nfma/*, along with other documents associated with this final rule. The analysis found that there no adverse civil rights or environmental justice impacts anticipated to the delivery of benefits or other program outcomes on a national level for any under-represented population or to other United States populations or communities.

Consultation With Indian Tribal Governments

Pursuant to Executive Order 13175 of November 6, 2000, "Consultation and Coordination with Indian Tribal Governments," the agency has assessed the impact of this final rule on Indian Tribal governments and has determined that the final rule does not significantly or uniquely affect communities of Indian Tribal governments. The final rule deals with the administrative procedures to guide the development, amendment, and revision of NFS land management plans and, as such, has no direct effect regarding the occupancy and use of NFS land. At § 219.9(a)(3), the final rule requires consultation with federally recognized Tribes when conducting land management planning.

The agency has also determined that this final rule does not impose substantial direct compliance cost on Indian Tribal governments. This final rule does not mandate Tribal participation in NFS planning. Rather, the final rule imposes an obligation on Forest Service officials to consult early with Tribal governments and to work cooperatively with them where planning issues affect Tribal interests.

No Takings Implications

This final rule has been analyzed in accordance with the principles and criteria contained in Executive Order 12630 issued March 15, 1988, and it has

been determined that the final rule does not pose the risk of a taking of Constitutionally protected private property.

Civil Justice Reform

This final rule has been reviewed under Executive Order 12988 of February 7, 1996, "Civil Justice Reform." The Department has not identified any State or local laws or regulations that are in conflict with this regulation or that would impede full implementation of this final rule. Nevertheless, in the event that such a conflict was to be identified, the final rule would preempt State or local laws or regulations found to be in conflict. However, in that case, (1) no retroactive effect would be given to this final rule; and (2) the final rule does not require the use of administrative proceedings before parties may file suit in court challenging its provisions.

Unfunded Mandates

Pursuant to Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538), the agency has assessed the effects of this final rule on State, local, and Tribal governments and the private sector. This final rule does not compel the expenditure of $100 million or more by any State, local, or Tribal governments or anyone in the private sector. Therefore, a statement under section 202 of the Act is not required.

List of Subjects in 36 CFR Part 219

Administrative practice and procedure, Environmental impact statements, Indians, Intergovernmental relations, Forest and forest products, National forests, Natural resources, Reporting and recordkeeping requirements, Science and technology.

■ Therefore, for the reasons set forth in the preamble, add subpart A to part 219 of title 36 of the Code of Federal Regulations to read as follows:

PART 219—PLANNING

Subpart A—National Forest System Land Management Planning

Sec.

Subpart B [Reserved]

Authority: 5 U.S.C. 301; 16 U.S.C. 1604, 1613.

§ 219.1 Purpose and applicability.

(a) The rules of this subpart set forth a process for land management planning, including the process for developing, amending, and revising land management plans (also referred to as plans) for the National Forest System, as required by the Forest and Rangeland Renewable Resources Planning Act of 1974, as amended by the National Forest Management Act of 1976 (16 U.S.C. 1600 *et seq.*), hereinafter referred to as NFMA. This subpart also describes the nature and scope of plans and sets forth the required components of a plan. This subpart is applicable to all units of the National Forest System as defined by 16 U.S.C. 1609 or subsequent statute.

(b) Consistent with the Multiple-Use Sustained-Yield Act of 1960 (16 U.S.C. 528–531), the overall goal of managing the National Forest System is to sustain the multiple uses of its renewable resources in perpetuity while maintaining the long-term productivity of the land. Resources are to be managed so they are utilized in the combination that will best meet the needs of the American people. Maintaining or restoring the health of the land enables the National Forest System to provide a sustainable flow of uses, benefits, products, services, and visitor opportunities.

(c) The Chief of the Forest Service shall establish planning procedures for this subpart for plan development, plan amendment, or plan revision in the Forest Service Directive System.

§ 219.2 Levels of planning and planning authority.

Planning occurs at multiple organizational levels and geographic areas.

(a) *National.* The Chief of the Forest Service is responsible for national planning, such as preparation of the Forest Service Strategic Plan required under the Government Performance and Results Act of 1993 (5 U.S.C. 306; 31 U.S.C. 1115—1119; 31 U.S.C. 9703–9704), which is integrated with the requirements of the Forest and Rangeland Renewable Resources Planning Act of 1974, as amended by the NFMA. The Strategic Plan establishes goals, objectives, performance measures, and strategies for management of the National Forest System, as well as the other Forest Service mission areas.

(b) *Forest, grassland, prairie, or other comparable administrative unit.* (1) Land management plans provide broad guidance and information for project and activity decisionmaking in a national forest, grassland, prairie, or other comparable administrative unit. The Supervisor of the National Forest, Grassland, Prairie, or other comparable administrative unit is the Responsible Official for development and approval of a plan, plan amendment, or plan revision for lands under the responsibility of the Supervisor, unless a Regional Forester, the Chief, or the Secretary chooses to act as the Responsible Official.

(2) When plans, plan amendments, or plan revisions are prepared for more than one administrative unit, a unit Supervisor identified by the Regional Forester, or the Regional Forester, the Chief, or the Secretary may be the Responsible Official. Two or more Responsible Officials may undertake joint planning over lands under their respective jurisdictions.

(3) The appropriate Station Director must concur with that part of a plan applicable to any experimental forest within the plan area.

(c) *Projects and activities.* The Supervisor or District Ranger is the Responsible Official for project and activity decisions, unless a higher-level official chooses to act as the Responsible Official. Requirements for project or activity planning are established in the Forest Service Directive System. Except as specifically provided, none of the requirements of this subpart applies to projects or activities.

(d) *Developing, amending, and revising plans.* (1) *Plan development.* If a new national forest, grassland, prairie, or other administrative unit of the National Forest System is established, the Regional Forester, or a forest, grassland, prairie, or other comparable unit Supervisor identified by the Regional Forester must either develop a plan for the unit or amend or revise an existing plan to apply to the lands within the new unit.

(2) *Plan amendment.* The Responsible Official may amend a plan at any time.

(3) *Plan revision.* The Responsible Official must revise the plan if the Responsible Official concludes that conditions within the plan area have significantly changed. Unless otherwise provided by law, a plan must be revised at least every 15 years.

§ 219.3 Nature of land management planning.

(a) *Principles of land management planning.* Land management planning is an adaptive management process that includes social, economic, and ecological evaluation; plan development, plan amendment, and plan revision; and monitoring. The overall aim of planning is to produce responsible land management for the National Forest System based on useful and current information and guidance. Land management planning guides the Forest Service in fulfilling its responsibilities for stewardship of the National Forest System to best meet the needs of the American people.

(b) *Force and effect of plans.* Plans developed in accordance with this subpart generally contain desired conditions, objectives, and guidance for project and activity decisionmaking in the plan area. Plans do not grant, withhold, or modify any contract, permit, or other legal instrument, subject anyone to civil or criminal liability, or create any legal rights. Plans typically do not approve or execute projects and activities. Decisions with effects that can be meaningfully evaluated (40 CFR 1508.23) typically are made when projects and activities are approved.

§ 219.4 National Environmental Policy Act compliance.

(a) In accordance with 16 U.S.C. 1604(g)(1) this subpart clarifies how the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4346) (hereinafter referred to as NEPA) applies to National Forest System land management planning.

(b) Approval of a plan, plan amendment, or plan revision, under the authority of this subpart, will be done in accordance with the Forest Service NEPA procedures and may be categorically excluded from NEPA documentation under an appropriate category provided in such procedures.

(c) Nothing in this subpart alters the application of NEPA to proposed projects and activities.

(d) Monitoring and evaluations, including those required by § 219.6, may be used or incorporated by reference, as appropriate, in applicable NEPA documents.

§ 219.5 Environmental management systems.

The Responsible Official must establish an environmental management system (EMS) for each unit of the National Forest System. The scope of an EMS will include, at the minimum, the land management planning process defined by this subpart. An EMS for any unit may include environmental aspects unrelated to the land management planning process under this subpart.

(a) Plan development, plan amendment, or plan revision must be completed in accordance with the EMS and § 219.14. An EMS may be established independently of the planning process.

(b) The EMS must conform to the consensus standard developed by the International Organization for Standardization (ISO) and adopted by the American National Standards Institute (ANSI) as "ISO 14001: Environmental Management Systems—Specification With Guidance For Use" (ISO 14001). The ISO 14001 describes EMSs and outlines the elements of an EMS. The ISO 14001 is available from the ANSI website at *http://webstore.ansi.org/ansidocstore/default.asp*.

(c) Pursuant to § 219.1(c), the Chief of the Forest Service shall establish procedures in the Forest Service Directive System to ensure that appropriate EMSs are in place. The Responsible Official may determine whether and how to change and improve an EMS for the plan area, consistent with applicable Forest Service Directive System procedures.

§ 219.6 Evaluations and monitoring.

(a) *Evaluations.* The Responsible Official shall keep the Plan Set of Documents up to date with evaluation reports, which will reflect changing conditions, science, and other relevant information. The following three types of evaluations are required for land management planning: comprehensive evaluations for plan development and revision, evaluations for plan amendment, and annual evaluations of monitoring information. The Responsible Official shall document evaluations in evaluation reports, make these reports available to the public as required in § 219.9, and include these reports in the Plan Set of Documents (§ 219.7(a)(1)). Evaluations under this section should be commensurate to the level of risk or benefit associated with the nature and level of expected management activities in the plan area.

(1) *Comprehensive evaluations.* These evaluate current social, economic, and ecological conditions and trends that contribute to sustainability, as described in § 219.10. Comprehensive evaluations and comprehensive evaluation reports must be updated at least every five years to reflect any substantial changes in conditions and trends since the last comprehensive evaluation. The Responsible Official must ensure that comprehensive evaluations, including any updates necessary, include the following elements:

(i) *Area of analysis.* The area(s) of analysis must be clearly identified.

(ii) *Conditions and trends.* The current social, economic, and ecological conditions and trends and substantial changes from previously identified conditions and trends must be described based on available information, including monitoring information, surveys, assessments, analyses, and other studies as appropriate. Evaluations may build upon existing studies and evaluations.

(2) *Evaluation for a plan amendment.* An evaluation for a plan amendment must analyze the issues relevant to the purposes of the amendment and may use the information in comprehensive evaluations relevant to the plan amendment. When a plan amendment is made contemporaneously with, and only applies to, a project or activity decision, the analysis prepared for the project or activity satisfies the requirements for an evaluation for an amendment.

(3) *Annual evaluation of the monitoring information.* Monitoring results must be evaluated annually and in accordance with paragraph (b)(2) of this section.

(b) *Monitoring.* The plan must describe the monitoring program for the plan area. Monitoring information in the Plan Document or Set of Documents may be changed and updated as appropriate, at any time. Such changes and updates are administrative corrections (§ 219.7(b)) and do not require a plan amendment or revision.

(1) The plan-monitoring program shall be developed with public participation and take into account:

(i) Financial and technical capabilities;

(ii) Key social, economic, and ecological performance measures relevant to the plan area: and

(iii) The best available science.

(2) The plan-monitoring program shall provide for:

(i) Monitoring to determine whether plan implementation is achieving multiple use objectives;

(ii) Monitoring to determine the effects of the various resource management activities within the plan area on the productivity of the land;

(iii) Monitoring of the degree to which on-the-ground management is maintaining or making progress toward the desired conditions and objectives for the plan; and

(iv) Adjustment of the monitoring program as appropriate to account for unanticipated changes in conditions.

(3) The Responsible Official may conduct monitoring jointly with others, including but not limited to, Forest Service units, Federal, State or local government agencies, federally recognized Indian Tribes, and members of the public.

§ 219.7 Developing, amending, or revising a plan.

(a) *General planning requirements.*

(1) *Plan Documents or Set of Documents.* The Responsible Official must maintain a Plan Document or Set of Documents for the plan. A Plan Document or Set of Documents includes, but is not limited to, evaluation reports; documentation of public involvement; the plan, including applicable maps; applicable plan approval documents; applicable NEPA documents, if any; the monitoring program for the plan area; and documents relating to the EMS established for the unit.

(2) *Plan components.* Plan components may apply to all or part of the plan area. A plan should include the following components:

(i) *Desired conditions.* Desired conditions are the social, economic, and ecological attributes toward which management of the land and resources of the plan area is to be directed. Desired conditions are aspirations and are not commitments or final decisions approving projects and activities, and may be achievable only over a long time period.

(ii) *Objectives.* Objectives are concise projections of measurable, time-specific intended outcomes. The objectives for a plan are the means of measuring progress toward achieving or maintaining desired conditions. Like desired conditions, objectives are aspirations and are not commitments or final decisions approving projects and activities.

(iii) *Guidelines.* Guidelines provide information and guidance for project and activity decisionmaking to help achieve desired conditions and objectives. Guidelines are not commitments or final decisions approving projects and activities.

(iv) *Suitability of areas.* Areas of each National Forest System unit are identified as generally suitable for various uses (§ 219.12). An area may be identified as generally suitable for uses that are compatible with desired conditions and objectives for that area. The identification of an area as generally suitable for a use is guidance for project and activity decisionmaking and is not a commitment or a final decision approving projects and activities. Uses of specific areas are approved through project and activity decisionmaking.

(v) *Special areas.* Special areas are areas within the National Forest System designated because of their unique or special characteristics. Special areas such as botanical areas or significant caves may be designated, by the Responsible Official in approving a plan, plan amendment, or plan revision. Such designations are not final decisions approving projects and activities. The plan may also recognize special areas designated by statute or through a separate administrative process in accordance with NEPA requirements (§ 219.4) and other applicable laws.

(3) *Changing plan components.* Plan components may be changed through plan amendment or revision, or through an administrative correction in accordance with § 219.7(b).

(4) *Planning authorities.* The Responsible Official has the discretion to determine whether and how to change the plan, subject to the requirement that the plan be revised at least every 15 years. A decision by a Responsible Official about whether or not to initiate the plan amendment or plan revision process and what issues to consider for plan development, plan amendment, or plan revision is not subject to objection under this subpart (§ 219.13).

(5) *Plan process.* (i) Required evaluation reports, plan, plan amendments, and plan revisions must be prepared by an interdisciplinary team; and

(ii) Unless otherwise provided by law, all National Forest System lands possessing wilderness characteristics must be considered for recommendation as potential wilderness areas during plan development or revision.

(6) *Developing plan options.* In the collaborative and participatory process of land management planning, the Responsible Official may use an iterative approach in development of a plan, plan amendment, and plan revision in which plan options are developed and narrowed successively. The key steps in this process shall be documented in the Plan Set of Documents.

(b) *Administrative corrections.* Administrative corrections may be made at any time and are not plan amendments or revisions. Administrative corrections include the following:

(1) Corrections and updates of data and maps;

(2) Corrections of typographical errors or other non-substantive changes;

(3) Changes in the monitoring program and monitoring information (§ 219.6(b));

(4) Changes in timber management projections; and

(5) Other changes in the Plan Document or Set of Documents, except for substantive changes in the plan components.

(c) *Approval document.* The Responsible Official must record approval of a new plan, plan amendment, or plan revision in a plan approval document, which must include:

(1) The rationale for the approval of the plan, plan amendment, or plan revision;

(2) Concurrence by the appropriate Station Director with any part of the plan applicable to any experimental forest within the plan area, in accordance with § 219.2(b)(3);

(3) A statement of how the plan, plan amendment, or plan revision applies to approved projects and activities, in accordance with § 219.8;

(4) Science documentation, in accordance with § 219.11; and

(5) The effective date of the approval (§ 219.14(a)).

§ 219.8 Application of a new plan, plan amendment, or plan revision.

(a) *Application of a new plan, plan amendment, or plan revision to existing authorizations and approved projects or activities.* (1) The Responsible Official must include in any document approving a plan amendment or revision a description of the effects of the plan, plan amendments, or plan revision on existing occupancy and use, authorized by permits, contracts, or other instruments implementing approved projects and activities. If not expressly excepted, approved projects and activities must be consistent with applicable plan components, as provided in paragraph (e) of this section. Approved projects and activities are those for which a Responsible Official has signed a decision document.

(2) Any modifications of such permits, contracts, or other instruments necessary to make them consistent with applicable plan components as developed, amended, or revised are subject to valid existing rights. Such modifications should be made as soon as practicable following approval of a new plan, plan amendment, or plan revision.

(b) *Application of a new plan, plan amendment, or plan revision to authorizations and projects or activities subsequent to plan approval.* Decisions approving projects and activities

subsequent to approval of a plan, plan amendment, or plan revision must be consistent with the plan as provided in paragraph (e) of this section.

(c) *Application of a plan.* Plan provisions remain in effect until the effective date of a new plan, plan amendment, or plan revision.

(d) *Effect of new information on projects or activities.* Although new information will be considered in accordance with agency NEPA procedures, nothing in this subpart requires automatic deferral, suspension, or modification of approved decisions in light of new information.

(e) *Ensuring project or activity consistency with plans.* Projects and activities must be consistent with the applicable plan. If an existing (paragraph (a) of this section) or proposed (paragraph (b) of this section) use, project, or activity is not consistent with the applicable plan, the Responsible Official may take one of the following steps, subject to valid existing rights:

(1) Modify the project or activity to make it consistent with the applicable plan components;

(2) Reject the proposal or terminate the project or activity, subject to valid existing rights; or

(3) Amend the plan contemporaneously with the approval of the project or activity so that it will be consistent with the plan as amended. The amendment may be limited to apply only to the project or activity.

§ 219.9 Public participation, collaboration, and notification.

The Responsible Official must use a collaborative and participatory approach to land management planning, in accordance with this subpart and consistent with applicable laws, regulations, and policies, by engaging the skills and interests of appropriate combinations of Forest Service staff, consultants, contractors, other Federal agencies, federally recognized Indian Tribes, State or local governments, or other interested or affected communities, groups, or persons.

(a) *Providing opportunities for participation.* The Responsible Official must provide opportunities for the public to collaborate and participate openly and meaningfully in the planning process, taking into account the discrete and diverse roles, jurisdictions, and responsibilities of interested and affected parties. Specifically, as part of plan development, plan amendment, and plan revision, the Responsible Official shall involve the public in developing and updating the comprehensive evaluation report, establishing the components of the plan, and designing the monitoring program. The Responsible Official has the discretion to determine the methods and timing of public involvement opportunities.

(1) *Engaging interested individuals and organizations.* The Responsible Official must provide for and encourage collaboration and participation by interested individuals and organizations, including private landowners whose lands are within, adjacent to, or otherwise affected by future management actions within the plan area.

(2) *Engaging State and local governments and Federal agencies.* The Responsible Official must provide opportunities for the coordination of Forest Service planning efforts undertaken in accordance with this subpart with those of other resource management agencies. The Responsible Official also must meet with and provide early opportunities for other government agencies to be involved, collaborate, and participate in planning for National Forest System lands. The Responsible Official should seek assistance, where appropriate, from other State and local governments, Federal agencies, and scientific and academic institutions to help address management issues or opportunities.

(3) *Engaging Tribal governments.* The Forest Service recognizes the Federal Government's trust responsibility for federally recognized Indian Tribes. The Responsible Official must consult with, invite, and provide opportunities for federally recognized Indian Tribes to collaborate and participate in planning. In working with federally recognized Indian Tribes, the Responsible Official must honor the government-to-government relationship between Tribes and the Federal Government.

(b) *Public notification.* The following public notification requirements apply to plan development, amendment, or revision, except when a plan amendment is approved contemporaneously with approval of a project or activity and the amendment applies only to the project or activity, in which case 36 CFR part 215 or part 218, subpart A, applies:

(1) *When formal public notification is provided.* Public notification must be provided at the following times:

(i) Initiation of development of a plan, plan amendment, or plan revision;

(ii) Commencement of the 90-day comment period on a proposed plan, plan amendment, or plan revision;

(iii) Commencement of the 30-day objection period prior to approval of a plan, plan amendment, or plan revision;

(iv) Approval of a plan, plan amendment, or plan revision; and

(v) Adjustment to conform to this subpart of a planning process for a plan, plan amendment, or plan revision initiated under the provisions of a previous planning regulation.

(2) *How public notice is provided.* Public notice must be provided in the following manner:

(i) All required public notices applicable to a new plan, plan revision, or adjustment of any ongoing plan revision as provided at § 219.14(e) must be published in the **Federal Register** and newspaper(s) of record.

(ii) Required notifications that are associated with a plan amendment or adjustment of any ongoing plan amendment as provided at § 219.14(e) and that apply to one plan must be published in the newspaper(s) of record. Required notifications that are associated with plan amendments and adjustment of any ongoing plan amendments (as provided at § 219.14(e)) and that apply to more than one plan must be published in the **Federal Register**.

(iii) Public notification of evaluation reports and monitoring program changes may be made in a manner deemed appropriate by the Responsible Official.

(3) *Content of the public notice.* Public notices must contain the following information:

(i) *Content of the public notice for initiating a plan development, plan amendment, or plan revision.* The notice must inform the public of the documents available for review and how to obtain them; provide a summary of the need to develop a plan or change a plan; invite the public to comment on the need for change in a plan and to identify any other need for change in a plan that they feel should be addressed during the planning process; and provide an estimated schedule for the planning process, including the time available for comments, and inform the public how to submit comments.

(ii) *Content of the public notice for a proposed plan, plan amendment, or plan revision.* The notice must inform the public of the availability of the proposed plan, plan amendment, or plan revision, including any relevant evaluation report; the commencement of the 90-day comment period; and the process for submitting comments.

(iii) *Content of the public notice for a plan, plan amendment, or plan revision prior to approval.* The notice must inform the public of the availability of the plan, plan amendment, or plan revision; any relevant evaluation report; and the commencement of the 30-day

objection period; and the process for objecting.

(iv) *Content of the public notice for approval of a plan, plan amendment, or plan revision.* The notice must inform the public of the availability of the approved plan, plan amendment, or plan revision, the approval document, and the effective date of the approval (§ 219.14(a)).

(v) *Content of the public notice for an adjustment to an ongoing planning process.* The notice must state how a planning process initiated before the transition period (§ 219.14(b) and (e)) will be adjusted to conform to this subpart.

§ 219.10 Sustainability.

Sustainability, for any unit of the National Forest System, has three interrelated and interdependent elements: social, economic, and ecological. A plan can contribute to sustainability by creating a framework to guide on-the-ground management of projects and activities; however, a plan by itself cannot ensure sustainability. Agency authorities, the nature of a plan, and the capabilities of the plan area are some of the factors that limit the extent to which a plan can contribute to achieving sustainability.

(a) *Sustaining social and economic systems.* The overall goal of the social and economic elements of sustainability is to contribute to sustaining social and economic systems within the plan area. To understand the social and economic contributions that National Forest System lands presently make, and may make in the future, the Responsible Official, in accordance with § 219.6, must evaluate relevant economic and social conditions and trends as appropriate during plan development, plan amendment, or plan revision.

(b) *Sustaining ecological systems.* The overall goal of the ecological element of sustainability is to provide a framework to contribute to sustaining native ecological systems by providing ecological conditions to support diversity of native plant and animal species in the plan area. This will satisfy the statutory requirement to provide for diversity of plant and animal communities based on the suitability and capability of the specific land area in order to meet overall multiple-use objectives (16 U.S.C. 1604(g)(3)(B)). Procedures developed pursuant to § 219.1(c) for sustaining ecological systems must be consistent with the following:

(1) *Ecosystem diversity.* Ecosystem diversity is the primary means by which a plan contributes to sustaining ecological systems. Plan components must establish a framework to provide the characteristics of ecosystem diversity in the plan area.

(2) *Species diversity.* If the Responsible Official determines that provisions in plan components, in addition to those required by paragraph (b)(1) of this section, are needed to provide appropriate ecological conditions for specific threatened and endangered species, species-of-concern, and species-of-interest, then the plan must include additional provisions for these species, consistent with the limits of agency authorities, the capability of the plan area, and overall multiple use objectives.

§ 219.11 Role of science in planning.

(a) The Responsible Official must take into account the best available science. For purposes of this subpart, taking into account the best available science means the Responsible Official must:

(1) Document how the best available science was taken into account in the planning process within the context of the issues being considered;

(2) Evaluate and disclose substantial uncertainties in that science;

(3) Evaluate and disclose substantial risks associated with plan components based on that science; and

(4) Document that the science was appropriately interpreted and applied.

(b) To meet the requirements of paragraph (a) of this section, the Responsible Official may use independent peer review, a science advisory board, or other review methods to evaluate the consideration of science in the planning process.

§ 219.12 Suitable uses and provisions required by NFMA.

(a) *Suitable uses.* (1) *Identification of suitable land uses.* National Forest System lands are generally suitable for a variety of multiple uses, such as outdoor recreation, range, timber, watershed, and wildlife and fish purposes. The Responsible Official, as appropriate, shall identify areas within a National Forest System unit as generally suitable for uses that are compatible with desired conditions and objectives for that area. Such identification is guidance for project and activity decisionmaking, is not a permanent land designation, and is subject to change through plan amendment or plan revision. Uses of specific areas are approved through project and activity decisionmaking.

(2) *Identification of lands not suitable for timber production.* (i) The Responsible Official must identify lands within the plan area as not suitable for timber production (§ 219.16) if:

(A) Statute, Executive order, or regulation prohibits timber production on the land; or

(B) The Secretary of Agriculture or the Chief of the Forest Service has withdrawn the land from timber production; or

(C) The land is not forest land (as defined at § 219.16); or

(D) Timber production would not be compatible with the achievement of desired conditions and objectives established by the plan for those lands.

(ii) This identification is not a final decision compelling, approving, or prohibiting projects and activities. A final determination of suitability for timber production is made through project and activity decisionmaking. Salvage sales or other harvest necessary for multiple-use objectives other than timber production may take place on areas that are not suitable for timber production.

(b) *NFMA requirements.* (1) The Chief of the Forest Service must include in the Forest Service Directive System procedures for estimating the quantity of timber that can be removed annually in perpetuity on a sustained-yield basis in accordance with 16 U.S.C. 1611.

(2) The Chief of the Forest Service must include in the Forest Service Directive System procedures to ensure that plans include the resource management guidelines required by 16 U.S.C. 1604(g)(3).

(3) Forest Service Directive System procedures adopted to fulfill the requirements of this paragraph shall provide public involvement as described in 36 CFR part 216.

§ 219.13 Objections to plans, plan amendments, or plan revisions.

(a) *Opportunities to object.* Before approving a plan, plan amendment, or plan revision, the Responsible Official must provide the public 30 calendar days for pre-decisional review and the opportunity to object. Federal agencies may not object under this subpart. During the 30-day review period, any person or organization, other than a Federal agency, who participated in the planning process through the submission of written comments, may object to a plan, plan amendment, or plan revision according to the procedures in this section, except in the following circumstances:

(1) When a plan amendment is approved contemporaneously with a project or activity decision and the plan amendment applies only to the project or activity, in which case the administrative review process of 36 CFR part 215 or part 218, subpart A, applies

instead of the objection process established in this section; or

(2) When the Responsible Official is an official in the Department of Agriculture at a level higher than the Chief of the Forest Service, in which case there is no opportunity for administrative review.

(b) *Submitting objections.* The objection must be in writing and must be filed with the Reviewing Officer within 30 days following the publication date of the legal notice in the newspaper of record of the availability of the plan, plan amendment, or plan revision. Specific details will be included in the Forest Service Directive System. An objection must contain:

(1) The name, mailing address, and telephone number of the person or entity filing the objection. Where a single objection is filed by more than one person, the objection must indicate the lead objector to contact. The Reviewing Officer may appoint the first name listed as the lead objector to act on behalf of all parties to the single objection when the single objection does not specify a lead objector. The Reviewing Officer may communicate directly with the lead objector and is not required to notify the other listed objectors of the objection response or any other written correspondence related to the single objection;

(2) A statement of the issues, the parts of the plan, plan amendment, or plan revision to which the objection applies, and how the objecting party would be adversely affected; and

(3) A concise statement explaining how the objector believes that the plan, plan amendment, or plan revision is inconsistent with law, regulation, or policy or how the objector disagrees with the decision and providing any recommendations for change.

(c) *Responding to objections.* (1) The Reviewing Officer (§ 219.16) has the authority to make all procedural determinations related to the objection not specifically explained in this subpart, including those procedures necessary to ensure compatibility, to the extent practicable, with the administrative review processes of other Federal agencies. The Reviewing Officer must promptly render a written response to the objection. The response must be sent to the objecting party by certified mail, return receipt requested.

(2) The response of the Reviewing Officer shall be the final decision of the Department of Agriculture on the objection.

(d) *Use of other administrative review processes.* Where the Forest Service is a participant in a multi-Federal agency effort that would otherwise be subject to objection under this subpart, the Reviewing Officer may waive the objection procedures of this subpart and instead adopt the administrative review procedure of another participating Federal agency. As a condition of such a waiver, the Responsible Official for the Forest Service must have agreement with the Responsible Official of the other agency or agencies that a joint agency response will be provided to those who file for administrative review of the multi-agency effort.

(e) *Compliance with the Paperwork Reduction Act.* The information collection requirements associated with submitting an objection have been approved by the Office of Management and Budget and assigned control number 0596–0158.

§ 219.14 Effective dates and transition.

(a) *Effective dates.* A plan, plan amendment, or plan revision is effective 30 days after publication of notice of its approval (§ 219.9(b)), except when a plan amendment is approved contemporaneously with a project or activity and applies only to the project or activity, in which case 36 CFR part 215 or part 218, subpart A, apply.

(b) *Transition period.* For each unit of the National Forest System, the transition period begins on January 5, 2005 and ends on the unit's establishment of an EMS in accordance with § 219.5 or on January 7, 2008 whichever comes first.

(c) *Initiation of plans, plan amendments, or plan revisions.* For the purposes of this section, initiation means that the agency has provided notice under § 219.9(b) or issued a Notice of Intent or other public notice announcing the commencement of the process to develop a plan, plan amendment, or plan revision.

(d) *Plan development, plan amendments, or plan revisions initiated during the transition period.* (1) Plan development and plan revisions initiated after January 5, 2005 must conform to the requirements of this subpart.

(2) Plan amendments initiated during the transition period may continue using the provisions of the planning regulations in effect before November 9, 2000 (See 36 CFR parts 200 to 299, Revised as of July 1, 2000) or may conform to the requirements of this subpart if the Responsible Official establishes an EMS in accordance with § 219.5.

(3) Plan amendments initiated after the transition period must conform to the requirements of this subpart.

(e) *Plan development, plan amendments, or plan revisions previously initiated.* Plan development, plan amendments, or plan revisions initiated before the transition period may continue to use the provisions of the planning regulations in effect before November 9, 2000 (See 36 CFR parts 200 to 299, Revised as of July 1, 2000), or may conform to the requirements of this subpart, in accordance with the following:

(1) The Responsible Official is not required to halt the process and start over. Rather, upon the unit's establishment of an EMS in accordance with § 219.5, the Responsible Official may apply this subpart as appropriate to complete the plan development, plan amendment, or plan revision process.

(2) The Responsible Official may elect to use either the administrative appeal and review procedures at 36 CFR part 217 in effect prior to November 9, 2000, (See 36 CFR parts 200 to 299, Revised as of July 1, 2000), or the objection procedures of this subpart, except when a plan amendment is approved contemporaneously with a project or activity and applies only to the project or activity, in which case 36 CFR part 215 or part 218, subpart A, apply.

(f) *Management indicator species.* For units with plans developed, amended, or revised using the provisions of the planning rule in effect prior to November 9, 2000, the Responsible Official may comply with any obligations relating to management indicator species by considering data and analysis relating to habitat unless the plan specifically requires population monitoring or population surveys for the species. Site-specific monitoring or surveying of a proposed project or activity area is not required, but may be conducted at the discretion of the Responsible Official.

§ 219.15 Severability.

In the event that any specific provision of this rule is deemed by a court to be invalid, the remaining provisions shall remain in effect.

§ 219.16 Definitions.

Definitions of the special terms used in this subpart are set out in alphabetical order.

Adaptive management: An approach to natural resource management where actions are designed and executed and effects are monitored for the purpose of learning and adjusting future management actions, which improves the efficiency and responsiveness of management.

Area of analysis: The geographic area within which ecosystems, their

components, or their processes are evaluated during analysis and development of one or more plans, plan revisions, or plan amendments. This area may vary in size depending on the relevant planning issue. For a plan, an area of analysis may be larger than a plan area. For development of a plan amendment, an area of analysis may be smaller than the plan area. An area of analysis may include multiple ownerships.

Diversity of plant and animal communities: The distribution and relative abundance or extent of plant and animal communities and their component species, including tree species, occurring within an area.

Ecological conditions: Components of the biological and physical environment that can affect diversity of plant and animal communities and the productive capacity of ecological systems. These components could include the abundance and distribution of aquatic and terrestrial habitats, roads and other structural developments, human uses, and invasive, exotic species.

Ecosystem diversity: The variety and relative extent of ecosystem types, including their composition, structure, and processes within all or a part of an area of analysis.

Environmental management system: The part of the overall management system that includes organizational structure, planning activities, responsibilities, practices, procedures, processes, and resources for developing, implementing, achieving, reviewing, and maintaining the environmental policy of the planning unit.

Federally recognized Indian Tribe: An Indian or Alaska Native Tribe, band, nation, pueblo, village, or community that the Secretary of the Interior acknowledges to exist as an Indian Tribe pursuant to the Federally Recognized Indian Tribe List Act of 1994, 25 U.S.C. 479a.

Forest land: Land at least 10 percent occupied by forest trees of any size or formerly having had such tree cover and not currently developed for nonforest uses. Lands developed for non-forest use include areas for crops; improved pasture; residential or administrative areas; improved roads of any width and adjoining road clearing; and power line clearings of any width.

ISO 14001: A consensus standard developed by the International Organization for Standardization and adopted by the American National Standards Institute that describes environmental management systems and outlines the elements of an environmental management system.

Newspaper(s) of record: The principal newspapers of general circulation annually identified and published in the **Federal Register** by each Regional Forester to be used for publishing notices as required by 36 CFR 215.5. The newspaper(s) of record for projects in a plan area is (are) the newspaper(s) of record for notices related to planning.

Plan: A document or set of documents that integrates and displays information relevant to management of a unit of the National Forest System.

Plan area: The National Forest System lands covered by a plan.

Productivity: The capacity of National Forest System lands and their ecological systems to provide the various renewable resources in certain amounts in perpetuity. For the purposes of this subpart it is an ecological, not an economic, term.

Public participation: Activities that include a wide range of public involvement tools and processes, such as collaboration, public meetings, open houses, workshops, and comment periods.

Responsible Official: The official with the authority and responsibility to oversee the planning process and to approve plans, plan amendments, and plan revisions.

Reviewing Officer: The supervisor of the Responsible Official. The Reviewing Officer responds to objections made to a plan, plan amendment, or plan revision prior to approval.

Species: Any member of the currently accepted and scientifically defined plant or animal kingdoms of organisms.

Species-of-concern: Species for which the Responsible Official determines that management actions may be necessary to prevent listing under the Endangered Species Act.

Species-of-interest: Species for which the Responsible Official determines that management actions may be necessary or desirable to achieve ecological or other multiple use objectives.

Timber production: The purposeful growing, tending, harvesting, and regeneration of regulated crops of trees to be cut into logs, bolts, or other round sections for industrial or consumer use.

Visitor opportunities: The spectrum of settings, landscapes, scenery, facilities, services, access points, information, learning-based recreation, wildlife, natural features, cultural and heritage sites, and so forth available for National Forest System visitors to use and enjoy.

Wilderness: Any area of land designated by Congress as part of the National Wilderness Preservation System that was established in the Wilderness Act of 1964 (16 U.S.C. 1131–1136).

Dated: December 22, 2004.

Mark Rey,

Under Secretary, Natural Resources and Environment.

[FR Doc. 05–21 Filed 1–4–05; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Forest Service

RIN 0596–AB86

National Environmental Policy Act Documentation Needed for Developing, Revising, or Amending Land Management Plans; Categorical Exclusion

AGENCY: Forest Service, USDA.

ACTION: Notice of proposed National Environmental Policy Act implementing procedures; request for comment.

SUMMARY: The Department of Agriculture, Forest Service, is requesting comment on a proposed revision to its procedures for implementing the National Environmental Policy Act (NEPA) and Council on Environmental Quality (CEQ) regulations. This proposed revision is being made to Forest Service Handbook 1909.15, Chapter 30, which describes categorical exclusions, that is, categories of actions that will not result in significant impacts on the human environment and which are therefore exempt from requirements to prepare further NEPA documentation absent extraordinary circumstances. The proposal would add one such category of actions to the agency's NEPA procedures for final decisions on proposals to develop, amend, or revise land management plans that are comprised of five components which are desired conditions, objectives, guidelines, suitability of areas, and special areas for a forest.

This proposal is being published in conjunction with the final Forest Service planning regulations published elsewhere in this part of today's **Federal Register**. Public comment is invited and will be considered in development of the final procedure.

DATES: Comments must be received in writing by March 7, 2005.

ADDRESSES: Send written comments by mail to: Content Analysis Team, ATTN: Planning CE, USDA Forest Service, P.O. Box 22777, Salt Lake City, UT 84122; by facsimile to 801–517–1015; or by e-mail at *planningce@fs.fed.us*. Please note that the Forest Service will not be able to receive hand-delivered comments. If you intend to submit comments in batched e-mails from the same server, please be aware that electronic security safeguards on Forest Service and Department of Agriculture computer systems for prevention of commercial spamming may limit batched e-mail access. The Forest Service is interested in receiving all comments on this proposed rule. Therefore, please call (801) 517–1020 to facilitate transfer of comments in batched e-mail messages. Comments may also be submitted via the World Wide Web/Internet Web site *http://www.regulations.gov*. Please note that all comments, including names and addresses when provided, will be placed in the record and will be available for public inspection and copying. The agency cannot confirm receipt of comments. Individuals wishing to inspect comments should call Jody Sutton at (801) 517–1023 to schedule an appointment.

FOR FURTHER INFORMATION CONTACT: Joe Carbone, USDA Forest Service, Ecosystem Management Coordination, (202) 205–0884. Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 4 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

History of Land Management Planning and NEPA Compliance

In developing this categorical exclusion the Forest Service took into account the experience it has gained over the past 25 years from developing, amending, and revising land management plans; the requirements of NEPA and the National Forest Management Act (NFMA), the Council on Environmental Quality (CEQ) regulations, and the recognition by the Supreme Court in *Ohio Forestry Ass'n* v. *Sierra Club* and *Norton* v. *Southern Utah Wilderness Alliance* regarding the nature of plans themselves. The Forest Service has concluded that land management plans, plan revisions, or plan amendments developed under the final Forest Service planning rule published elsewhere today's **Federal Register** comprised of five strategic components which do not approve projects or activities, do not individually or cumulatively result in significant effects on the human environment. The intended effect of this categorical exclusion is to facilitate efficient planning and timely development, amendment, or revision of land management plans.

The Forest Service's first planning rule published in 1979 required an environmental impact statement (EIS) for development of plans, significant amendments, and revisions. This requirement continued in the revised rule adopted in 1982. At the time, the Forest Service believed that a NEPA analysis and document prepared for a plan would suffice for making most project-level decisions. However, the agency came to understand that this approach to complying with NEPA was impractical, inefficient, and frequently inaccurate. Over the course of implementing NFMA during the past 25 years, the agency has learned that environmental effects of projects and activities cannot be meaningfully evaluated without knowledge of the specific timing and location of the projects and activities.

At the time of plan approval, the Forest Service does not have detailed information about what projects and activities will be proposed over the expected 15 year life of a plan, how many projects will be approved, where they will be located, or how they will be designed. At the point of plan approval, the Forest Service can only speculate about the projects that may be proposed and budgeted and the natural events, such as fire, flood, insects, and disease that may occur that will make uncontemplated projects necessary or force changes in the projects and the effects of projects that were contemplated. Indeed, the Forest Service has learned that over the life of a plan it must deal with the unexpected and will face numerous situations where analyses contained in the EISs that accompanied the plan can not be relied upon when considering specific projects and activities.

In the course of completing NEPA analyses and documentation on the first generation of NFMA plans, the Forest Service also became more aware of the difficulties of scale created by the size of the national forests and grasslands. The National Forest System includes 192 million acres, and individual planning units, such as the Tongass National Forest, may be as large as 17 million acres. These vast landscapes contain an enormous variety of different ecosystems which will respond differently to the same management practices. As the Committee of Scientists said on page 26 of the Committee of Scientists Report:

> Because of the wide variation in site-specific practices and local environmental conditions (*e.g.*, vegetation type, topography, geology, and soils) across a given national forest or rangeland, the direct and indirect effects of management practices may not always be well understood or easily predicted. (Committee of Scientists Report, March 15, 1999, U.S. Department of Agriculture, Washington, DC 193 p.)

Secretary Glickman named the Committee of Scientists (COS) on December 11, 1997. The charter for the COS states that the Committee's purpose is to provide scientific and technical advice to the Secretary of Agriculture and the Chief of the Forest on

improvements that can be made in the National Forest System Land and Resource Management Planning Process.

Forest Service experience confirmed the conclusion in the COS report, quoted above showing that it is usually infeasible to do meaningful environmental analysis for a national forest as a whole that is sufficiently site specific to allow projects to be carried out without further detailed NEPA analysis after the plan has been approved.

Even after completing an EIS for specific land management plans, the agency has found itself preparing much more extensive NEPA analysis and documentation for specific projects than it had anticipated when it adopted the 1979 and 1982 planning rules. Moreover, the extensive changes to conditions in the plan area that have occurred during the life of each plan, including unforeseen natural events such as fires and floods, have made it increasingly impractical to tier project-level NEPA analysis and documentation to the plan EIS. The requirements of the 1979 and 1982 planning rules that created an inefficient and ineffective system for complying with NEPA.

The 2000 planning rule continued to require an EIS for plan development or revision notwithstanding concerns raised by the Committee of Scientists. The Committee of Scientists said on page 117 of the Committee of Scientists Report:

> Perhaps the most difficult problem is that the current EA/EIS process assumes a one-time decision. The very essence of small-landscape planning is an adaptive management approach, based upon monitoring and learning. Although small-landscape planning can more readily do real-time cumulative effects analysis * * *, this kind of analysis is difficult to integrate with a one-time decision approach. Developing a decision disclosure and review process that is ongoing and uses monitoring information to adjust or change treatments and activities will need to be a high priority * * *. (Committee of Scientists Report, March 15, 1999, U.S. Department of Agriculture, Washington, DC 193 p.)

In addition to concern about timely and accurate disclosure of environmental effects, the agency's experience with planning has demonstrated the need to clarify what plans, in fact, actually do. Neither the 1982 nor the 2000 planning rule clearly described or contrasted the differences between the effects of plans and the effects of projects and activities. This has been confusing to the public and agency employees. Plan components have not been applied or interpreted consistently throughout the agency, and often have been characterized as final decisions or actions, rather than guidance for projects and activities over time.

The new 2004 planning rule (published elsewhere in today's **Federal Register**) clarifies that plans will generally be strategic rather than prescriptive in nature. Plans will have five principal components—desired conditions, objectives, guidelines, suitability of areas and special areas. These five components set aspirational goals and general guidance for land management. They provide flexibility in implementation based on changing conditions. They do not result in specific on-the-ground action.

Desired conditions are the social, economic, and ecological attributes toward which management of the land and resources of the plan area is to be directed. Desired conditions are long-term in nature and aspirational, but are neither commitments nor final decisions approving projects and activities.

Objectives are concise projections of intended outcomes of projects and activities to contribute to maintenance or achievement of desired conditions. Objectives are measurable and time-specific and, like desired conditions, are aspirational, but are neither commitments nor final decisions approving projects and activities.

Guidelines provide information and guidance for the design of projects and activities to help achieve objectives and desired conditions. Guidelines are not commitments or final decisions approving projects and activities.

Suitability of areas is the identification of the general suitability of an area in an NFS unit for a variety of uses. The identification of an area as generally suitable for a use or uses is neither a commitment nor a decision approving activities and uses.

Special areas are areas within the National Forest System designated because of their unique or special characteristics. The Responsible Official in approving a plan, plan amendment, or plan revision may designate special areas such as botanical areas or significant caves. Such designations are not final decisions approving projects and activities. Plans also may recognize special areas designated by statute or through a separate administrative process.

While plans will identify the general suitability of lands for various uses, they typically will not result in final decisions on suitable uses with accompanying environmental effects. Such decisions will occur, if appropriate, at the time of project approval. Plan objectives, guidelines, suitable uses, and special area identifications will be designed to inform and guide projects and activities, so they will more effectively help to achieve the desired conditions.

Decisions approving actions with environmental effects that can be meaningfully evaluated typically will be made when projects or activities are designed and approved. In essence, a plan simply is a description of a vision for the future that, coupled with evaluation, provides a starting point for project and activity NEPA analysis. Therefore, approval of a plan, plan amendment, or plan revision typically will not have environmental effects that can be meaningfully evaluated at the time of the plan decision.

The formulation of plans under the final rule as strategic rather than prescriptive is further evident in the five components of plans under the final rule. As described above, none of the five components is intended to directly dictate on the ground decisions that have impacts on the environment. Rather, they provide for project and activity decisions.

Statutory and Regulatory Direction and Case Law

NFMA requires the Secretary of Agriculture to determine how to comply with NEPA during the course of NFMA planning. Section 106 (g)(1) of NFMA directs the Secretary to specify in land management regulations procedures to insure that plans are prepared in accordance with NEPA, including direction on when and for what plans an EIS is required (16 U.S.C. 1604 (g)(1)). The CEQ regulations direct Federal agencies to adopt procedures that designate major decision points for the agency's principal programs likely to have a significant effect on the human environment and to assure that the NEPA process corresponds with them (40 CFR 1505.1(b)).

Under NEPA and the CEQ regulations, an EIS is required for every report or recommendation on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment (16 U.S.C. 4321 *et seq.*, 40 CFR 1502.3). The CEQ regulations explain that a "proposal" that can trigger the requirement for an EIS exists "at that stage in the development of an action when an agency subject to the Act has a goal and is actively preparing to make a decision on one or more alternative means of accomplishing that goal and the effects can be meaningfully evaluated" (40 CFR 1508.23).

CEQ regulations explain that "Federal actions" generally tend to fall within

several categories. Although these categories include adoption of formal agency plans within the definition of "Federal action", not all Federal actions are major Federal actions. As applied to the final rule, land management plans under the 2004 planning rule, as evidenced by their five components, are strategic and aspirational in nature and generally will not include decisions with on-the-ground effects that can be meaningfully evaluated and thus generally will not be "major Federal actions." During plan development, amendment or revision, the agency generally is not at the stage in National Forest planning of proposing actions to accomplish the goals in land management plans. Proposals for actions with effects that can be meaningfully evaluated, and which may be significant, generally are made at the project and activity stage. While a plan expresses desired conditions, goals, and objectives, the Forest Service does not actively prepare to make a decision on an action aimed at achieving desired conditions, goals, or objectives except in extraordinary circumstances, such as when the agency proposes projects and activities in connection with the plan adoption or revision. Thus, the decision to adopt, amend, or revise a plan is typically not the point in the decisionmaking process at which the agency is proposing an action likely to have a significant effect on the human environment.

The approach in this final rule is consistent with the nature of Forest Service land management plans acknowledged in *Ohio Forestry Ass'n* v. *Sierra Club,* 523 U.S. 726 (1998). In *Ohio Forestry,* the Supreme Court held that the timber management provisions of land management plans are tools for further agency planning and guide, but do not direct, future management. When considering the role of land management plans with respect to timber harvesting, the Supreme Court explained that:

> Although the Plan sets logging goals, selects the areas of the forest that are suited to timber production, and determines which "probable methods of timber harvest" are appropriate, it does not itself authorize the cutting of any trees. Before the Forest Service can permit the logging, it must: (a) Propose a specific area in which logging will take place and the harvesting methods to be used; (b) ensure that the project is consistent with the Plan; (c) provide those affected by proposed logging notice and an opportunity to be heard; (d) conduct an environmental analysis pursuant to the National Environmental Policy Act of 1969, to evaluate the effects of the specific project and to contemplate alternatives; and (e) subsequently make a final decision to permit logging, which affected persons may challenge in an administrative appeals process and in court.

The Supreme Court repeated its characterization of analogous plan decisions as strategic without any immediate on the ground impact in the recent *SUWA* decision: *Norton* v. *Southern Utah Wilderness Alliance,* 124 S. Ct. 2373, 2382 (2004). The Supreme Court again observed that "land use plans are a preliminary step in the overall process of managing public lands—'designed to guide and control future management actions and the development of subsequent, more detailed and limited scope plans for resources and uses.'" In addition, "a land use plan is not ordinarily the medium for affirmative decisions that implement the agency's 'project[ion]s'" (542 U.S. 13 (2004)).

Under the Final Rule, plans will continue to be strategic in nature, as described by the Supreme Court in Ohio Forestry and SUWA. As described above, the five elements of a plan under the planning rule do not authorize site-specific decisions, but rather characterize general future conditions and guidance for such decisions. Only in extraordinary circumstances will project and activity decisions be implemented at the time of a plan adoption or amendment.

In accordance with NFMA, NEPA, and the CEQ regulations, the final planning rule at 36 CFR part 219 *et seq.* will ensure that Forest Service NEPA analysis and documentation will be timed to coincide with meaningful stages in agency planning and decisionmaking. The planning rule emphasizes the clear distinction between the adoption or amendment of a plan with projects and activities having on-the-ground environmental effects. In the planning rule, the Department clarifies the nature of National Forest land management plans, and based on the nature of plans, specifies which plans, plan amendments and plan revisions may be categorically excluded from NEPA documentation and which may require an EIS or an EA.

Land management plans are strategic and aspirational in nature, a reality reinforced by the final planning rule. Absent extraordinary circumstances, plans under the new planning rule will not contain final decisions that approve projects and activities. Desired conditions and objectives are not commitments or final decisions approving projects and activities in the plan area. Guidelines, which are intended to provide guidance for project design and implementation, have no influence until they are applied in a project or activity and are not commitments or decisions approving projects and activities. The identification of an area as generally suitable for a use is not a commitment or decision approving projects and activities. Any proposed use in an area identified as suitable for that use must be considered under agency NEPA procedures at the time of a project decision. Special areas may be designated by statute or through plan development, plan amendment, or plan revision or a separate administrative process under NEPA and other applicable laws.

When a project or activity is proposed in connection with a plan adoption, the agency will look at whether the project or activity itself warrants further nepa analysis. Some proposed projects may themselves fall within another categorical exclusion. In other instances, the agency will examine the effect of the project on resource conditions, as it would in considering any other project, in deciding whether an EA or EIS is appropriate.

In summary, none of these plan components is permanent or final, in that all are subject to reconsideration and change through plan amendment or plan revision at any time and all provide flexibility to respond to on-the-ground conditions and changing circumstances. Should a Responsible Official nevertheless choose to include projects or activities within the context of a plan, plan revision, or plan amendment, extraordinary circumstances may be present such that an EIS or an EA may be required.

The Proposed Categorical Exclusion

The CEQ regulations (40 CFR parts 1500–1508) require that each agency establish specific criteria for and identification of three types of actions: (1) Those that normally require preparation of an environmental impact statement (EIS); (2) those that normally require the preparation of an environmental assessment (EA); and (3) those that normally do not require either an EA or EIS because they "do not individually or cumulatively have a significant effect on the human environment" (40 CFR 1508.4). Actions qualifying for this third type of action are defined as categorical exclusions because they do not individually or cumulatively have a significant impact on the human environment; therefore, neither an environmental assessment nor an environmental impact statement is required (40 CFR 1508.4).

A categorical exclusion is not an exemption from the requirements of

NEPA. Categorical exclusions are an essential part of NEPA that provide a categorical determination that certain actions do not result in significant impacts, eliminating the need for individual analyses and lengthier documentation for those actions.

CEQ regulations at 40 CFR 1500.4(p), 1507.3 and 1508.4 direct agencies to use categorical exclusions to define categories of actions which do not individually or cumulatively have a significant effect on the human environment and do not require the preparation of an environmental assessment or an environmental impact statement, thereby reducing excessive paperwork. Current Forest Service procedures for complying with and implementing NEPA are set out in Forest Service Handbook (FSH) 1909.15. Categorical exclusions are set forth in chapter 30 of the FSH. The categorical exclusion proposed in this notice would require four changes in the chapter 30.

1. A category would be added to section 31.2 that would allow development, amendment, and revision of plan components, or portions thereof, to be categorically excluded unless extraordinary circumstances exist.

2. A paragraph would be added to section 30.3 to define the extraordinary circumstances pertinent to the new category. It would specify that the inclusion of a project or activity decision in a plan component may constitute an extraordinary circumstance.

3. A paragraph would be added to section 30.3 to clarify that the extensive public participation requirements in the land management planning regulations at 36 CFR 219.9 are sufficient to satisfy the scoping requirements currently included in section 30.3.

4. A paragraph would be added to section 30.2 to clarify that the plan approval document required by the land management planning regulations at 36 CFR 219.7(c) is sufficient to satisfy the decision memo requirements of chapter 30.

The Department emphasizes that project or activity decisions are generally not appropriate for inclusion in a plan level document. Rather, experience has shown that including project and activity decisionmaking in planning has actually delayed the planning and project and activity processes without improving natural resource management or public participation. Thus, by sharpening the distinction between planning and project and activity decisions, the Department expects both better planning decisions and more useful and timely environmental analysis for project and activity decisionmaking.

Regulatory Certifications

Environmental Impact

This proposed categorical exclusion would add direction to guide employees in the USDA Forest Service regarding requirements for National Environmental Policy Act (NEPA) documentation for land management planning activities. The Council on Environmental Quality does not direct agencies to prepare a NEPA analysis or document before establishing agency procedures that supplement the CEQ regulations for implementing NEPA. Agencies are required to adopt NEPA procedures that establish specific criteria for, and identification of, three classes of actions: those that require preparation of an environmental impact statement; those that require preparation of an environmental assessment; and those that are categorically excluded from further NEPA review (40 CFR 1507.3(b)). Categorical exclusions are one part of those agency procedures, and therefore establishing categorical exclusions does not require preparation of a NEPA analysis or document. Agency NEPA procedures are internal procedural guidance to assist agencies in the fulfillment of agency responsibilities under NEPA, but are not the agency's final determination of what level of NEPA analysis is required for a particular proposed action. The requirements for establishing agency NEPA procedures are set forth at 40 CFR 1505.1 and 1507.3. The USDA Forest Service is providing an opportunity for public review and consulted with the Council on Environmental Quality during the development of this categorical exclusion. The determination that establishing categorical exclusions does not require NEPA analysis and documentation has been upheld in *Heartwood, Inc.* v. *U.S. Forest Service,* 73 F. Supp. 2d 962, 972–73 (S.D. Ill. 1999), *aff'd,* 230 F.3d 947, 954–55 (7th Cir. 2000).

Regulatory Impact

This proposed categorical exclusion has been reviewed under USDA procedures and Executive Order 12866, Regulatory Planning and Review. It has been determined that this is not an economically significant action. This action to issue agency direction will not have an annual effect of $100 million or more on the economy nor adversely affect productivity, competition, jobs, the environment, public health or safety, nor State or local governments. This action will not interfere with an action taken or planned by another agency. Finally, this action will not alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients of such programs.

Moreover, the proposed categorical exclusion has been considered in light of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), and it is hereby certified that the proposed categorical exclusion will not have a significant economic impact on a substantial number of small entities as defined by the act because it will not impose record-keeping requirements on them; it will not affect their competitive position. in relation to large entities; and will not affect their cash flow, liquidity, or ability to remain in the market.

Federalism

The agency has considered this proposed categorical exclusion under the requirements of Executive Order 13132, Federalism, and has concluded that it conforms with the federalism principles set out in this Executive Order; will not impose any compliance costs on the States; and will not have substantial direct effects on the States or the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, the agency has determined that no further assessment of federalism implications is necessary.

Consultation and Coordination With Indian Tribal Governments

Pursuant to Executive Order 13175 of November 6, 2000, "Consultation and Coordination with Indian Tribal Governments," the agency has assessed the impact of this categorical exclusion on Indian tribal governments and has determined that the categorical exclusion does not significantly or uniquely affect communities of Indian tribal governments. The categorical exclusion deals with requirements for National Environmental Policy Act (NEPA) documentation for land management planning activities and, as such, has no direct effect regarding the occupancy and use of NFS land.

The agency has also determined that this categorical exclusion does not impose substantial direct compliance cost on Indian tribal governments. This categorical exclusion does not mandate tribal participation in NFS planning. Rather, the agency planning rule, with which this categorical exclusion is associated, imposes an obligation on Forest Service officials to consult early with tribal governments and to work

cooperatively with them where planning issues affect tribal interests.

No Takings Implications

This proposed categorical exclusion has been analyzed in accordance with the principles and criteria contained in Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights, and it has been determined that the proposed categorical exclusion does not pose the risk of a taking of Constitutionally protected private property.

Civil Justice Reform

This categorical exclusion has been reviewed under Executive Order 12988 of February 7, 1996, "Civil Justice Reform." The agency has not identified any State or local laws or regulations that are in conflict with this regulation or that would impede full implementation of this categorical exclusion. Nevertheless, in the event that such a conflict was to be identified, the categorical exclusion would preempt State or local laws or regulations found to be in conflict. However, in that case, (1) no retroactive effect would be given to this categorical exclusion; and (2) the categorical exclusion does not require the use of administrative proceedings before parties may file suit in court challenging its provisions.

Unfunded Mandates

Pursuant to title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538), which the President signed into law on March 22, 1995, the agency has assessed the effects of this proposed categorical exclusion on State, local, and tribal governments and the private sector. This proposed categorical exclusion does not compel the expenditure of $100 million or more by any State, local, or tribal government or anyone in the private sector. Therefore, a statement under section 202 of the act is not required.

Energy Effects

This proposed categorical exclusion has been reviewed under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. It has been determined that this proposed categorical exclusion does not constitute a significant energy action as defined in the Executive order.

Controlling Paperwork Burdens on the Public

This proposed categorical exclusion does not contain any additional record keeping or reporting requirements or other information collection requirements as defined in 5 CFR part 1320 that are not already required by law or not already approved for use, and therefore, imposes no additional paperwork burden on the public. Accordingly, the review provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR part 1320 do not apply.

Dated: December 22, 2004.

Dale N. Bosworth,

Chief.

Note: The Forest Service organizes its directive system by alphanumeric codes and subject headings. Only those sections of the Forest Service Handbook that are the subject of this notice are set out here. Reviewers wishing to review the entire chapter 30 may obtain a copy electronically from the Forest Service's directives Web site on the World Wide Web/Internet at *http://www.fs.fed.us/im/directives/.*

Forest Service Handbook

1909.15—Environmental Policy and Procedures Handbook

Chapter 30—Categorical Exclusion From Documentation

* * * * *

30.3—Policy

Redesignate existing paragraphs 3 and 4 as paragraphs 4 and 6 and add new paragraphs 3 and 5 as follows:

* * * * *

3. Development, revision, or amendment of land management plans or components, or portions thereof, that propose projects or activities may constitute an extraordinary circumstance. The degree of the effect of the project or activity on resource conditions, rather than the mere presence of resource conditions, determines whether further analysis and documentation in an EA or EIS is required.

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5. If the proposed action is approval of a land management plan, plan amendment, or plan revision, the public participation requirements of 36 CFR 219.9 satisfy the scoping requirement of paragraph 4 of this section.

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31.2—Categories of Actions for Which a Project or Case File and Decision Memo Are Required

Add a new paragraph 16 as follows:

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16. Development, revision, or amendment of land management plan components, or portions thereof, pursuant to 36 CFR part 219 *et seq.*, except where extraordinary circumstances exist as defined in section 30.3 paragraph 3.

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32.2—Decision Memo Required

Add the following as a third unnumbered paragraph:

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If the proposed action is approval of a land management plan, plan amendment, or plan revision, the plan approval document required by 36 CFR 219.7(c) satisfies the decision memo requirements of this chapter.

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Part IV

Office of Personnel Management

5 CFR Parts 353, 530, et al.
Restoration to Duty From Uniformed Service or Compensable Injury; Payrates and Systems (General); Pay Under the General Schedule; Pay Administration (General); Pay Administration Under the Fair Labor Standards Act; Recruitment and Relocation Bonuses; Retention Allowances; Supervisory Differentials; Hours of Duty; and Absence and Leave; Proposed Rule

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Parts 353, 530, 531, 550, 575, 610, and 630

RIN 3206–AK61

Restoration to Duty From Uniformed Service or Compensable Injury; Payrates and Systems (General); Pay Under the General Schedule; Pay Administration (General); Pay Administration Under the Fair Labor Standards Act; Recruitment and Relocation Bonuses; Retention Allowances; Supervisory Differentials; Hours of Duty; and Absence and Leave

AGENCY: Office of Personnel Management.

ACTION: Proposed rule.

SUMMARY: The Office of Personnel Management is issuing proposed regulations to amend the rules concerning the determination of official duty station for location-based pay entitlements, compensatory time off for religious observance, hours of work and alternative work schedules, and absence and leave. In addition, the proposed regulations are being issued to aid and support the standardization of pay policies under the e-Payroll initiative. The regulations have been rewritten and, in some instances, reordered to enhance reader understanding.

DATES: Comments must be received on or before March 7, 2005.

ADDRESSES: Send or deliver comments to Donald J. Winstead, Deputy Associate Director for Pay and Performance Policy, Strategic Human Resources Policy Division, Office of Personnel Management, Room 7H31, 1900 E Street NW., Washington, DC 20415, FAX: (202) 606–0824, or e-mail them to *pay-performance-policy@opm.gov*.

FOR FURTHER INFORMATION CONTACT: Sharon Herzberg by telephone at (202) 606–2858; by fax at (202) 606–0824; or by e-mail at *pay-performance-policy@opm.gov*.

SUPPLEMENTARY INFORMATION: The Office of Personnel Management (OPM) is issuing proposed regulations to revise the rules concerning the determination of official duty station for location-based pay entitlements, compensatory time off for religious observances, hours of work and alternative work schedules, and absence and leave. Except as otherwise stated in this supplementary information, the purpose of these revisions is to standardize and simplify pay, leave, and hours of work rules to simplify payroll processing under the e-Payroll initiative and in general to aid agencies in the administration of these programs. We are also taking this opportunity to make these parts more readable. As part of this rewriting effort, the proposed regulations have been reorganized and renumbered to aid in accessibility. In addition, we have replaced the verb "shall" with "must" for added clarity and readability. We intend that any provision using the verb "must" has the same meaning and effect as previous provisions using "shall."

Military Leave

Section 353.208 of title 5, Code of Federal Regulations, states that an employee on military leave is permitted, upon request, to use any accrued annual leave (or sick leave, if appropriate), or military leave during such service. However, the Uniformed Services Employment and Reemployment Rights Act of 1994, Public Law 103–353, December 12, 1994, which was implemented by this regulation, states that an employee must be permitted during a period of military service to use any vacation, annual, or similar leave with pay accrued by the person before the commencement of such service. We do not believe that sick leave is similar to annual leave in this context. Sick leave is intended to provide income to an employee who must be excused from work on account of sickness. Long-standing Comptroller General opinions have held an employee who is already on extended leave without pay cannot be said to be prevented from working by a period of sickness and therefore is not entitled to use sick leave. Likewise, an employee on extended leave without pay for military service cannot be said to be prevented from working at his civilian job by a period of illness. Therefore, we are proposing to delete the reference to sick leave from § 353.208.

In addition, the last sentence of § 353.208 states that an employee may not use military leave for inactive duty training. However, authority to use military leave for inactive duty training was added by section 1106 of the National Defense Authorization Act for Fiscal Year 2000 (Public Law 106–65, October 5, 1999). Section 1106 amended 5 U.S.C. 6323(a)(1) to permit an employee to use his or her entitlement to 15 days of military leave for "inactive-duty training" (as defined in section 101 of title 37, United States Code) in addition to active duty and active duty training. Therefore, we are proposing the deletion of the last sentence of § 353.208 consistent with this change in law.

Official Duty Station

We are proposing to add a new 5 CFR 531.605 to specifically define the requirements for determining an employee's official duty station for location-based pay entitlements, including special salary rates under 5 CFR part 530, subpart C, special pay for law enforcement officers under 5 CFR part 531, subpart C, and locality based comparability payments under 5 CFR part 531, subpart F. New § 531.605 also addresses the official duty station determination for employees temporarily working at another location or teleworking from an alternative worksite. Under § 531.605, the official duty station is the location where the employee regularly performs his or her duties. For employees who telework, the official duty station is the employee's telework site. However, if an agency schedules an employee to report at least once a week to the regular work site (*i.e.*, the location of his or her assigned organization), the official duty station is the regular worksite. Agencies may make temporary exceptions to this requirement in appropriate circumstances.

We are proposing to revise the definition of *official duty station* at §§ 531.301 and 531.602 to refer to the new requirements found at revised § 531.605. In addition, we propose to add the definition of *position of record* to §§ 531.301 and 531.602. The definition of *position of record* builds on the language found in current regulations in § 530.303(i) and clarifies that the term incorporates employing agency, grade, occupational series, and position duties—all of which may be relevant in determining an employee's coverage under a special rate schedule. In addition, we propose to revise § 530.303(i), which concerns conditions for coverage under special salary rates, to incorporate these new definitions. Finally, we are adding the definitions of *telework* and *telework arrangement* to § 531.602.

Time Limits for Use of Compensatory Time Off

The consolidation of payroll systems has revealed varying policies among agencies concerning time limits for the use of compensatory time off. As part of our effort to support consolidation through standardization of payroll processes, we are proposing to amend the regulations at 5 CFR 550.114 and 551.531 to provide a consistent 26-pay period time limitation on the period during which an employee may use compensatory time off. Under current regulations at § 550.114(d), the head of

an agency may require that an employee who is not covered by the Fair Labor Standards Act must use earned compensatory time off within a certain time period or risk forfeiture of unused compensatory time off, unless failure to use the compensatory time off is due to an exigency of the service beyond the employee's control. Under this discretionary authority, many agencies have established policies to provide payment for unused compensatory time off upon expiration of the agency's established time limit. The proposed regulations would establish a Governmentwide time limit of 26 pay periods for using earned compensatory time off, but agencies would retain their discretionary authority to provide payment for, or require forfeiture of, compensatory time off that is not used within the 26-pay period time limit. The proposed regulations also would require that if an employee who is not covered by the Fair Labor Standards Act separates or goes on extended leave without pay to perform service in one of the uniformed services or because of an on-the-job injury with entitlement to injury compensation under 5 U.S.C. chapter 81, he or she would be entitled to receive pay for the overtime work at the overtime rate in effect for the period during which compensatory time off was earned.

Under the proposed regulations at § 551.531, if an employee who is covered by the Fair Labor Standards Act fails to use compensatory time off earned under paragraph (a) or (b) of that section within 26 pay periods, or if the employee separates before the earned compensatory time off is used, he or she must be paid for the overtime work at the overtime rate in effect for the period during which the compensatory time off was earned. In addition, the proposed regulations require that if an employee who is covered by the Fair Labor Standards Act goes on extended leave without pay to perform service in one of the uniformed services or because of an on-the-job injury with entitlement to injury compensation under 5 U.S.C. chapter 81, he or she is entitled to receive pay for the overtime work at the overtime rate in effect for the period during which compensatory time off was earned. To aid payroll providers in transitioning to the new time limitations, the proposed regulations provide that employees with unused compensatory time off to their credit under § 550.114 or § 551.531 as of the effective date of the final regulations would have 26 pay periods after the effective date of the final regulations to use such compensatory time off. Time limitations for paying earned compensatory time off to employees covered by the Federal Wage System will be discussed by the Federal Prevailing Rate Advisory Committee before OPM issues final regulations.

Compensatory Time Off for Religious Observances

We are proposing to add definitions of three terms in 5 CFR 550.1002. The term employee is used in defining coverage. The term *rate of basic pay* is used in proposed § 550.1008 in the context of determining the monetary value of compensatory time off for religious observances. The term *scheduled tour of duty for leave purposes* is used in proposed § 550.1001 to make clear that religious compensatory time off is used in place of hours within the employee's tour of duty as established for leave purposes.

Proposed § 550.1003 provides that an agency may require documentation to ensure that an employee's request for compensatory time off for religious observances is legitimate. Also, this section empowers agencies to require employees who are submitting requests for this time off to make the requests sufficiently in advance to allow for work schedule adjustments that may be required to accommodate the time off. These provisions are consistent with the past guidance we have given agencies concerning the administration of this program.

Proposed § 550.1004 includes a new requirement that, if an employee fails to perform compensatory overtime work within 3 pay periods after using advanced compensatory time off, the agency should charge the employee annual leave to eliminate the negative balance. This is consistent with longstanding OPM policy. In addition, proposed § 550.1005 provides that agencies may allow employees to accumulate only the number of hours of earned compensatory time off needed to cover past absences and anticipated absences for specifically identified religious observances. While agencies have always been able to require employees to identify specific future religious observances as a condition for allowing them to earn religious compensatory time off, this new section now makes it *mandatory* that agencies require employees to identify the specific future religious observances for which the compensatory time off will be used. This requirement is intended to prohibit the practice of "stockpiling" religious compensatory time off and ensures that this benefit will be used as intended by law.

Proposed § 550.1007 includes a new sentence documenting the fact that earned compensatory time off for religious observances under 5 U.S.C. 5550a is not considered in applying the premium pay limitations in 5 U.S.C. 5547 and 5 CFR 550.105–550.107. (See 62 CG 590, July 26, 1983.) In contrast, the dollar value of overtime work resulting in earned compensatory time off under 5 U.S.C. 5543 is considered to be premium pay in applying those limitations.

Proposed § 550.1008 provides rules regarding how an agency must deal with employees who have a negative or positive balance of earned compensatory time off for religious observances when they separate from an agency. Consistent with previous OPM policy, in converting earned but unused compensatory time off to a monetary value, agencies must use the rates of basic pay in effect at the time the religious compensatory overtime work was performed.

If an employee has a negative balance of religious compensatory time off hours upon separation from the agency, the employee's annual leave balance would be reduced by the amount of the negative balance of hours to the extent possible. If it is necessary for the agency to determine the monetary value of the employee's negative balance, that value would be computed using the employee's rate of basic pay in effect at the time the religious compensatory time was taken.

Federal Wage System

OPM is proposing to revise its regulations in 5 CFR part 550, subpart L, on lump-sum payments for accumulated and accrued annual leave for employees who separate from Federal service (64 FR 36763, July 8, 1999) to ensure consistency with the guidance provided in the OPM Operating Manual on the Federal Wage System. This change ensures that a lump-sum payment for employees who work a regular rotating schedule involving work on both day and night shifts is calculated as if the employee had continued to work beyond the effective date of separation. To further ensure that the regulations are consistent with the guidance provided in the Operating Manual, we are proposing to amend the definition of *rate of basic pay* in the regulations at 5 CFR 575.103, 575.203, and 575.303 for purposes of recruitment and relocation bonuses and retention allowances. The revised definition will clarify that night pay and environmental differential pay under the Federal Wage System are not

included in the definition of rate of basic pay for those purposes.

Weekly and Daily Scheduling of Work

In 5 CFR 610.102, we are proposing to add the definitions of *authorized agency official* and *unpaid meal period*. In addition, we propose to change the reference in § 610.111 from "overtime pay" in paragraph (a)(1)(ii) to "premium pay" to be consistent with other references within the section. We are also proposing to add paragraph (e) to § 610.121 to clarify that the regulations on work schedules do not apply to employees on flexible and compressed work schedules in those areas where the law and regulation on flexible and compressed work schedules conflict with the requirements of this section.

In § 610.123, we are proposing to change the word "shall" to "should" to indicate that while an agency official may require an employee to travel outside duty hours, every effort should be made to avoid doing so. In addition, we are clarifying that an agency may not adjust the regular working hours of an employee solely for the purpose of including time spent traveling as hours of work. We are also proposing the addition of § 610.124 to clarify that agencies have authority to establish a mandatory unpaid break for meal periods under 5 U.S.C. 6101(a)(3)(F) and that there is no explicit entitlement to a meal period. An agency may require or permit unpaid meal periods during overtime hours, and the policy may be different from that for the basic workweek. An unpaid meal period may not be counted as hours of work.

Holidays

In 5 CFR 610.201, we are proposing the addition of the definitions of *administrative workweek, agency, authorized agency official, basic workday, basic workweek, employee, rate of basic pay,* and *the United States*. In addition, we are revising § 610.202 to clarify when an employee is entitled to a paid holiday. This section reflects the requirements of Executive Order 11582 and previous OPM guidance. We are also proposing the revision of § 610.203(b) to clarify how to determine holidays for employees, as provided by 5 U.S.C. 6103(b) and (d) and Executive Order 11582. In addition, we are proposing to add a note to new § 610.203(c), to clarify that an employee on a compressed work schedule is not entitled to an additional "in-lieu-of" holiday if his or her duty station is closed by an administrative action (if for example, the installation is closed due to inclement weather) on a day that has been designated as his or her alternate legal holiday. We are also proposing to move parts of former §§ 610.405 and 610.406 to § 610.203(d) for ease of administration. New § 610.203(d) clarifies that part-time employees on flexible or compressed work schedules are not entitled to an "in-lieu-of" holiday when the holiday falls on their regularly scheduled nonworkday.

We are also proposing to add new § 610.204 in response to numerous inquiries OPM receives from agencies and employees as to an employee's entitlement to pay for a holiday when the employee has been in a nonpay status before and/or after the holiday. Employees normally are paid on a holiday on which they do not work under the assumption that, but for the holiday, they would have worked and received pay. It is logical to assume that employees who are in a nonpay status on the workdays before and after a holiday would not have worked on the holiday itself. However, it may also be assumed that employees who are in a pay status for a portion of the day before or after the holiday would have been in a pay status on the holiday. Therefore, we are proposing to clarify that if an employee is in a pay status for at least 4 hours on the day before or after the holiday, he or she is entitled to be paid for the holiday.

Administrative Dismissals of Daily, Hourly, and Piecework Employees

We are proposing to revise the definition of *regular employees* in 5 CFR 610.302 to clarify that 5 CFR part 610, subpart C, does not apply to employees who have a scheduled annual rate of pay—for example, employees paid from the General Schedule. We are also proposing to revise § 610.303 to make clear that Federal Wage System employees are not covered by subpart C, consistent with Public Law 92–392.

Flexible and Compressed Work Schedules

Unless otherwise stated, the additions to 5 CFR 610.401 through 610.411 codify current OPM policy and interpretation of law (5 U.S.C. chapter 61, subchapter II) as published in the "Handbook on Alternative Work Schedules." In § 610.402 we are proposing the addition of *alternative work schedule, basic work requirement, compressed work schedule, core hours, flexible hours, flexible work schedule, rate of basic pay,* and *tour of duty*. We are also proposing to add language to § 610.403 to make it clear that there is no authority that would allow an agency to combine elements from flexible and compressed work schedules to create a "hybrid" schedule. In addition, we propose to add § 610.411 to stipulate that overtime hours under a flexible work schedule must be officially ordered in advance.

By law (5 U.S.C. 6124 and 6128) employees on a flexible work schedule are entitled to 8 hours of paid absence on a holiday, while employees on a compressed schedule are entitled to the number of hours of paid absence equal to the number of hours they are scheduled to work. We are proposing to revise current § 610.405, which will be renumbered as § 610.412, to add language to stipulate that full-time employees under a flexible work schedule are entitled to 8 hours of holiday pay and that part-time employees are entitled to holiday pay for the number of hours regularly scheduled for that day, not to exceed 8 hours. In addition, we are proposing to add § 610.413 to clarify that full-time employees on a flexible work schedule who perform work on a holiday are entitled to up to 8 hours of holiday premium pay, their rate of basic pay for nonovertime hours within the basic work requirement, and, if applicable, overtime pay for hours in excess of the basic work requirement that are officially ordered and approved. In addition, this section also explains that part-time employees who perform work on a holiday are entitled to holiday premium pay for hours of work performed during their basic work requirement on a holiday, not to exceed 8 hours. Finally, this section clarifies that part-time employees scheduled to work on a day designated as an "in lieu of" holiday for full-time employees are not entitled to holiday premium pay.

We are proposing the addition of § 610.414 to clarify the treatment of credit hours earned under a flexible work schedule. We propose to make clear that full-time employees may carry forward up to 24 credit hours from one pay period to the next and part-time employees may carry forward a proportional amount. Paragraph (a) incorporates language currently found in § 610.408, which prohibits members of the Senior Executive Service from earning credit hours.

We are proposing to add § 610.421 to clarify that, for full-time employees who are not covered by the Fair Labor Standards Act (FLSA) (FLSA-exempt employees) and have compressed work schedules, overtime hours are those officially ordered and approved in excess of the compressed schedule for the day. For part-time FLSA-exempt employees, overtime hours are those officially ordered and approved but must be in excess of 8 hours in a day or 40 hours in a week. For full-time

employees who are covered by the FLSA (FLSA-non-exempt employees), overtime hours are those in excess of the compressed work schedule that are officially ordered and approved or "suffered or permitted." For part-time FLSA-nonexempt employees, overtime hours are those in excess of the compressed schedule for the day that are officially ordered and approved but must be in excess of 8 hours in a day or 40 hours in a week. Full-time and part-time employees may not be credited with FLSA overtime hours on the basis of periods of duty in excess of 8 hours in a day when the hours are *not* hours of work for purposes of computing overtime pay under 5 CFR 410.402, 5 CFR Parts 550 or 532 and 5 U.S.C. 5544 (*e.g.*, suffered or permitted overtime work). Suffered or permitted overtime work is always credited towards an employee's weekly FLSA overtime standard. The daily overtime standard applies only to hours of work that would be considered overtime hours under title 5, United States Code, for General Schedule or prevailing rate (wage) employees.

Leave and Overtime Hours

We have been asked whether an employee whose tour of duty includes regularly scheduled overtime work may earn or be charged leave during those overtime hours. Leave cannot be earned or charged during overtime hours, except as provided in 5 CFR 630.204 for employees on uncommon tours of duty. We propose to revise §§ 630.202 and 630.205 to clarify that both full-time and part-time employees earn and use leave based on their regularly scheduled administrative workweek, exclusive of overtime hours. In addition, for clarity and consistency, the term "regularly scheduled administrative workweek" and "intermittent work schedule" are defined in § 630.201.

Charging Leave for Part-Time Employees

We have been asked whether part-time employees should be charged leave for additional hours outside their "normal" work schedule if they are unable to work the additional hours. We propose to revise § 630.205 to make clear that a part-time employee earns leave based on the number of nonovertime hours (*i.e.*, hours less than 8 hours in a day and 40 hours in a week) in a pay status, without regard to the number of hours in his or her regularly scheduled workweek. Thus, a part-time employee would be charged leave for any nonovertime hours the employee is unable to work during the regularly scheduled workweek, as long as the employee's work schedule is established in advance of the pay period. However, a part-time employee would not be charged leave for hours not worked that were scheduled in addition to the employee's regularly scheduled administrative workweek after the beginning of the pay period. For example, if a part-time employee who is scheduled to work 62 hours in a pay period is required to work a total of 70 hours, he or she would earn leave based on the 70-hour total. However, if the employee is not able to work more than 62 hours, he or she could not be charged leave for the excess 8 hours because it was not scheduled in advance of the pay period.

A part-time employee who has hours in a pay status that are fewer than the number of hours necessary to accrue 1 hour of leave is entitled to have those hours in a pay status carried forward into the next pay period and credited toward leave accrual. For example, an employee who is entitled to accrue 1 hour of leave for every 13 hours in a pay status and who works 56 hours is credited with 4 hours of leave, and the remaining 4 hours in a pay status must be carried forward. Therefore, we are proposing to add § 630.205(d) to clarify that, for part-time employees, hours in a pay status that are insufficient to accrue 1 hour of leave must be carried forward into the next pay period and credited toward leave accrual.

In addition, we are adding a new § 630.301 to clarify that, for both part-time and full-time employees whose duty station is the United States, the maximum amount of annual leave that may be carried over from one leave year into the next is 240 hours (30 days). This limitation is found in law at 5 U.S.C. 6304(a) and is being restated in regulation for clarification. The maximum amount of annual leave that may be carried over by an employee who transfers from an overseas assignment is prescribed in 630.302(c).

Leave for Employees on Uncommon Tours of Duty

New 5 CFR 630.204 would give agencies the authority to require that employees with uncommon tours of duty accrue and use leave based on that uncommon tour. We propose to revise paragraphs (a) and (b) of § 630.204 to clarify that for employees who accrue and use leave on the basis of an uncommon tour of duty, the ceiling on the amount of annual leave that may be carried over into the next leave year under 5 U.S.C. 6304(a), (b), or (c), or the amount of annual or sick leave that may be advanced under 5 U.S.C. 6302(d) or 6307(d), must be adjusted along with accrual rates and leave balances to reflect the uncommon tour of duty. For example, when an uncommon tour of duty is established for a firefighter with a 144-hour biweekly tour of duty, the annual leave ceiling for that firefighter must be adjusted to 432 hours (144/80 × 240 hours).

In addition, consistent with the "directly proportional rule" applied in § 630.204, the amount of sick leave that may be advanced to an employee with an uncommon tour of duty must be calculated using the ratio of the employee's biweekly hours to an 80-hour pay period. For example, for a firefighter with a biweekly tour of duty of 144 hours, the maximum amount of sick leave that may be advanced is 432 hours (144/80 × 240). The amount of annual leave that may be advanced is equal to the amount of annual leave such firefighters would earn during the remainder of the current leave year.

The proposed revision of § 630.204 also provides that when an employee is converted to a different tour of duty, the employee's leave accrual rates, leave balances, advanced leave, and leave ceiling must be converted simultaneously. Lastly, we propose to revise § 630.905 (currently found at § 630.906(c)) to permit an agency that has employees who earn and use annual leave on the basis of an uncommon tour of duty to establish procedures for administering the transfer of annual leave to or from such employee under both the leave transfer and leave bank programs established under 5 U.S.C. chapter 63, subchapters III and IV.

90-Day Appointment

Agencies have requested clarification from OPM on the annual leave accrual status of an employee who has been appointed for a term limited to less than 90 days. Section 6303(b) of title 5, United States Code, limits the annual leave accrual of employees whose current appointment is limited to less than 90 calendar days. However, employees may accrue annual leave if they receive consecutive appointments, all less than 90 days, that cumulatively total more than 90 calendar days of employment without a break in service. We are proposing to add a new 5 CFR 630.206 to clarify that an employee who receives an initial appointment limited to *less* than 90 days is not eligible to accrue annual leave. However, if the appointment is extended or the employee receives one or more successive appointments without a break in service, the employee becomes eligible to accrue annual leave on the 90th day of employment, and in addition, the employee is entitled to the

annual leave that would have accrued during the initial 90-day period. Employees whose appointments are not limited to less than 90 days are not subject to this provision, nor are employees who are serving in a less-than-90-day appointment to which they transferred, without a break in service, from a leave-earning position. Also, the limits on leave accrual for an employee who has been appointed to a less-than-90-day appointment applies only to annual leave. Such employees earn 4 hours of sick leave in each biweekly pay period of the appointment.

Fractional Pay Periods and Reduction in Leave Credits

We are proposing to revise 5 CFR 630.207 to provide that when an employee's service is interrupted by a *non-leave-earning* period, such as a period of intermittent employment or a period during which an employee receives benefits from the Department of Labor's Office of Workers' Compensation Programs (OWCP), he or she earns leave on a prorated basis for that portion of each pay period during which he or she is eligible to earn leave as long as there is no break in Federal service. An employee who moves back and forth between part-time and intermittent employment has periods when he or she is eligible to earn leave and periods when he or she is not. This change in eligibility to earn leave also occurs when an employee is carried in a leave without pay status while receiving disability compensation (*i.e.*, workers' compensation) and is not eligible to earn leave under the rules governing dual compensation. Agencies must credit a prorated amount of annual and sick leave to employees who become *ineligible* to accrue leave in the middle of a pay period.

However, employees who begin an extended period of leave without pay in the middle of a pay period (*e.g.*, extended leave for military service or under the Family and Medical Leave Act) are entitled to accrue leave in that pay period. By law, employees accrue leave when they are employed for a full biweekly pay period. Proposed § 630.202 states that a full-time employee earns leave during each full biweekly pay period while in a pay status or in a combination of a pay status and a nonpay status. The effect of leave without pay on the accrual of annual and sick leave is addressed in new § 630.208, which requires reduction in leave credits for excess hours in a nonpay status. A full-time employee who is *eligible to earn leave* under § 630.202 may, through the intermittent or extended use of leave without pay, accumulate a number of hours in a nonpay status. When this number equals the number of hours in the pay period, the employee forfeits the leave that would have been earned in that pay period. For example, employee A earns 8 hours of annual leave in each full biweekly pay period. He or she is intermittently on leave without pay during the months of February through the last pay period in September, but has continued during this period to earn 8 hours of annual leave and 4 hours of sick leave each pay period. In the last pay period in September, the employee's leave without pay balance reaches 80 hours (the number of hours in the pay period), and he or she must forfeit the hours of annual and sick leave he or she would have accrued. In effect, the employee earns no leave in the last pay period in September. (Any hours in a nonpay status that are not offset by the forfeiture of annual and sick leave will be carried forward to the next pay period.) The employee continues to earn annual and sick leave at his or her regular rate until the leave without pay total again reaches 80 hours (the number of hours in the pay period). If an employee who earns 6 hours of annual leave in a pay period reaches 80 hours of leave without pay during the last full biweekly pay period of the year (the pay period during which he or she would receive an additional 4 hours), the employee forfeits the full 10 hours.

Employee B is carried on the rolls in a leave without pay status while receiving disability compensation. The rules governing dual compensation state that an employee who is receiving disability compensation is not entitled to earn leave. Since employee B is in a "non-leave earning period," no reduction in leave credits is required. Employee B may earn leave on that portion of a pay period during which he or she is eligible to earn leave under § 630.207.

Employee C is on continuous leave without pay and is actually still earning leave at his or her normal rate. However, the employee is simultaneously forfeiting the leave he or she would have earned each time he or she reaches a number of hours of leave without pay that is equal to twice the number of hours in the regularly scheduled workweek. Since the employee's leave without pay reaches 80 hours of leave without pay each pay period, he or she earns no annual or sick leave.

If, at the end of the leave year, an employee has an accumulation of hours of leave without pay that is less than the number of hours in the pay period, the agency must drop those hours. An employee may have one or more breaks in service in a year, during which he or she is ineligible to accrue leave (*e.g.*, as a result of the employee's intermittent status or receipt of workers' compensation). However, when counting hours of leave without pay, an agency may count only those hours in a nonpay status that occurred during those periods in which the employee was eligible to accrue leave, including fractional pay periods under § 630.207.

Minimum Charge for Leave

Section 630.205 of title 5, Code of Federal Regulations, currently states that the minimum charge to an employee's leave account is 1 hour, unless an agency establishes a minimum charge of less than 1 hour, or establishes a different minimum charge through negotiations. As a result, agencies have established policies that have resulted in leave being charged in a variety of increments ranging from 1 minute to 1 hour. OPM, as the managing partner of e-Payroll consolidation and standardization, is proposing to establish a uniform, Governmentwide policy on the minimum charge to leave. In § 630.209, we are proposing to provide two alternatives for charging leave. Agencies may charge leave in increments of one-tenth of an hour (6 minutes) or one-quarter of an hour (15 minutes). Limiting the charge to leave to just two methods will simplify time and attendance recording and further our goal to standardize payroll processing. In addition, this change will further the work scheduling flexibilities available to agencies and employees. The final issuance of the new rules for charging leave will not invalidate the provisions of any existing collective bargaining agreement (CBA). If the leave provisions of a CBA were proper under the regulations existing at the time they were negotiated, but conflict with the proposed changes, the existing provisions will stand for the duration of the agreement. Upon expiration of the CBA, no provision that conflicts with the new regulations may be renewed.

We are also proposing to modify the regulation concerning the transfer of leave from one agency to another at § 630.501, to standardize and simplify that procedure. New § 630.501 states that when an employee transfers to a position covered by a different leave accounting system, his or her leave must be converted by the gaining agency into the minimum increment that can be accommodated.

Advancing Leave

In response to requests for clarification on the amount of annual leave that may be advanced to an

employee, we are proposing to add 5 CFR 630.210 to provide that an employee (full-time or part-time) may be advanced, at the beginning of the leave year or at-any time thereafter, only the amount of annual leave that he or she is expected to accrue during the *remainder* of the leave year.

A full-time employee may be advanced up to 30 days (240 hours) of sick leave for serious disability or ailment or for purposes related to the adoption of a child. Section 6302(c) of title 5, United States Code, establishes that a part-time employee is entitled to leave benefits under section 6307 (sick leave) on a pro rata basis. Therefore, § 630.210(b) would also provide that the maximum amount of sick leave that may be advanced to a part-time employee or an employee on an uncommon tour of duty is prorated according to the number of hours in the employee's regularly scheduled administrative workweek. For example, since a full-time employee is limited to a maximum of 240 hours (6 weeks × 40 hours = 240) of advanced sick leave, an employee who has a regularly scheduled administrative workweek of 24 hours may be advanced up to 144 hours (6 weeks × 24 hours = 144) of sick leave for serious disability or ailment (including childbirth and its recuperation) or for purposes relating to the adoption of a child.

We have been asked to clarify how an employee may repay advanced leave. We propose to add paragraph (d) to § 630.210 to clarify that an employee may liquidate a debt for advanced leave through the retroactive substitution of paid leave or through a cash payment that equals the amount paid to the employee for the period of advanced leave. In addition, we are proposing to add a definition of advanced leave to § 630.201 to clarify that advance of annual or sick leave is left to the discretion of the employing agency.

Leave for Bone-Marrow and Organ Donation

Section 629 of Public Law 103–329, the Treasury, Postal Service and General Government Appropriations Act for fiscal year 1995, added section 6327 to title 5, United States Code, to provide employees with an entitlement of up to 7 days of paid leave each calendar year (in addition to annual and sick leave) to serve as a bone-marrow or organ donor. The law provides that an employee is entitled to use this leave without loss of or reduction in pay, leave to which otherwise entitled, credit for time or service, or performance or efficiency rating. Public Law 106–56, the "Organ Donor Leave Act," amended section 6327 to increase the amount of paid time off available for Federal employees to serve as organ donors from 7 days to 30 days each calendar year. The amount of leave available for bone-marrow donation remains at 7 days each calendar year under 5 U.S.C. 6327.

We have been asked how these "days" of leave should be charged for a full-time employee who works other than 8-hour days (*e.g.*, an employee on a flexible or compressed work schedule) or for a part-time employee or an employee who has an uncommon tour of duty. We are proposing the addition of 5 CFR 630.215 to make clear that a full-time (80-hour per pay period) employee is entitled to 56 hours (7 days) of leave each calendar year for bone-marrow donation purposes and 240 hours (30 days) of leave each calendar year to serve as an organ donor. These amounts are prorated for part-time employees and employees on uncommon tours of duty. In addition, we have been asked whether bone-marrow or organ donation leave is appropriate for absences related to compatibility testing that does not ultimately result in the employee's actual donation. The legislative history of Public Law 103–329 makes clear that this legislation was enacted in an effort to encourage Federal employees to be tested for and participate in bone-marrow and organ donation programs. It was hoped that giving time off for testing would increase the pool of possible donors and the chances of finding a match for someone in need of a transplant. Therefore, proposed § 630.215 states that the employee is entitled to this leave for compatibility testing purposes even if he or she ultimately does not become a bone-marrow or organ donor.

We are also proposing to add a final paragraph establishing OPM's authority to make future determinations that other medical procedures are sufficiently similar to bone-marrow or organ donation to permit the use of bone-marrow or organ donor leave for those purposes. For example, we believe that peripheral blood stem cell donation is sufficiently similar to bone-marrow donation in the commitment required from an individual in the time needed for testing and actual donation to warrant granting of bone-marrow donor leave. We believe that similar medical procedures may be developed that will allow more Federal employees to become part of the donation process and that it is within the spirit of the legislation creating this program to grant OPM the flexibility to approve the future use of bone-marrow or organ donor leave for such donations.

Restoration of Annual Leave

Section 6304(d), of title 5, United States Code, provides that annual leave in excess of the maximum limitations that is forfeited as a result of exigencies of the public business or sickness of the employee must have been scheduled in advance to be eligible for restoration. Current 5 CFR 630.308(a) provides that such annual leave must have been scheduled in writing before the start of the third biweekly pay period prior to the end of the leave year. In the interest of clarity and simplicity, OPM is proposing to provide that such annual leave may be considered for restoration if the leave is scheduled in writing before November 15 of each leave year. (See new § 630.304(a).) Specifying a single, uniform date greatly simplifies the process for both employees and agencies.

Accrual and Use of Sick Leave

We are proposing to add 5 CFR 630.205 to clarify the accrual rates of sick leave for part-time employees. In addition, we are proposing to modify § 630.401 to remove the requirement that an employee must maintain 80 hours of sick leave in his or her sick leave account in order to use more than 40 hours of his or her sick leave for family care or bereavement purposes. Removing the 80-hour sick leave balance requirement greatly simplifies the administration of this policy and eliminates the need for manual recordkeeping of employee sick leave balances. Employees are responsible for managing their use of sick leave to ensure that they retain enough sick leave for personal needs. An employee would continue to be limited to 13 days of sick leave each leave year for general family care and bereavement purposes and a maximum of 12 weeks of sick leave each leave year to care for a family member with a serious health condition. In addition, removing the 80-hour sick leave balance requirement would permit agencies to advance up to 30 days of sick leave to an employee so that he or she may care for a family member with a "serious disability or ailment."

We are also proposing to modify § 630.403(b) to establish a Governmentwide policy on the time limit for the receipt of medical documentation for an employee's use of sick leave. The proposed regulation states that an employee must provide the written medical certification required by the agency for use of sick leave under § 630.401, signed by the health care provider, no later than 15 calendar days after the date his or her agency requests such medical

certification. This will ensure that all employees are treated equitably and aid in establishing standardized Governmentwide pay and leave policies. We have also defined "healthcare provider" at § 630.201 as well as 630.903 (Voluntary Leave Transfer Program) and 630.1003 (Voluntary Leave Ban Program), using the definition currently used in the Family and Medical Leave regulations at § 630.1204, so that the term is used consistently throughout part 630.

Recredit of Leave

OPM has received inquiries from agencies and employees concerning the transfer of annual and sick leave balances when an employee transfers from a position in the U.S. Postal Service to a position covered by chapter 63 of title 5, United States Code. We propose to add 5 CFR 630.502(b) and 630.503(d) to state that an individual who transfers from the U.S. Postal Service to a position covered by chapter 63 is entitled to have his or her annual and sick leave transferred to the new agency. This is consistent with section 1005(f) of Public Law 91–375, August 12, 1970, which permits the continuation of leave benefits provided in chapter 63 to Postal Service employees unless specifically changed by the U.S. Postal Service.

The maximum amount of annual leave that may be transferred from the U.S. Postal Service to the new agency may not exceed the maximum annual leave limitation allowed for the employee's former position in the U.S. Postal Service. If the amount of annual leave transferred exceeds the maximum annual leave accumulation limitations in 5 U.S.C. 6304(a), (b), or (f), as applicable, the agency must establish a personal leave ceiling for the employee, subject to reduction in the same manner as provided in 5 U.S.C. 6304(c) until the employee's accumulated annual leave is equivalent to or less than the maximum limitation for the new position.

Under 5 U.S.C. 6301, employees of the Congress are not covered by the Federal leave system established under 5 U.S.C. chapter 63. Therefore, leave earned as an employee of the Congress cannot be transferred to a position in an executive agency. We are proposing to add paragraph (c) to § 630.502 and paragraph (e) to § 630.503 to clarify that employees of the House or Senate, or both, may not have annual leave or sick leave transferred to an executive branch agency.

Application To Become a Leave Recipient Under the Leave Transfer/ Leave Bank Programs

Agencies have asked whether they may establish a time limit for accepting an application to become a leave recipient from an employee who was affected by a medical emergency that has since terminated (*e.g.*, for the birth of a child that occurred in a previous year). We are proposing to revise 5 CFR 630.906(a) and 630.1010(b) to clarify that agencies may designate a time period during which employees must submit an application to become a leave recipient under the voluntary leave transfer or leave bank programs if the employee was unable to submit the application before the medical emergency terminated. (Agencies and employees may download forms for donating or requesting annual leave from OPM's Web site at *http://www.opm.gov/FORMS/html/opm.asp.*)

Agencies have also questioned whether they must allow an employee to use transferred annual leave indefinitely when there is a need to fill the employee's position and there is little or no likelihood that the employee will return to work. Agencies have discretion to approve or disapprove an employee's requests to use donated annual leave and the use of donated leave should be treated in the same manner as the use of accrued annual leave. Participation in the leave transfer program was not meant to be a substitute for disability retirement. If there is little likelihood that an employee will be able to return to work, either because of his or her own medical emergency or that of a family member, we do not believe the agency should be obligated to carry the employee in a transferred leave status indefinitely. In addition, a decision by the United States Court of Appeals, Federal Circuit, affirmed an agency's authority to deny the use of donated leave when there is little likelihood that the employee will return to Federal service. (*See F. Paul Jones* v. *Department of Transportation*, 295 F. 3d 1298 (Fed.Cir. 2002).) Therefore, we are proposing to add new §§ 630.914(f) and 630.1012(f) to provide that an agency may choose to establish a maximum period of time, not less than 6 months, during which an employee may remain a qualified leave recipient for any particular medical emergency. When the applicant is approved for leave transfer, the agency is required to notify him or her in writing of the maximum period of time during which he or she may continue to be an approved leave recipient, if the agency has chosen to establish such a time limit.

Definition of a Medical Emergency Under the Leave Transfer/Leave Bank Programs

In response to agency requests for assistance in recognizing what constitutes a medical emergency under the voluntary leave transfer and leave bank programs, we are proposing to clarify the definition of *medical emergency* in 5 CFR 630.903. We are proposing to define a *medical emergency* as a *serious health condition* as that term is defined in § 630.1204 (Family and Medical Leave) that affects an employee or a family member of such employee and is likely to require the employee's absence from duty for a prolonged period of time and to result in a substantial loss of income to the employee because of the unavailability of paid leave. We are also adding the definition of *transferred leave* to § 630.903.

Annual Leave That May Be Donated

We have received questions from agencies on whether employees may donate restored annual leave or annual leave that has been advanced under the voluntary leave transfer and leave bank programs. We are proposing to clarify in new 5 CFR 630.910(a) and 630.1008(a) that an employee may donate his or her accrued annual leave, including annual leave restored under 5 U.S.C. 6304(d) and 5595(b)(1)(B)(i) (back pay), but excluding annual leave advanced to an employee under 5 U.S.C. 6302(d).

An agency also asked whether a Presidential appointee whose annual leave is being held in abeyance under 5 U.S.C. 5551(b) may donate that leave to another employee. We are proposing to add § 630.910(b) to permit an employee to donate the leave held in abeyance as long as the leave was earned under 5 U.S.C. chapter 63. In addition, we are proposing to limit in new § 630.912(c) the amount of annual leave a leave donor who is no longer covered by chapter 63 may donate to no more than one-half the amount of annual leave he or she was entitled to accrue in the last leave year the donor was covered by chapter 63. An agency may waive this limitation in the same manner that current limitations on donated leave may be waived under the voluntary leave transfer and leave bank programs.

Use of Donated Annual Leave

Agencies have questioned whether a leave recipient may use donated annual leave for a purpose other than that for which the leave was donated—*e.g.*, to care for a different family member. We

have also received questions about whether an employee on leave restriction continues to be subject to the conditions of the restriction notice when using donated annual leave.

We have added language to proposed §§ 630.914 and 630.1012 to clarify that donated leave may be used only for the particular medical emergency for which it is donated. In addition, these sections would make it clear that an employee on an official notice of leave restriction continues to be subject to the terms and conditions of the leave restriction notice when requesting and using donated leave.

Accrual of Annual and Sick Leave While Using Donated Leave

Some agency officials have expressed confusion regarding the statutory requirement in 5 U.S.C. 6337 to establish separate "set-aside" accounts for leave recipients using donated leave under the voluntary leave transfer and leave bank programs. Section 6337(b)(1)(A) and (B) provide that the maximum amount of annual or sick leave which may be accrued by an employee while using donated leave "in connection with any particular emergency" may not exceed 5 days (*i.e.*, 40 hours of annual leave and 40 hours of sick leave). Therefore, we propose to revise 5 CFR 630.916 to clarify that "set-aside" leave accrual is limited to 40 hours of annual leave and 40 hours of sick leave for each medical emergency. If a leave recipient gains the use of leave in his or her set-aside accounts, as provided in § 630.917, before he or she reaches the 40-hour limit, the recipient, in the event of receiving more donated leave, continues to accrue leave in the set-aside account until the total amount accrued during the particular medical emergency has reached 40 hours of annual leave and 40 hours of sick leave. Once the employee uses all of the 40 hours of annual leave and 40 hours of sick leave allowable in the set-aside account, the set-aside account is terminated and no more leave may be accrued by the employee while using donated leave for that particular emergency.

In addition, we propose to revise § 630.918 to clarify that when a leave recipient's employing agency advances leave at the beginning of the leave year and 40 hours of that advanced leave are placed in a set-aside account, the employee may accrue leave while using donated leave only to the extent necessary to liquidate the debt incurred by placing that advanced leave in the set-aside account.

The rules concerning set-aside accounts under the leave bank program are identical to those for the leave transfer program, and the maximum accruals allowed under 5 U.S.C. 6337 apply to the total leave accrued under both the leave transfer and leave bank programs. Therefore, we propose to remove the instructions for set-aside accounts under the leave bank program at current § 630.1008. Instead, new § 630.1013 refers the reader to the applicable sections of the leave transfer regulations at §§ 630.915 through 630.919.

Inclusion of "Excepted Agencies" in the Leave Transfer Program

New section 322 of Public Law 107–307 (November 27, 2002) revised 5. U.S.C. 6339 to add a new paragraph (c)(1) which provides that the head of an excepted agency may establish a program under which an individual employed in or under an excepted agency may participate in a leave transfer program. Under the provisions of section 322, a previously excluded agency may now establish a voluntary leave transfer program. The new provisions also provide previously excluded agencies with the authority to establish procedures for administering a leave transfer program, consistent with OPM's regulations governing the administration of the Voluntary Leave Transfer Program.

We have added § 630.922(a) to make it clear that the head of an excepted agency may establish a program under which an individual employed in or under such excepted agency may participate in the leave transfer program under subpart I, including provisions permitting the transfer of annual leave accrued or accumulated by such employee to, or permitting such employee to receive transferred leave from, an employee of any other agency (including another excepted agency). In addition, we have added § 630.922(b) to clarify that an excepted agency's policy may include provisions that protect the anonymity of its employees. Other agencies (including other excepted agencies that choose to participate in the leave transfer program) must accept leave from such an excepted agency, regardless of whether the donating employee is identified.

Records and Reports

We are proposing to delete the reporting requirement at 5 CFR 610.122(c) concerning variations in work schedules for educational purposes. In addition, we are proposing to delete the reporting requirement currently in § 630.211(d). The responsibility to make decisions on excluding certain Presidential appointees from entitlement to annual and sick leave consistent with requirements and criteria in § 630.211 has been delegated to the heads of agencies, and we no longer require reports on these exclusions. The agency must continue to maintain records of exclusions or revocations of exclusions.

We are proposing to remove the reporting requirements in current § 630.408 and to reduce the amount of information that agencies must maintain on the use of sick leave for family care purposes. Agencies would be required to maintain records sufficient to ensure that employees do not exceed their entitlement to sick leave for family care purposes.

We are proposing to delete the reporting requirements currently in §§ 630.913 and 630.1012 on the voluntary leave transfer and leave bank programs. Agencies would be required to maintain sufficient records to permit the transfer of donated leave when a leave recipient transfers to a new agency.

We are also proposing to remove the reporting requirements for family and medical leave currently in § 630.1211. Agencies would be required to maintain sufficient records to ensure that employees do not exceed their entitlement to family and medical leave.

Miscellaneous

We are proposing to revise § 630.101 to affirm OPM's authority to administer Governmentwide leave policies and procedures. We are also proposing to delete § 630.407(b) concerning the holiday premium pay entitlement of an employee on a compressed work schedule. This section was numbered in error and the information is properly found in current § 610.407(b).

We are also proposing to delete § 630.203 which gives instructions for earning leave in other than biweekly pay periods, since we have been assured by the Government's payroll providers that there are no longer any employees to which such procedures would apply. We are proposing to delete the procedures currently in § 630.409 for the retroactive substitution of sick leave for annual leave used for adoption related purposes between September 1991 and September 1994. The time limit for retroactive substitution under this section expired on September 30, 1996, making this information obsolete.

We are also proposing to delete current §§ 630.301(d)(1), (d)(2), and (e) concerning the treatment of members of the Senior Executive Service (SES) in 1994 when SES leave ceilings were first established. Similarly, we are proposing to delete § 630.309, which dealt with the

treatment of Y2K essential personnel during the leave years 1999 and 2000.

We are also proposing to delete subpart M of part 630, the Reservist Leave Bank, since these regulations now are obsolete. These regulations implemented section 331 of Public Law 102–25, the Department of Defense Desert Storm Supplemental Authorization and Military Personnel Benefits Act for Fiscal Year 1991, April 6, 1991. The regulations established a leave bank to provide time off for Federal civilian employees returning from active military duty in Operation Desert Storm and Operation Desert Shield in 1991. OPM collected annual leave donations and divided the total amount contributed among all eligible returnees in 1991.

In addition, we are proposing to delete the prohibitions against coercion in the voluntary leave transfer and leave bank programs currently in §§ 630.912 and 630.1011, since these sections are restatements of the law at 5 U.S.C. 6338 and 6370. Similarly, we propose to delete paragraphs (c) and (d) currently in § 630.1208 concerning employee protections under the Family and Medical Leave Act, since these also are restatements of the law at 5 U.S.C. 6384(c). Finally, we propose to revise the procedures in current § 630.1108 for recrediting unused annual leave donated to the donors under the emergency leave transfer program. New § 630.1120 would eliminate the requirement to return unused leave to the donors if the number of hours of unused leave is less than the number of eligible donors. This provision would simplify the administration of the emergency leave transfer program and make its administration consistent with the procedures for the voluntary leave transfer program at § 630.921.

E.O. 12866, Regulatory Review

This rule has been reviewed by the Office of Management and Budget in accordance with E.O. 12866.

Regulatory Flexibility Act

I certify that these regulations would not have a significant economic impact on a substantial number of small entities because they would apply only to Federal agencies and employees.

List of Subjects in 5 CFR Parts 353, 530, 531, 550, 551, 575, 610, and 630

Administrative practice and procedure, Claims, Government employees, Holidays, Law enforcement officers, Reporting and recordkeeping requirements, Wages.

U.S. Office of Personnel Management.

Kay Coles James,

Director.

Accordingly, OPM is proposing to amend 5 CFR parts 353, 530, 531, 550, 575, 610, and 630 to read as follows:

PART 353—RESTORATION TO DUTY FROM UNIFORMED SERVICE OR COMPENSABLE INJURY

1. The authority citation for part 353 continues to read as follows:

Authority: 38 U.S.C. 4301 *et seq.*, and 5 U.S.C. 8151.

Subpart B—Uniformed Service

2. Section 353.208 is revised to read as follows:

§ 353.208 Use of paid leave during uniformed service.

An employee performing service with the uniformed services must be permitted, upon request, to use any accrued annual leave or military leave during such service.

PART 530—PAY RATES AND SYSTEMS (GENERAL)

3. The authority citation for part 530 continues to read as follows:

Authority: 5 U.S.C. 5305 and 5307; E.O. 12748, 56 FR 4521, 3 CFR, 1991 Comp., p. 316; Subpart B also issued under secs. 302(c) and 404(c) of the Federal Employees Pay Comparability Act of 1990 (Pub. L. 101–509), 104 Stat. 1462 and 1466, respectively; Subpart C also issued under sec. 4 of the Performance Management and Recognition System Termination Act of 1993 (Pub. L. 103–89), 107 Stat. 981.

Subpart C—Special Salary Rate Schedules for Recruitment and Retention

4. In § 530.303, paragraph (i) is revised to read as follows:

§ 530.303 Establishing and adjusting special salary rate schedules.

* * * * *

(i) The determination as to whether an employee is covered by a special salary rate schedule must be based on the employee's position of record and the official duty station for that position as those terms are defined in 5 CFR 531.602.

PART 531—PAY UNDER THE GENERAL SCHEDULE

5. The authority citation for part 531 continues to read as follows:

Authority: 5 U.S.C. 5115, 5307, and 5338; sec. 4 of Pub. L. 103–89, 107 Stat. 981; and E.O. 12748, 56 FR 4521, 3 CFR, 1991 Comp., p. 316.

Subpart B also issued under 5 U.S.C. 5303(g), 5333, 5334(a), and 7701(b)(2);

Subpart C also issued under 5 U.S.C. 5304, 5305, and 5553; sections 302 and 404 of the Federal Employees Pay Comparability Act (FEPCA), Pub. L. 101–509, 104 Stat. 1462 and 1466; and section 3(7) of Pub. L. 102–378, 106 Stat. 1356;

Subpart D also issued under 5 U.S.C. 5335(g) and 7701(b)(2);

Subpart E also issued under 5 U.S.C. 5336;

Subpart F also issued under 5 U.S.C. 5304, 5305(g)(1), and 5553; and E.O. 12883, 58 FR 63281, 3 CFR, 1993 Comp., p. 682; and E.O. 13106, 63 FR 68151; 3 CFR 1998 Comp., p. 224;

Subpart G also issued under 5 U.S.C. 5304, 5305, and 5553; section 302 of FEPCA, Pub. L. 101–509, 104 Stat. 1462; and E.O. 12786, 56 FR 67453, 3 CFR, 1991 Comp., p. 376.

Subpart C—Special Pay Adjustments for Law Enforcement Officers

6. In § 531.301 the definition of *position of record* is added in alphabetical order, and the definition of *official duty station* is revised to read as follows:

§ 531.301 Definitions.

* * * * *

Official duty station means the duty station for the law enforcement officer's position of record where the officer performs his or her duties as determined by the requirements in § 531.605.

Position of record has the same meaning given that term in § 531.602.

* * * * *

Subpart F—Locality-Based Comparability Payments

7. In § 531.602 the definition of *official duty station* is revised, and the definitions of *position of record, telework,* and *telework arrangement* are added in alphabetical order to read as follows:

§ 531.602 Definitions.

In this subpart:

* * * * *

Official duty station means the location of the employee's position of record where he or she performs more of his or her duties as determined by the requirements in § 531.605.

Position of record means an employee's official position (defined by employing agency, grade, occupational series, and position duties) as documented on the employee's most recent notification of personnel action and the current position description. This excludes any position to which an employee is temporarily detailed without a change in the official position. For an employee whose change in his or her official position is followed within 3 workdays by a reduction in force

resulting in the employee's separation before he or she is required to report for duty in the new position, the position of record in effect immediately before the position change is deemed to remain the position of record through the date of separation.

* * * * *

Telework means work performed by an employee at an alternative work site instead of the location of the employee's assigned organization. Alternative work sites may include the employee's home, telecenter, satellite office, field installation or other location.

Telework arrangement means a formal oral or written agreement between a supervisor and employee to permit an employee to work at an alternative work site (*i.e.*, telework) instead of the location of the employee's assigned organization.

§§ 531.605, 531.606, 531.607 [Redesignated]

8. Sections 531.605, 531.606, and 531.607 are redesignated as §§ 531.606, 531.607, and 531.608, respectively, and a new § 531.605 is added to read as follows:

§ 531.605 Determining an employee's official duty station.

(a) Except as otherwise provided in this section, the official duty station is the location of the employee's position of record where the employee regularly performs his or her duties or, if his or her work involves regular travel, where his or her work activities are based, as determined by the employing agency. An agency must document an employee's official duty station on an employee's notification of personnel action (Standard Form 50 or equivalent).

(b) For an employee who is relocated and authorized to receive relocation expenses under 5 U.S.C. chapter 57, subchapter II (or similar authority), the official duty station is the established work site in the area to which the employee has been relocated. This includes employees authorized to receive relocation expenses under 5 U.S.C. 5737 in connection with an extended assignment resulting in a temporary change of station, in which case the duty station associated with the extended assignment is the official duty station. (See 41 CFR part 302–1.1.)

(c) For an employee whose assignment to a new duty station is followed within 3 workdays by a reduction in force resulting in the employee's separation before he or she is required to report for duty at the new location, the official duty station in effect immediately before the assignment remains the official duty station through the date of separation.

(d) For an employee who is under a telework agreement, the official duty station must be the location of the employee's telework site unless the employee is scheduled (while in duty status) to report at least once a week to the regular work site for the employee's position of record, in which case the regular work site is the official duty station. Agencies may make temporary exceptions to this requirement in appropriate situations, such as when an employee is recovering from an injury or medical condition that prevents the employee from commuting to the regular work site. Agencies must determine a telework employee's official duty station on a case-by-case basis.

PART 550—PAY ADMINISTRATION (GENERAL)

Subpart A—Premium Pay

9. The authority citation for subpart A continues to read as follows:

Authority: 5 U.S.C. 5304 note, 5305 note, 5541(2)(iv), 5545a(h)(2)(B) and (i), 5547(b) and (c), 5548, and 6101(c); sections 407 and 2316, Pub. L. 105–277, 112 Stat. 2681–101 and 2681–828 (5 U.S.C. 5545a); E.O. 12748, 3 CFR, 1992 Comp., p. 316.

10. In § 550.114, paragraph (d) is revised, paragraph (e) is redesignated as paragraph (f) and a new paragraph (e) is added to read as follows:

§ 550.114 Compensatory time off.

* * * * *

(d) Except as provided in paragraph (e)(2) of this section, an employee must use accrued compensatory time off to which he is entitled under paragraph (a) or (b) of this section by the end of the 26th pay period after the pay period during which it was credited. Compensatory time off to an employee's credit as of [insert effective date of final regulations] must be used by the end of the 26th pay period following [insert effective date of final regulations]. The head of an agency, at his or her sole and exclusive discretion, may provide that an employee who fails to take compensatory time off to which he is entitled within 26 pay periods after the pay period during which it was credited must—

(1) Receive payment for such unused compensatory time off at the dollar value prescribed in paragraph (f) of this section; or

(2) Forfeit the unused compensatory time off, unless the failure to take the compensatory time off is due to an exigency of the service beyond the employee's control, in which case the agency head must provide payment for the unused compensatory time off at the dollar value prescribed in paragraph (f) of this section.

(e)(1) Except as provided in paragraph (e)(2) of this section, an employee with unused compensatory time off under paragraph (a) or (b) of this section who transfers to another agency or separates from Federal service before the expiration of the time limit established under paragraph (d) of this section may receive overtime pay or forfeit the unused compensatory time off, consistent with the employing agency's policy established under paragraph (d) of this section.

(2) If an employee with unused compensatory time off under paragraph (a) or (b) of this section separates from Federal service or is placed in a leave without pay status under the following circumstances, the employee must be paid for unused compensatory time off at the dollar value prescribed in paragraph (f) of this section:

(i) The employee separates or is placed in a leave without pay status to perform service in the uniformed services (as defined in 38 U.S.C. 4303 and 5 CFR 353.102); or

(ii) The employee separates or is placed in a leave without pay status because of an on-the-job injury with entitlement to injury compensation under 5 U.S.C. chapter 81.

* * * * *

Subpart J—Compensatory Time Off for Religious Observances

11. Subpart J is revised to read as follows:

Authority: 5 U.S.C. 5550a.

Subpart J—Compensatory Time Off for Religious Observances

§ 550.1001 Purpose.

This subpart contains OPM regulations implementing 5 U.S.C. 5550a, which allows employees to earn and use compensatory time off to modify work schedules to satisfy religious obligations to abstain from work. When an employee has personal

religious beliefs that require him or her to abstain from work during the employee's scheduled tour of duty established for leave purposes, the employee may be granted time off to meet those religious requirements. The employee earns this time off by performing an equal amount of compensatory overtime work at another time.

§ 550.1002 Definitions.

In this subpart:

Agency means an Executive agency as defined in 5 U.S.C. 105.

Employee means an employee who satisfies the definition of that term in 5 U.S.C. 2105.

Rate of basic pay means the rate of pay fixed by law or administrative action for the position held by the employee, including the following types of pay, as applicable, but not including any other additional pay of any kind:

(1) A locality payment under 5 U.S.C. 5304 or similar geographic-based payment under another authority (provided that the similar payment is creditable as part of basic pay for retirement purposes);

(2) A special pay adjustment for law enforcement officers under section 404 of the Federal Employees Pay Comparability Act of 1990 (Public Law 101–509); and

(3) A continued rate adjustment under 5 CFR part 531, subpart G.

Scheduled tour of duty for leave purposes means an employee's regular hours for which he or she may be charged leave under 5 CFR part 630 when absent. For full-time employees, it is the 40-hour basic workweek as defined in 5 CFR 610.102. For employees with an uncommon tour of duty as defined in 5 CFR 630.201, it is the uncommon tour of duty.

§ 550.1003 Agency requirements.

An agency must grant an employee's request to take time off to meet religious requirements to abstain from work and to work compensatory overtime unless granting the request would interfere with the efficient accomplishment of the agency's mission. An agency may require an employee requesting time off under these provisions to submit written requests for an adjusted schedule in advance and to provide acceptable written documentation of the employee's religious requirement to abstain from work.

§ 550.1004 Time limits.

(a) The employee may perform compensatory overtime work before or after using the compensatory time off for religious observances, subject to agency approval. The agency must take into account its mission requirements and operational efficiencies in determining when to schedule compensatory overtime work.

(b) When an agency grants advanced compensatory time off for religious observances to an employee, the agency must require that the employee perform the required amount of compensatory overtime work within 3 pay periods. If the employee fails to perform compensatory overtime work within 3 pay periods, the agency must charge the employee annual leave to eliminate the negative balance, even if this results in a negative annual leave balance.

§ 550.1005 Limits on the amount of earned compensatory time off an employee may accumulate.

An agency may allow an employee to accumulate only the number of hours of earned compensatory time off (based on the performance of compensatory overtime work) needed to make up for previous approved absences or anticipated absences for specific religious observances.

§ 550.1006 Crediting and recording of compensatory time off.

The agency must credit an employee with compensatory time off for performing compensatory overtime work on an hour-for-hour basis. The agency may authorize credit in increments of one-tenth of an hour (6 minutes) or one-quarter of an hour (15 minutes). The agency must keep appropriate records of the compensatory time off each employee earns and uses.

§ 550.1007 Premium pay and compensatory overtime work.

The overtime hours worked to earn compensatory time off under this subpart do not create any entitlement to premium pay (including overtime pay) under 5 CFR part 550, subpart A, or overtime pay under 5 CFR part 551. Earned compensatory time off for religious observances is not considered in applying the premium pay limitations described in 5 CFR 550.105, 550.106, and 550.107.

§ 550.1008 Transfer or separation of an employee with a positive or negative balance of compensatory time off for religious observances.

(a) If an employee separates from Federal service or transfers to another agency, the losing agency must compensate the employee for any positive amount of earned compensatory time off to his or her credit. The agency must pay the employee for hours of earned compensatory time off for religious observances at the hourly rate of basic pay in effect when the extra hours of work were performed.

(b) If an employee separates from Federal service or transfers to another agency and owes the losing agency for used compensatory time off that was advanced and not yet repaid through compensatory overtime work, the losing agency must reduce the employee's annual leave balance by the amount of the negative balance of hours to the extent possible. If the negative balance cannot be eliminated by adjusting the employee's annual leave balance, the employee owes a monetary debt to the agency for any remaining hours of advanced compensatory time off. The hours must be valued using the hourly rate of basic pay in effect at the time the hours of religious compensatory time off were used.

(c) For purposes of applying paragraphs (a) and (b) of this section, an hourly rate of basic pay is computed by dividing the annual rate of basic pay by 2087 hours (or 2756 hours for firefighter hours subject to that divisor under subpart F of this part).

Subpart L—Lump-Sum Payment for Accumulated and Accrued Annual Leave

12. The authority citation for subpart L continues to read as follows:

Authority: 5 U.S.C. 5553, 6306, and 6311.

13. In § 550.1205, revise paragraph (b)(5)(i) to read as follows:

§ 550.1205 Calculating a lump-sum payment.

* * * * *

(b) * * *

(5) * * *

(i) Night differential under 5 U.S.C. 5343(f) at the applicable percentage rate received by a prevailing rate employee for all regularly scheduled periods of night shift duty covered by the unused annual leave as if the employee had continued to work beyond the effective date of separation, death, or transfer. In the case of an employee who is assigned to a regular rotating schedule involving work on both day and night shifts, the night differential is payable for that portion of the lump-sum period that would have occurred when the employee was scheduled to work night shifts.

* * * * *

PART 551—PAY ADMINISTRATION UNDER THE FAIR LABOR STANDARDS ACT

14. The authority citation for part 551 continues to read as follows:

Authority: 5 U.S.C. 5542(c); Sec. 4(f) of the Fair Labor Standards Act of 1938, as amended by Pub. L. 93–259, 88 Stat. 55 (29 U.S.C. 204f).

Subpart E—Overtime Pay Provisions

15. In § 551.531, paragraph (d) is revised, paragraph (e) is redesignated as paragraph (f) and a new paragraph (e) is added to read as follows:

§ 551.531 Compensatory time off.

* * * * *

(d) If compensatory time off earned under paragraph (a) or (b) of this section is not taken within 26 pay periods or if the employee separates before using the compensatory time, the employee must be paid for overtime work at the dollar value prescribed in paragraph (f) of this section. Compensatory time off to an employee's credit as of [insert effective date of final regulations] must be used by the end of the 26th pay period following [insert effective date of final regulations].

(e) If an employee with unused compensatory time off under paragraph (a) or (b) of this section is placed in a leave without pay status under the following circumstances, the employee must be paid for overtime work at the overtime rate at the dollar value prescribed in paragraph (f) of this section:

(1) The employee is placed in a leave without pay status to perform service in the uniformed services (as defined in 38 U.S.C. 4303 and 5 CFR 353.102); or

(2) The employee is placed in a leave without pay status because of an on-the-job injury with entitlement to injury compensation under 5 U.S.C. chapter 81.

* * * * *

PART 575—RECRUITMENT AND RELOCATION BONUSES; RETENTION ALLOWANCES; SUPERVISORY DIFFERENTIALS

16. The authority citation for part 575 continues to read as follows:

Authority: 5 U.S.C. 1104(a)(2), 5753, 5754, and 5755; secs. 302 and 404 of the Federal Employees Pay Comparability Act of 1990 (FEPCA) (Pub. L. 101–509), 104 Stat. 1462 and 1466, respectively; E.O. 12748, 3 CFR, 1992 Comp., p. 316.

Subpart A—Recruitment Bonuses

17. In § 575.103, the definition of *rate of basic pay* is revised to read as follows:

§ 575.103 Definitions.

* * * * *

Rate of basic pay means the rate of pay fixed by law or administrative action for the position to which the employee is or will be newly appointed before deductions and exclusive of additional pay of any kind, such as locality-based comparability payments under 5 U.S.C. 5304, special pay adjustments for law enforcement officers under section 404 of the Federal Employees Pay Comparability Act of 1990 (Pub. L. 101–509), night shift differentials under 5 U.S.C. 5343(f), or environmental differentials under 5 U.S.C. 5343(c)(4).

* * * * *

Subpart B—Relocation Bonuses

18. In § 575.203, the definition of *rate of basic pay* is revised to read as follows:

§ 575.203 Definitions.

* * * * *

Rate of basic pay means the rate of pay fixed by law or administrative action for the position to which the employee is being relocated or, in the case of an employee who is entitled to grade or pay retention, the employee's retained rate of pay, before deductions and exclusive of additional pay of any kind, such as locality-based comparability payments under 5 U.S.C. 5304, special pay adjustments for law enforcement officers under section 404 of the Federal Employees Pay Comparability Act of 1990 (Pub. L. 101–509), night shift differentials under 5 U.S.C. 5343(f), or environmental differentials under 5 U.S.C. 5343(c)(4).

* * * * *

Subpart C—Retention Allowances

19. In § 575.303, the definition of *rate of basic pay* is revised to read as follows:

§ 575.303 Definitions.

* * * * *

Rate of basic pay means the rate of pay fixed by law or administrative action for the position held by the employee or, in the case of an employee who is entitled to grade or pay retention, the employee's retained rate of pay, before deductions and exclusive of additional pay of any kind, such as locality-based comparability payments under 5 U.S.C. 5304, special pay adjustments for law enforcement officers under section 404 of the Federal Employees Pay Comparability Act of 1990 (Pub. L. 101–509), night shift differentials under 5 U.S.C. 5343(f), or environmental differentials under 5 U.S.C. 5343(c)(4).

20. Part 610 is revised to read as follows:

PART 610—HOURS OF WORK

Subpart A—Weekly and Daily Scheduling of Work

Subpart B—Holidays

Subpart C—Administrative Dismissal of Daily, Hourly, and Piecework Employees

Subpart D—Flexible and Compressed Work Schedules

Subpart A—Weekly and Daily Scheduling of Work

Authority: 5 U.S.C. 6101; sec. 1(1) of E.O. 11228, 3 CFR, 1964–1965 Comp., p. 317.

§ 610.101 Coverage.

Notwithstanding subpart D of this part, implementing flexible work schedules and compressed work schedules established under 5 U.S.C. chapter 61, subchapter II, the regulations on the weekly and daily scheduling of work in this subpart apply to—

(a) Each employee to whom 5 CFR part 550, subpart A, applies; and

(b) Each employee whose pay is fixed and adjusted from time to time under 5 U.S.C. 5343 or 5349 or by a wage board or similar administrative authority serving the same purpose.

§ 610.102 Definitions.

In this subpart:

Administrative workweek means any period of 7 consecutive 24-hour periods designated in advance by the head of the agency under 5 U.S.C. 6101.

Agency means an executive agency as defined in 5 U.S.C. 105. For the purposes of this subpart, a military department as defined in 5 U.S.C. 102 is treated as a separate agency.

Authorized agency official means the head of an agency or an official who is authorized to act for the head of the agency in the matter concerned.

Basic workweek, for full-time employees, means the 40-hour workweek established under § 610.111.

Employee means an employee of an agency to whom this subpart applies, as described in § 610.101.

Regularly scheduled administrative workweek, for a full-time employee, means the period within an administrative workweek, established under § 610.111, within which the employee is regularly scheduled to work. For a part-time employee, this term means the officially prescribed days and hours within an administrative workweek during which the employee is regularly scheduled to work.

Regularly scheduled work means work that is scheduled in advance of an administrative workweek under an agency's procedures for establishing workweeks in accordance with § 610.111.

Tour of duty means the hours of a day (a daily tour of duty) and the days of an administrative workweek (a weekly tour of duty) that constitute an employee's regularly scheduled administrative workweek.

Unpaid meal period means an approved period of time in a nonpay and nonwork status that interrupts a daily tour of duty or a period of overtime work for the purpose of permitting employees to eat or engage in permitted personal activities.

Workweeks

§ 610.111 Establishing workweeks.

(a)(1) For each full-time employee, an authorized agency official must establish the following by a written agency policy statement:

(i) A basic workweek of 40 hours which does not extend over more than 6 of any 7 consecutive days. The written agency policy statement must specify the days and hours within the adminisurative workweek that constitute the basic workweek, except as provided in paragraphs (b), (c), and (d) of this section.

(ii) A regularly scheduled administrative workweek that consists of the 40-hour basic workweek established under paragraph (a)(1) of this section, plus the period of regularly scheduled overtime work, if any, required of each employee. The written agency policy statement, for leave and premium pay administration purposes, must specify by days and hours of each day the periods included in the regularly scheduled administrative workweek that do not constitute a part of the basic workweek, except as provided in paragraphs (b), (c), and (d) of this section.

(2) The basic workweek and regularly scheduled administrative workweek established under paragraph (a)(1) of this section must be used for premium pay and leave administration purposes, as appropriate.

(b) When it is impracticable to prescribe a regular schedule of definite hours of work for each workday of a regularly scheduled administrative workweek, an authorized agency official may establish the first 40 hours of work performed within a period of not more than 6 days of the administrative workweek as the basic workweek. A first 40-hour tour of duty is the basic workweek without the requirement for specific days and hours within the administrative workweek. All work performed by an employee within the first 40 hours is considered regularly scheduled work for premium pay and leave administration purposes. Any additional hours of officially ordered or approved work within the administrative workweek are overtime hours.

(c) (1) When an employee receives annual premium pay for regularly scheduled standby duty under 5 U.S.C. 5545(c)(1), his or her regularly scheduled administrative workweek is the total number of regularly scheduled hours of duty a week, including on-duty sleep and meal periods. (See 5 CFR 550.112(m)(2) and 551.432(e).)

(2) When an employee has a tour of duty which includes a period during which he or she remains at or within the confines of his or her station in a standby status rather than performing actual work, his or her regularly scheduled administrative workweek is the total number of regularly scheduled hours of duty each week. This includes time in a standby status, but does not include time that is allowed for sleep and meal periods by a written agency policy statement, subject to the requirements of 5 CFR 550.112(k) and (m), 551.411(c), 551.431, and 551.432.

(3) When an employee is a firefighter compensated under 5 U.S.C. 5545b, the agency must establish a regular tour of duty instead of a basic workweek and a regularly scheduled administrative workweek, consistent with the requirements of 5 CFR part 550, subpart M.

(d) When an authorized agency official establishes a flexible or compressed work schedule under 5 U.S.C. 6122 or 6127, he or she must establish a basic work requirement for each employee as defined in 5 U.S.C. 6121 and subpart D of this part. A flexible or compressed work schedule is a scheduled tour of duty, and all work performed by an employee within the basic work requirement is considered regularly scheduled work for premium pay and leave administration purposes.

(e) The basic workweeks established under this section are not affected by a holiday. Employees are entitled to paid holidays as provided in subpart B of this part.

Work Schedules

§ 610.121 Establishing work schedules.

(a) Except when an authorized agency official determines that the agency would be seriously handicapped in carrying out its functions or that costs would be substantially increased, he or she must provide that—

(1) Assignments to tours of duty are scheduled in advance of the administrative workweek over periods of not less than 1 week;

(2) The 40-hour basic workweek is scheduled on 5 days, Monday through Friday when possible, and the 2 days outside the basic workweek are consecutive;

(3) The working hours in each day of the basic workweek are the same;

(4) The basic nonovertime workday may not exceed 8 hours;

(5) The occurrence of holidays may not affect the designation of the basic workweek; and

(6) Breaks in working hours of more than 1 hour may not be scheduled in a basic workday.

(b) An authorized agency official must schedule the work of his or her employees to accomplish the mission of the agency. An authorized agency official must schedule an employee's regularly scheduled administrative workweek so that it corresponds with his or her actual work requirements.

(c) When an authorized agency official knows in advance of an

administrative workweek that the specific days and/or hours of a day actually required of an employee in that administrative workweek will differ from those required in the current administrative workweek, he or she must reschedule the employee's regularly scheduled administrative workweek to correspond with those specific days and hours. An authorized agency official must inform the employee of the change and must record the change on the agency's official document for recording work schedules.

(d) If it is determined that an authorized agency official should have scheduled a period of work as part of the employee's regularly scheduled administrative workweek and failed to do so in accordance with paragraphs (b) and (c) of this section, the employee is entitled to the payment of premium pay for that period of work as regularly scheduled work under 5 CFR part 550, subpart A. In this regard, it must be determined that the authorized agency official—

(1) Had knowledge of the specific days and hours of the work requirement in advance of the administrative workweek; and

(2) Had the opportunity to determine which employee had to be scheduled, or rescheduled, to meet the specific days and hours of that work requirement.

(e) To the extent that the requirements of this section are inconsistent with the provisions for flexible and compressed work schedules in 5 U.S.C. chapter 61, subchapter II, and subpart D of this part, the requirements of this section do not apply to employees on such flexible or compressed work schedules.

§ 610.122 Variation for educational purposes.

(a) Notwithstanding § 610.121, an authorized agency official may authorize a special tour of duty of not less than 40 hours to permit an employee to take one or more courses in a college, university, or other educational institution when he or she determines that—

(1) The courses the employee takes are not training under 5 U.S.C. chapter 41;

(2) The rearrangement of the employee's tour of duty will not appreciably interfere with the accomplishment of the work required to be performed;

(3) Additional costs for personal services will not be incurred; and

(4) Completion of the courses will equip the employee for more effective work in the agency.

(b) An agency may not pay an employee any premium pay solely because the special tour of duty authorized under this section causes the employee to work on a day, or at a time during the day, for which premium pay otherwise would be payable.

§ 610.123 Travel outside duty hours.

(a) An employee may earn overtime pay or earn compensatory time off for travel outside his or her regularly scheduled administrative workweek only under the limited conditions prescribed in 5 CFR 550.112(g)(2) for all employees, whether exempt or non-exempt from coverage by the Fair Labor Standards Act, and in 5 CFR 551.422 for employees who are covered by the Fair Labor Standards Act. Insofar as practicable, an authorized agency official should not require an employee to travel during nonduty hours. When it is essential that an employee travel during nonduty hours under circumstances that do not permit payment of overtime pay under 5 CFR 550.112(e), the supervisor or other approving official must record his or her reasons for ordering travel at those hours and must, upon request, furnish a copy of this statement to the employee concerned.

(b) An agency must not adjust the regular working hours that normally apply to an employee solely for the purpose of including time spent traveling that would not otherwise be considered hours of work under 5 CFR 550.112 or 5 CFR 551.422.

§ 610.124 Unpaid meal periods.

An authorized agency official may schedule employees for an unpaid meal period during the basic workday in accordance with § 610.121(a)(6). An unpaid meal period may not be counted as hours of work. If an agency schedules an unpaid meal period, an employee may not choose to work through that meal period to shorten his or her workday or to earn overtime pay.

Subpart B—Holidays

Authority: 5 U.S.C. 6101; sec. 1(1) of E.O. 11228, 3 CFR, 1964–1965 Comp., p. 317.

§ 610.201 Definitions.

In this subpart:

Administrative workweek means any period of 7 consecutive 24-hour periods designated in advance by the head of the agency under 5 U.S.C. 6101.

Agency means an executive agency as defined in 5 U.S.C. 105. For the purposes of this subpart, a military department as defined in 5 U.S.C. 102 is treated as a separate agency.

Authorized agency official means the head of an executive agency or an official who is authorized to act for the head of the executive agency in the matter concerned.

Basic workday means the hours within an employee's basic workweek that occur during one of the 24-hour periods comprising the employee's administrative workweek. For employees on flexible or compressed work schedules as described in subpart D of this part, this term also means the daily basic work requirement.

Basic workweek, for full-time employees, means the 40-hour workweek established in accordance with § 610.111. For employees on flexible or compressed work schedules, as described in subpart D of this part, this term also means the basic work requirement.

Employee means an employee of an agency who satisfies the definition of that term in 5 U.S.C. 2105.

Rate of basic pay means the rate of pay fixed by law or administrative action for the position held by the employee, including the following types of pay, as applicable, but not including additional pay of any other kind:

(1) A locality payment under 5 U.S.C. 5304 or similar geographic-based payment under another authority (provided that the similar payment is treated as part of basic pay for computing retirement contributions and benefits);

(2) A special pay adjustment for law enforcement officers under section 404 of the Federal Employees Pay Comparability Act of 1990 (Public Law 101–509); and

(3) A continued rate adjustment under 5 CFR part 531, subpart G.

The United States means—

(1) A State of the United States;

(2) The District of Columbia;

(3) Puerto Rico;

(4) The U.S. Virgin Islands;

(5) Outer Continental Shelf Lands, as defined in the Outer Continental Shelf Lands Act (67 Stat. 462);

(6) American Samoa;

(7) Guam;

(8) Midway Atoll;

(9) Wake Island;

(10) Johnston Island; and

(11) Palmyra.

Workday means hours of the day that constitute an employee's daily tour of duty. For purposes of this subpart, a *workday* includes a day on which employees may be excused from duty by statute, Executive order, or administrative action.

§ 610.202 Entitlement to paid holidays.

(a) Employees are entitled to paid holidays under the conditions set forth in this subpart. Agencies must determine the legal holidays on which

employees may be excused from duty with pay consistent with the requirements of 5 U.S.C. 6103, Executive Order 11582 of February 11, 1971, and § 610.203.

(b) Employees are excused from duty with pay on a holiday as follows:

(1) Full-time employees are excused for 8 hours.

(2) Part-time employees are excused for the number of nonovertime hours in the employee's daily tour of duty on the holiday (not to exceed 8 hours).

(3) Notwithstanding paragraphs (b)(1) and (2) of this section, employees on compressed work schedules are excused for the number of hours in the employee's daily basic work requirement on the holiday, consistent with § 610.422.

(4) If an employee on a flexible work schedule has a daily basic work requirement in excess of 8 hours on a holiday, the agency must charge the employee leave for any excess hours, allow the employee to use credit hours or compensatory time off, or arrange for the employee to meet the work requirement on another day.

(c) An agency must compute the basic pay for a holiday on which an employee is excused from duty by multiplying the appropriate number of hours as provided in paragraph (b) of this section by the employee's hourly rate of basic pay.

(d) If any part of an employee's basic workday falls on a holiday, the entire basic workday must be treated as if it fell on the holiday. However, if an employee has two basic workdays that overlap a single holiday, the employee is entitled to a paid holiday only with respect to the basic workday commencing on the legal holiday.

(e) An employee is not entitled to pay when not working on a holiday if the employee is barred from receiving premium pay for working on a holiday under 5 U.S.C. 5546(b) based on receipt of standby duty premium pay under 5 U.S.C. 5545(c)(1) or compensation under 5 U.S.C. 5545b (dealing with firefighters).

Note to § 610.202: The President may excuse specified employees from duty on a given day by Executive order and require that the day be considered as falling within the scope of Executive Order 11582 of February 11, 1971, and of 5 U.S.C. 5546 and 6103(b) and other similar statutes insofar as they relate to the pay and leave of affected employees.

§ 610.203 How to determine a holiday.

(a) An employee's holiday is the day designated by 5 U.S.C. 6103(a) whenever that day is part of the employee's basic workweek or basic work requirement, except as provided in paragraph (e) of this section.

(b) When a holiday falls on a nonworkday outside an employee's basic workweek, an agency must determine the day to be treated as his or her holiday (*i.e.*, "in-lieu-of" holiday) in accordance with 5 U.S.C. 6103(b) and Executive Order 11582 as follows:

(1) For employees whose basic workweek is Monday through Friday—

(i) If a holiday falls on a Saturday, the Friday immediately before is the legal holiday.

(ii) If a holiday falls on a Sunday, the following Monday is the legal holiday.

(2) For employees whose basic workweek is other than Monday through Friday, but does not include Sunday—

(i) If a holiday falls on one of the employee's regular nonworkdays other than a Sunday, the employee's workday immediately before that regular nonworkday is the legal holiday.

(ii) If a designated holiday falls on a Sunday, the employee's next workday is the legal holiday.

(3) For employees whose basic workweek includes Sunday, the agency must designate one of the employee's nonworkdays to be the employee's deemed Sunday and determine the holiday as follows:

(i) If a holiday falls on one of the employee's regular nonworkdays other than the deemed Sunday, the employee's workday immediately before that regular nonworkday is the legal holiday.

(ii) If a holiday falls on the deemed Sunday, the employee's next workday is the legal holiday.

(c) As authorized by 5 U.S.C. 6103(d), an agency may prescribe rules under which an employee (as defined in 5 U.S.C. 6121) under a compressed work schedule (as established under subpart D of this part) may be required to observe a holiday on another workday other than would otherwise be required by paragraph (b) of this section, provided that—

(1) The actual holiday falls on a regularly scheduled nonworkday;

(2) An authorized agency official has determined that selection of an alternative legal holiday (as compared to the legal holiday that would be designated under paragraph (b) of this section) is necessary to prevent an adverse agency impact, as defined in 5 U.S.C. 6131(b); and

(3) The alternative legal holiday is in the same biweekly pay period as the date of the actual holiday designated under 5 U.S.C. 6103(a) or in the biweekly pay period immediately preceding *or* following that pay period.

Note to § 610.203(c): In the event that the designated alternate legal holiday for an employee on a compressed work schedule occurs on a workday on which his or her duty station is closed by administrative action, that workday continues to be the alternate legal holiday.

(d) Part-time employees, including part-time employees on flexible or compressed work schedules, are not entitled to an "in-lieu-of" holiday, as provided in paragraph (b) of this section, when a holiday falls on the employee's regularly scheduled nonworkday.

(e) The holiday for employees under a first 40-hour tour of duty, as described in § 610.111(b), is determined as provided in section 4 of E.O. 11582.

(f) The provisions of 5 U.S.C. 6103(b)(3) on determining holidays for certain employees at duty posts outside the United States apply to covered employees who are working outside the United States at a permanent or temporary station or under travel orders.

§ 610.204 Employee in nonpay status immediately preceding or following a holiday.

An employee who is in a nonpay status on his or her entire workday immediately preceding *and* following a holiday is not entitled to receive pay for that holiday. A full-time employee who is in a pay status for at least 4 hours during any part of his or her workday immediately preceding *or* following a holiday is entitled to receive pay for that holiday. For a part-time employee or an employee on an uncommon tour of duty, the required number of hours in a pay status on the day immediately preceding or following the holiday must be prorated, based upon the number of hours the employee was scheduled to work on that day in relation to an 8-hour day.

Subpart C—Administrative Dismissal of Daily, Hourly, and Piecework Employees

Authority: 5 U.S.C. 6104; E.O. 10552, 3 CFR, 1954–1958 Comp., p. 201.

§ 610.301 Purpose.

This subpart contains OPM regulations implementing 5 U.S.C. 6104, which authorizes agencies to grant administrative dismissals for certain daily, hourly, and piece-work employees.

§ 610.302 Definitions.

In this subpart:

Administrative order means an order issued by an authorized official of an agency relieving regular employees from

an authorized duty without charge to leave or loss of pay.

Regular employees means employees paid at daily, hourly, or piecework rates who have a regular tour of duty and whose appointments are not limited to 90 days or less or who have been currently employed for a continuous period of 90 days under one or more appointments without a break in service. Regular employees do not include employees who have a scheduled annual rate of pay (*e.g.*, employees under the General Schedule).

§ 610.303 Coverage.

This subpart applies to regular employees of the Federal Government paid at daily, hourly, or piecework rates. This subpart does not apply to—

(a) Federal Wage System employees as described in section 610.101(b); or

(b) Experts and consultants appointed under 5 U.S.C. 3109.

§ 610.304 Use of administrative dismissal.

(a) An agency may grant administrative dismissal for employees paid at daily, hourly, or piece work rates only to the extent warranted by good administration and only for short periods of time not generally exceeding 3 consecutive workdays in a single period of excused absence. An agency may not use this authority in situations of extensive duration or for periods of interrupted or suspended operations that ordinarily would be covered by the scheduling of leave, furlough, or the assignment of other work. Insofar as practicable, each administrative order issued under this subpart must provide benefits for regular employees paid at daily, hourly, or piecework rates similar to those provided for employees who have a scheduled annual rate of pay.

(b) A Federal agency may issue an administrative order under this subpart when—

(1) Normal operations of an establishment are interrupted by events beyond the control of management or employees;

(2) For managerial reasons, the closing of an establishment or portions thereof is required for short periods;

(3) It is in the public interest to relieve employees from work to participate in civil activities which the Government is interested in encouraging; or

(4) The circumstances are such that an administrative order under paragraph (b)(1), (b)(2), or (b)(3) of this section is not appropriate and the agency under its regulations excuses, or is authorized to excuse, without charge to leave or loss of pay, employees paid a scheduled annual rate of pay.

§ 610.305 Supplemental agency regulations.

Agencies may issue supplemental regulations for their regular employees consistent with this subpart.

Subpart D—Flexible and Compressed Work Schedules

Authority: 5 U.S.C. 5548, 5 U.S.C. 6124, and 5 U.S.C. 6133(a).

General Provisions

§ 610.401 Purpose.

Notwithstanding 5 U.S.C. 6101 and subpart A of this part, this subpart implements certain provisions of 5 U.S.C., chapter 61, subchapter II, which authorizes the use of alternative work schedules. These regulations supplement that subchapter and must be read together with those provisions of law.

§ 610.402 Definitions.

Agency means an executive agency as defined in 5 U.S.C. 105, the Government Printing Office, and the Library of Congress. For the purpose of this subpart, a military department as defined in 5 U.S.C. 102 is treated as a separate agency.

Alternative work schedule means a flexible work schedule or a compressed work schedule.

Basic work requirement means the number of hours, excluding overtime hours, an employee is required to work or to account for by charging leave (including leave without pay), credit hours, excused absence, holiday hours, compensatory time off, or time off as an award.

Compressed work schedule means, for a full time-employee, an 80-hour biweekly basic work requirement that is scheduled by an agency for less than 10 workdays. For a part-time employee, a compressed work schedule means a biweekly basic work requirement of less than 80 hours which is scheduled by an agency for less than 10 workdays and which may require the employee to work more than 8 hours in a day. A compressed work schedule is a schedule that is *fixed by the agency—i.e.*, a schedule with arrival and departure times that are fixed by the agency and days fixed by the agency that comprise the basic work requirement.

Core hours means the time periods during the workday, workweek, or pay period that are within the tour of duty during which an employee covered by a flexible work schedule is required by the agency to be present for work or to be in an approved leave status or other paid time off status.

Credit hours means those hours within a flexible work schedule which an employee elects to work, with supervisory approval, in excess of his or her basic work requirement so as to vary the length of a workweek or workday. An employee covered by a compressed work schedule may not earn credit hours.

Employee has the meaning given that term in 5 U.S.C. 6121.

Flexible hours means the time during the workday, workweek, or pay period within the tour of duty during which an employee covered by a flexible work schedule may choose to vary his or her times of arrival to and departure from the worksite consistent with the duties and requirements of the position.

Flexible work schedule means, for a full-time employee, a work schedule that has an 80-hour biweekly basic work requirement that allows an employee to determine his or her own schedule within the limits set by the agency. For a part-time employee, a flexible work schedule means a biweekly basic work requirement of less than 80 hours that allows an employee to determine his or her own schedule within limits set by the agency.

Rate of basic pay means the rate of pay fixed by law or administrative action for the position held by an employee, including the following types of pay, as applicable, but not including additional pay of any other kind:

(1) A locality payment under 5 U.S.C. 5304 or similar geographic-based payment under another authority (provided that the similar payment is treated as part of basic pay for the purpose of computing retirement contributions and benefits);

(2) A special pay adjustment for law enforcement officers under section 404 of the Federal Employees Pay Comparability Act of 1990 (Public Law 101–509); and

(3) A continued rate adjustment under 5 CFR part 531, subpart G.

Tour of duty under a flexible work schedule means the limits set by an agency within which an employee must complete his or her basic work requirement. Under a compressed work schedule or other fixed work schedule, *tour of duty* is synonymous with an employee's basic work requirement.

§ 610.403 Covered work schedules.

This subpart applies only to flexible work schedules (including maxiflex schedules) and compressed work schedules established under 5 U.S.C. chapter 61, subchapter II. Agencies may not combine provisions from the flexible work schedule and compressed work schedule authorities in subchapter

II in an effort to create a hybrid alternative work schedule program—for example, a compressed schedule in which the employee has the flexibility to change his or her hours or a flexible schedule that permits more than 8 hours of paid absence on a holiday.

§ 610.404 Time-accounting method.

An agency that authorizes a flexible work schedule or a compressed work schedule under this subpart must establish a time-accounting method that will provide affirmative evidence that each employee subject to the schedule has worked the proper number of hours in a biweekly pay period.

Flexible Work Schedules

§ 610.411 Overtime hours for employees on flexible work schedules.

For an employee on a flexible work schedule, overtime hours are all hours of work in excess of 8 hours in a day or 40 hours in a week that are officially ordered and approved in advance by management. An employee on a flexible work schedule who is covered by the Fair Labor Standards Act may not earn overtime compensation as a result of "suffered or permitted" work as defined in 5 CFR 551.104.

§ 610.412 Pay for a holiday for employees on flexible work schedules.

A full-time employee on a flexible work schedule who is relieved or prevented from working on a day within his or her scheduled tour of duty that is designated as a holiday by Federal statute or Executive order is entitled to basic pay with respect to that holiday for 8 hours. A part-time employee on a flexible work schedule is entitled to basic pay with respect to the holiday for the number of hours the employee is scheduled to work on that day, not to exceed 8 hours.

§ 610.413 Holiday premium pay for employees on flexible work schedules.

(a) A full-time employee on a flexible work schedule who performs nonovertime work on a holiday that is ordered and approved is entitled to his or her rate of basic pay plus premium pay equal to his or her rate of basic pay for up to 8 hours of holiday work. For work in excess of 8 hours that is ordered and approved, a full-time employee is entitled to overtime compensation under the applicable provisions of law.

(b) A part-time employee on a flexible work schedule is entitled to his or her rate of basic pay plus premium pay equal to his or her rate of basic pay for up to 8 hours of work that is ordered and approved performed during his or her basic work requirement on a holiday. For work in excess of 8 hours that is ordered and approved, a part-time employee is entitled to overtime compensation under the applicable provisions of law. However, a part-time employee scheduled to work on a day designated as an "in-lieu-of" holiday for full-time employees under § 610.203(b) is not entitled to holiday premium pay for working on the "in-lieu-of" holiday.

(c) An employee on a flexible work schedule is not entitled to holiday premium pay while engaged in training, except as provided in 5 CFR 410.402.

§ 610.414 Credit hours.

(a) An agency may permit a full-time or a part-time employee on a flexible work schedule to earn credit hours by performing work in excess of the employee's biweekly basic work requirement. An employee uses credit hours by being excused from duty during the employee's basic work requirement, as approved by the employee's supervisor or other authorized official. Members of the Senior Executive Service and employees on compressed work schedules may not earn credit hours.

(b) A full-time employee may carry forward up to 24 credit hours from one pay period to the next. A part-time employee may carry forward from one pay period to the next a number of credit hours that represents up to one-fourth of his or her biweekly basic work requirement.

(c) An employee may not use credit hours before they are earned. Agencies may permit employees to use credit hours in the same biweekly pay period within which they are earned.

(d) An agency may establish a timeframe within which accumulated credit hours must be used. If an employee does not use his or her accumulated credit hours within the established timeframe, he or she is entitled to be paid for each credit hour at his or her hourly rate of basic pay in effect at the time of payment. Members of the Senior Executive Service may not receive compensation in lieu of unused credit hours accumulated prior to their appointment in the Senior Executive Service; however, they may use such credit hours subject to approval by their supervisor or other authorized official.

(e) When an employee is no longer covered by a flexible work schedule, he or she must be paid for accumulated credit hours at his or her rate of basic pay in effect at the time of payment, up to a maximum of 24 unused credit hours for full-time employees and one-fourth of the biweekly basic work requirement for part-time employees.

(f) An employee may not receive overtime, Sunday, or holiday premium pay or night pay under 5 U.S.C. 5545(a) when he or she earns or uses credit hours.

Compressed Work Schedules

§ 610.421 Overtime hours for employees on compressed work schedules.

(a) For a full-time employee on a compressed work schedule who is exempt from the Fair Labor Standards Act (FLSA), overtime hours are those hours in excess of the compressed work schedule that are officially ordered and approved. For a part-time employee on a compressed work schedule who is exempt from the FLSA, overtime hours are those hours in excess of the compressed work schedule for the day or week that are officially ordered and approved, but must be in excess of 8 hours in a day or 40 hours in a week.

(b) For a full-time employee on a compressed work schedule who is covered by the FLSA, overtime hours are those hours in excess of the compressed work schedule that are officially ordered and approved or are "suffered or permitted." For a part-time employee on a compressed work schedule who is covered by the FLSA, overtime hours are those hours in excess of the compressed work schedule for the day or week that are officially ordered and approved or are "suffered or permitted," but must be in excess of 8 hours in a day or 40 hours in a week. Full-time and part-time employees may not be credited with FLSA overtime hours on the basis of periods of duty in excess of 8 hours in a day when the hours are *not* hours of work for purposes of computing overtime pay under 5 CFR 410.402, 5 CFR Parts 550 or 532 and 5 U.S.C. 5544 (*e.g.*, suffered or permitted overtime work). Suffered or permitted overtime work is always credited towards an employee's weekly FLSA overtime standard. The daily overtime standard applies only to hours of work that would be considered overtime hours under title 5, United States Code, for General Schedule or prevailing rate (wage) employees.

§ 610.422 Pay for a holiday for employees on compressed work schedules.

A full-time or part-time employee on a compressed work schedule who is relieved or prevented from working on a day within his or her scheduled tour of duty that is designated as a holiday by Federal statute or Executive order is entitled to basic pay with respect to that holiday for the number of hours of his or her compressed work schedule on that day.

§ 610.423 Holiday premium pay for employees on compressed work schedules.

(a) An employee on a compressed schedule who performs work on a holiday is entitled to his or her rate of basic pay, plus premium pay at a rate equal to his or her rate of basic pay, for the work that is not in excess of the employee's compressed work schedule for that day. For hours worked on a holiday in excess of the compressed work schedule, a full-time employee is entitled to overtime compensation under applicable provisions of law.

(b) A part-time employee on a compressed work schedule who performs work on a holiday is entitled to his or her rate of basic pay plus premium pay equal to his or her rate of basic pay for work that is not in excess of the employee's compressed work schedule for that day. However, a part-time employee scheduled to work on a day designated as an "in-lieu-of" holiday for full-time employees under § 610.203(b) is not entitled to premium pay for working on the "in-lieu-of" holiday.

(c) An employee on a compressed work schedule is not entitled to holiday premium pay while engaged in training, except as provided in 5 CFR 410.402.

21. Part 630 is revised to read as follows:

PART 630—ABSENCE AND LEAVE

Authority: 5 U.S.C. 6311; Sec. 630.205 also issued under 5 U.S.C. 6133(a); Sec. 630.303 also issued under Pub. L. 103–356, 108 Stat. 3410; Secs. 630.305 and 630.307 also issued under 5 U.S.C. 6304(d)(3), Pub. L. 102–484, 106 Stat. 2722, and Pub. L. 103–337, 108 Stat. 2663; subpart D also issued under Pub. L. 103–329, 108 Stat. 2423; Sec. 630.501, 630.502, and subpart F also issued under E.O. 11228, 30 FR 7739, 3 CFR, 1974 Comp., p. 163; subpart G also issued under 5 U.S.C. 6305; subpart H also issued under 5 U.S.C. 6326; subpart I also issued under 5 U.S.C. 6332, Pub. L. 100–566, 102 Stat. 2834, and Pub. L. 103–103, 107 Stat. 1022; subpart J also issued under 5 U.S.C. 6362, Pub. L. 100–566 and Pub. L. 103–103; subpart K also issued under Pub. L. 105–18, 111 Stat. 158; and subpart L also issued under 5 U.S.C. 6387 and Pub. L. 103–3, 107 Stat. 23.

Subpart A—General Provisions

§ 630.101 Responsibility for administration.

The head of each agency having employees subject to this part is responsible for the proper administration of this part so far as it pertains to employees under his or her jurisdiction and for maintaining an account of leave for each employee in accordance with policies and procedures prescribed by OPM.

Subpart B—General Provisions for Annual and Sick Leave

§ 630.201 Definitions.

(a) In 5 U.S.C. 6301(2)(iii), the term *temporary employee engaged in construction work at an hourly rate* means an employee hired on a temporary basis solely for the purpose of work on a specific construction project and paid an hourly rate.

(b) In subparts B through G of this part:

Accrued leave means leave earned by an employee during the current leave year which remains unused at any given time during that year.

Accumulated leave means unused leave remaining to the credit of an employee at the beginning of a leave year.

Advanced leave means annual or sick leave an agency may choose to advance to an employee in advance of the date the leave is accrued (earned).

Authorized agency official means the head of an executive agency or an official who is authorized to act for the head of the executive agency in the matter concerned.

Employee means an employee to whom 5 U.S.C. chapter 63, subchapter I, applies.

Family member means the following relatives of the employee:

(1) Spouse, and parents thereof;

(2) Children, including adopted children and spouses thereof;

(3) Parents;

(4) Brothers and sisters, and spouses thereof; and

(5) Any individual related by blood or affinity whose close association with the employee is the equivalent of a family relationship.

Health care provider has the meaning given that term in § 630.1204.

Intermittent work schedule means employment without a regularly scheduled tour of duty during each administrative workweek.

Leave year means the period beginning with the first day of the first full pay period in a calendar year and ending with the day immediately before the first day of the first full pay period in the following calendar year.

Medical certificate means a written statement signed by a healthcare provider certifying to the incapacitation, examination, or treatment or to the period of disability while the patient was receiving professional treatment.

Regularly scheduled administrative workweek has the meaning given that term in 5 CFR 610.102.

Serious health condition has the meaning given that term in § 630.1204.

Uncommon tour of duty means an established tour of duty that exceeds 80 hours of work in a biweekly pay period, provided the tour—

(1) Includes hours for which the employee is compensated by standby duty pay under 5 U.S.C. 5545(c)(1) and 5 CFR 550.141;

(2) Is a regular tour of duty (as defined in 5 CFR 550.1302) established for firefighters compensated under 5 U.S.C. 5545b and 5 CFR part 550, subpart M; or

(3) Is authorized for a category of employees by OPM.

United States means the several States and the District of Columbia.

§ 630.202 Earning leave in a full biweekly pay period.

A full-time employee earns leave during each full biweekly pay period during which the employee is in a pay status or in a combination of a pay status and a nonpay status, except as provided in § 630.207. A full-time employee earns and uses leave based on the hours in his or her regularly scheduled administrative workweek (excluding overtime hours as defined in 5 CFR 550.111(a)), except as provided in §§ 630.204, 630.915, and 630.1013. Employees who enter Federal service after the beginning of a biweekly pay period or before the end of a biweekly pay period do not earn leave during that pay period unless they complete their full biweekly work requirement for that pay period.

§ 630.203 [Reserved]

§ 630.204 Leave accrual for employees on uncommon tours of duty.

(a) An agency may require that a Federal employee on an uncommon tour of duty accrue and use leave on the basis of that uncommon tour of duty. The employee's leave accrual rates must be directly proportional (based on the number of hours in the biweekly tour of duty and the accrual rate of the corresponding leave category) to the standard leave accrual rates for employees who accrue and use leave on the basis of an 80-hour biweekly tour of duty. The agency must charge 1 hour (or appropriate fraction thereof) of leave for each hour (or appropriate fraction thereof) of absence from the uncommon tour of duty.

(b) When an employee is converted to a different tour of duty for leave purposes, his or her leave balances must be converted to the proper number of hours based on the proportion of hours in the new tour of duty compared to a standard 80-hour tour of duty.

(c) An agency must establish an uncommon tour of duty for each firefighter compensated under 5 CFR part 550, subpart M. The uncommon tour of duty must correspond directly to the firefighter's regular tour of duty, as defined in 5 CFR 550.1302, so that each firefighter accrues and uses leave on the basis of that regular tour of duty.

§ 630.205 Leave accrual for part-time employees.

(a) A part-time employee for whom an agency has established in advance of a biweekly pay period a regular tour of duty on 1 or more days during each administrative workweek, or a part-time employee on a flexible work schedule for whom an agency has established only a biweekly work requirement, earns leave under 5 U.S.C. 6303 and 6307 based on the total number of hours in a pay status in each biweekly pay period, excluding overtime hours as defined in 5 CFR 550.111(a), except as provided in §§ 630.204, 630.915, and 630.1013.

(b) A part-time employee earns annual leave as follows:

(1) A part-time employee with fewer than 3 years of service earns 1 hour of annual leave for each 20 hours in a pay status.

(2) A part-time employee with at least 3 but fewer than 15 years of service earns 1 hour of annual leave for each 13 hours in a pay status.

(3) A part-time employee with 15 or more years of service earns 1 hour of annual leave for each 10 hours in a pay status.

(c) A part-time employee earns 1 hour of sick leave for each 20 hours in a pay status.

(d) When a part-time employee has hours in a pay status that are fewer than the number necessary to accrue 1 hour of leave, the agency must carry forward those hours into the next pay period and credit them toward the employee's leave accrual.

(1) When a part-time employee moves to a full-time position, he or she loses any unapplied hours not previously used towards a leave accrual.

(2) When a part-time employee moves to or from a part-time position from or to an intermittent position, he or she may carry the unapplied hours.

(e) A part-time employee may be charged leave only for the hours not worked that were scheduled in advance of his or her regularly scheduled administrative workweek. A part-time employee may not be charged leave for hours not worked that were scheduled in addition to the employee's regularly scheduled administrative workweek after the beginning of the pay period.

§ 630.206 Appointments limited to fewer than 90 calendar days.

An employee whose appointment is limited to fewer than 90 calendar days is not entitled to accrue annual leave but is entitled to accrue sick leave under 5 U.S.C. 6307. If the appointment is extended or the employee receives one or more successive appointments without a break in service that extend the period of employment to 90 calendar days or more, the employee is entitled to accrue annual leave, and the agency must, on the 90th day, credit the employee with the annual leave that would have accrued to him or her under 5 U.S.C. 6303(a) during the 90-day period. Employees who transfer without a break in service from a leave-earning position to a less-than-90-day appointment are not subject to this provision.

§ 630.207 Earning leave in a fractional pay period.

An employee is ineligible to earn leave when he or she is receiving benefits from the Office of Workers' Compensation Programs (OWCP) under 20 U.S.C. chapter I or subject to an intermittent work schedule. When an employee's service is interrupted by such an event, he or she earns leave only for that portion of each pay period during which he or she is eligible to earn leave (*i.e.*, not receiving OWCP benefits or moving from an intermittent work schedule to a full-time or part-time work schedule.) This section does not apply to employees who enter Federal service after the beginning of a pay period or who separate from Federal service before the end of a pay period.

§ 630.208 Effect of nonpay status on earning leave.

(a) If an employee is in an extended nonpay status (*e.g.*, leave without pay), he or she continues to earn annual and sick leave until the number of hours in the nonpay status equals the number of hours in a pay period. An employee does not earn any annual or sick leave during a pay period (including the last pay period in the year when he or she might normally earn 10 hours of annual leave) in which he or she reaches the cumulative number of hours in a nonpay status that is equal to the number of hours in a pay period (80 hours for most full-time employees). The agency must carry forward and apply to the next pay period any hours in a nonpay status in excess of the number of hours in a pay period. The employee earns leave in the next and succeeding pay periods until he or she again accumulates the number of hours in a nonpay status that is equal to the number of hours in a pay period. At the end of the leave year, the agency must drop any remaining time in a nonpay status that does not require a reduction in leave earnings.

(b) If an employee is in a nonpay status for the entire leave year, he or she does not earn leave.

(c) When a reduction in leave earnings results in a negative leave balance in an employee's annual leave account at the end of a leave year, the agency must—

(1) Carry the negative balance forward as a charge against the annual leave the employee will earn in the next leave year; or

(2) Require the employee to refund the amount paid him or her for the

period covering the excess leave that resulted in the debit.

(d) A period covered by a refund for unearned advanced leave is deemed not a period of nonpay status under this section.

§ 630.209 Minimum charge for leave.

(a) An agency may charge leave in increments of one-tenth of an hour (6 minutes) or one-quarter of an hour (15 minutes). Additional charges to leave must be made in multiples thereof.

(b) When an employee is charged leave for an unauthorized absence or tardiness, the agency may not require him or her to perform work for any part of the leave period charged against the employee's account.

§ 630.210 Advanced annual and sick leave.

(a) At the beginning of the leave year or at any time thereafter, an agency may advance the amount of annual leave an employee is expected to accrue during the remainder of that leave year.

(b) An agency may advance a maximum of 30 days of sick leave to a full-time employee at the beginning of a leave year or at any time thereafter when required by the exigencies of the situation for a serious disability or ailment of the employee or a family member or for purposes relating to the adoption of a child. Thirty days is the maximum amount of advanced sick leave that an employee may have to his or her credit at any one time. For a part-time employee (or an employee on an uncommon tour of duty), the maximum amount of sick leave an agency may advance must be prorated according to the number of hours in the employee's regularly scheduled administrative workweek.

(c) When an employee is serving under a time-limited appointment or one that will terminate on a specified date, an agency may advance sick leave to him or her up to the total amount of sick leave the employee would otherwise earn during the term of his or her appointment, not to exceed the 30-day maximum in 630.210(b). For the purposes of this paragraph, an employee serving a probationary or trial period is not serving under a limited appointment.

(d) An employee may liquidate a debt for advanced leave in the following ways:

(1) Through the retroactive substitution of accumulated annual leave;

(2) Through the retroactive substitution of donated annual leave;

(3) Through the application of annual leave as it is accrued;

(4) Through the application of sick leave as it is accrued if the debt is for advanced sick leave; or

(5) Through a cash payment equal to the amount paid to the employee for the period covered by the advanced leave.

(e) When an employee separates from Federal service under circumstances other than those listed in paragraphs (g)(1) through (3) of this section with an indebtedness for advanced leave, the agency must—

(1) Require the employee to refund the amount paid him or her for the period covering the leave for which the employee is indebted; or

(2) Deduct that amount from any pay due the employee.

(f) An employee who enters active military service with a right of restoration is deemed not separated for the purpose of paragraph (e) of this section.

(g) An employee is not required to pay back advanced leave when he or she—

(1) Dies;

(2) Retires for disability; or

(3) Resigns or is separated because of a disability that prevents him or her from returning to duty or continuing in the service, and which is the basis of the separation, as determined by the agency on medical evidence acceptable to the agency.

§ 630.211 Excusing employees from work for less than 1 hour.

If an employee is unavoidably or necessarily tardy or absent for less than 1 hour, an authorized agency official may excuse him or her without charge to leave or loss of pay if there is adequate reason for the absence.

§ 630.212 Travel time for employees whose post of duty is outside the U.S.

Under 5 U.S.C. 6303(d), the travel time granted to a Federal employee whose post of duty is outside the United States includes the time necessary to travel to and from the post of duty and the United States or to and from the employee's place of residence if the place of residence is outside the employee's area of employment and in the Commonwealth of Puerto Rico or the territories or possessions of the United States. The employee must designate his or her place of residence in any request for leave under 5 U.S.C. 6303(d).

§ 630.213 Exclusion of Presidential appointees.

(a) *Authority.* (1) Section 6301(2)(B)(xi) of title 5, United States Code, authorizes the President to exclude certain Presidential appointees in the executive branch or the government of the District of Columbia from the annual and sick leave provisions of 5 U.S.C. chapter 63, subchapter I, and from the related provisions of this part.

(2) The President, by Executive Order 10540, as amended, has delegated to OPM the responsibility for making exclusions under 5 U.S.C. 6301(2)(B)(xi), and OPM has delegated this responsibility to the head of each agency, consistent with the provisions of this section.

(3) Presidential appointees in positions where the rate of basic pay is equal to or exceeds the rate for level V of the Executive Schedule are already excluded from the annual and sick leave provisions by 5 U.S.C. 6301(2)(B)(x). Therefore, no further action by an agency is necessary to exclude these appointees.

(b) *Criteria for exclusions.* The head of an agency may exclude an officer in the agency from the annual and sick leave provisions only if the officer meets all of the following criteria:

(1) The officer is a Presidential appointee;

(2) The officer is not a United States attorney or United States marshal; and

(3) The officer's responsibilities for carrying out the duties of the position continue outside normal duty hours and while away from the normal duty post.

(c) *Revocation of exclusion.* An authorized agency official may revoke an exclusion from the annual and sick leave provisions which was made under this section.

(d) *Records.* The agency must maintain records of any exclusion, or revocation of an exclusion, authorized under this section.

(e) *Continuation of previous authorizations.* Any officer in an agency who was excluded by action of the President or the Civil Service Commission prior to February 15, 1979, from the annual and sick leave provisions under the authority of 5 U.S.C. 6301(2)(B)(xi) must continue to be excluded from annual and sick leave unless the exclusion is revoked by the agency under the provisions of this section.

§ 630.214 Use of annual leave to establish initial eligibility for retirement or continuation of health benefits.

(a) An employee may elect to use annual leave and remain on the agency's rolls in order to establish initial eligibility for immediate retirement under 5 U.S.C. 8336, 8412, or 8414, and/or to establish initial eligibility under 5 U.S.C. 8905 to continue health benefits coverage into retirement, as provided in:

(1) 5 CFR 351.606(b)(1) for an employee who otherwise would have

been separated by reduction-in-force procedures under 5 CFR part 351; or

(2) 5 CFR 351.606(b)(2) for an employee who otherwise would have been separated by adverse action procedures under 5 CFR part 752 because of the employee's decision to decline relocation (including transfer of function).

(b)(1) Annual leave that may be used for the purposes described in paragraph (a) of this section includes all accumulated, accrued, and restored annual leave to the employee's credit prior to the effective date of the reduction in force or relocation (including transfer of function) and annual leave earned by an employee while in a paid leave status after the effective date of the reduction in force or relocation (including transfer of function).

(2) Annual leave that is advanced to an employee under 5 U.S.C. 6302(d), including any advanced annual leave that may be credited to an employee's leave account after the effective date of the reduction in force or relocation (including transfer of function), may not be used for purposes of this section.

(3) For purposes of this section, an authorized agency official may approve the use of any or all annual leave donated to an employee under subpart I of this part (Voluntary Leave Transfer Program), or made available to the employee under subpart J of this part (Voluntary Leave Bank Program), as of the effective date of the reduction in force or relocation.

§ 630.215 Leave for bone-marrow and organ donation.

(a) A full-time employee is entitled to up to 7 days (56 hours) of leave in a leave year to serve as a bone-marrow donor. The amount of bone-marrow donation leave available to a part-time employee or an employee on an uncommon tour of duty must be prorated according to the number of regularly scheduled hours in his or her biweekly pay period. Leave for bone-marrow donation may be used for compatibility testing as well as actual donation and recuperation.

(b) A full-time employee is entitled to up to 30 days (240 hours) of leave in a leave year to serve as an organ donor. The amount of organ donation leave available to a part-time employee or an employee on an uncommon tour of duty must be prorated according to the number of regularly scheduled hours in his or her biweekly pay period. Leave for organ donation may be used for compatibility testing as well as actual donation and recuperation.

(c) OPM may make a determination that other donation procedures are sufficiently similar to bone-marrow donation or organ donation to warrant the granting of bone-marrow or organ donor leave.

Subpart C—Annual Leave

§ 630.301 Maximum annual leave limitation for employees stationed in the U.S.

A full-time or part-time employee whose official duty station is in the United States may accumulate annual leave for use in succeeding years until it totals not more than 30 days (240 hours) at the beginning of the first full biweekly pay period in a leave year, except as provided in § 630.204.

§ 630.302 Maximum annual leave limitation for employees stationed outside the U.S.

(a) A full-time or part-time employee whose official duty station is outside the United States may accumulate annual leave for use in succeeding years until it totals not more than 45 days (360 hours) at the beginning of the first full biweekly pay period in a leave year, except as provided in § 630.204.

(b) The effective date on which an otherwise eligible employee becomes subject to the 45-day maximum annual leave limitation is—

(1) The date of the employee's entry on duty when he or she is employed locally;

(2) The date of the employee's arrival at a post of regular assignment for duty; or

(3) The date on which he or she begins to perform that duty in an area outside the United States, if the employee is required to perform that duty en route to his or her post of regular assignment and is outside the area of recruitment or the area from which he or she was transferred.

(c) Subject to 5 U.S.C. 6304(c), the maximum amount of annual leave an employee may carry forward into the next leave year when he or she is transferred or reassigned to a position in which he or she is no longer subject to section 6304(b) of that title is determined as follows:

(1) When, on the date prescribed by paragraph (d) of this section, the amount of an employee's accumulated and accrued annual leave is 30 days or less, he or she may carry forward up to 30 days as prescribed by 5 U.S.C. 6304(a).

(2) When, on the date prescribed by paragraph (d) of this section, the amount of an employee's accumulated and accrued annual leave is more than 30 days but not more than 45 days, he or she may carry forward the full amount thereof that is unused at the end of the current leave year, not to exceed 45 days.

(3) When, on the date prescribed by paragraph (d) of this section, the amount of an employee's accumulated and accrued annual leave is more than 45 days, he or she may carry forward the amount of unused annual leave to the employee's credit at the end of the current leave year that does not exceed—

(i) Forty-five days, if he or she is not entitled to a greater accumulation under 5 U.S.C. 6304(c); or

(ii) The amount he or she is entitled to accumulate under section 5 U.S.C. 6304(c), if that amount is greater than 45 days.

(d) For the purposes of paragraph (c) of this section, an agency must determine the amount of an employee's accumulated and accrued annual leave at the end of the pay period that includes:

(1) The date on which the employee departs from his or her post of regular assignment for transfer or reassignment;

(2) The date on which an employee ceases to perform duty, when he or she is required to perform that duty en route to an area in which he or she would be subject to 5 U.S.C. 6304(b) if assigned there; or

(3) The date on which final administrative approval is given to effect a change in an employee's duty station when he or she is on detail or on leave in the United States or in the Commonwealth of Puerto Rico or a territory or possession of the United States if that is the area from which he or she was recruited or transferred.

§ 630.303 Maximum annual leave limitation for members of the Senior Executive Service.

(a) Unused annual leave accrued by an employee while serving under an appointment in the Senior Executive Service (SES) under 5 U.S.C. chapter 33, subchapter VIII, may accumulate for use in succeeding years until it totals not more than 90 days (720 hours) at the beginning of the first full biweekly pay period in a leave year.

(b) When an employee in a position outside of the SES moves to a position in the SES, all unused accumulated annual leave remains to the employee's credit and is subject to the 90-day limitation in paragraph (a) of this section.

(c) If an employee serves less than a full pay period under an appointment in the SES, his or her unused accumulated annual leave is subject to the maximum annual leave limitations in 5 U.S.C. 6304(a), (b), or (c), as appropriate.

(d) When an employee in the SES moves to a position outside the SES, any

unused accumulated annual leave that is in excess of the amount allowed for the new position by 5 U.S.C. 6304(a), (b), or (c) remains to the employee's credit and is subject to reduction under procedures identical to those described in 5 U.S.C. 6304(c).

(e) Agencies must maintain records on the accumulated annual leave credited to each employee under this section. If the employee transfers to another agency, the losing agency must provide such records to the gaining agency.

§ 630.304 Scheduling annual leave to ensure its restoration.

(a) Except as provided in paragraph (b) of this section and § 630.309, before an agency may consider restoration of annual leave forfeited at the beginning of the leave year under 5 U.S.C 6304, the annual leave that was forfeited must have been scheduled in writing before November 15 of the previous leave year.

(b) The requirement for advance scheduling of annual leave in paragraph (a) of this section does not apply to an employee who is covered by 5 U.S.C. 6304(d)(3) which exempts employees of the Department of Defense at installations undergoing closure or realignment pursuant to the Defense Base Closure and Realignment Act of 1990 (part A of title XXIX of Public Law 101–510; 10 U.S.C. 2687 note). When coverage under 5 U.S.C. 6304(d)(3) terminates during a leave year, the employee must make a reasonable effort to comply with the scheduling requirement in paragraph (a) of this section. An authorized agency official may exempt an employee from the advance scheduling requirement in paragraph (a) of this section if coverage under 6304(d)(3) terminated during the leave year and the employee was unable to comply with the advance scheduling requirement because of circumstances beyond his or her control.

§ 630.305 Designating an agency official to approve exigencies of the public business.

An authorized agency official must make the determination that an exigency exists and that the exigency is of such major importance that employees may not use annual leave to avoid forfeiture. This determination must be made before an agency may restore annual leave under 5 U.S.C. 6304. An agency official whose leave would be affected by the decision (except the head of the agency) may not make this determination.

§ 630.306 Time limits for using restored annual leave.

(a) Except as otherwise authorized under paragraphs (b) and (c) of this section or other regulation, an employee must schedule and use annual leave restored under 5 U.S.C. 6304(d) not later than the end of the leave year ending 2 years after—

(1) The date of restoration of the annual leave, if the annual leave was forfeited because of administrative error;

(2) The date fixed by an authorized agency official as the termination date of the exigency of the public business that resulted in forfeiture of the annual leave; or

(3) The date the employee is determined to be recovered and able to return to duty if the leave was forfeited because of his or her sickness.

(b) An employee must schedule and use annual leave restored under 5 U.S.C. 6304(d)(3) within the time limits prescribed in paragraphs (b)(1) and (b)(2) of this section, as follows:

(1) A full-time employee must schedule and use excess annual leave of 416 hours or less by the end of the leave year in progress 2 years after the date he or she is no longer subject to 5 U.S.C. 6304(d)(3). The agency must extend this period by 1 leave year for each additional 208 hours of excess annual leave or any portion thereof.

(2) A part-time employee must schedule and use excess annual leave in an amount equal to or less than 20 percent of the number of hours in his or her scheduled annual tour of duty by the end of the leave year in progress 2 years after the date the employee is no longer subject to 5 U.S.C. 6304(d)(3). The agency must extend this period by 1 leave year for each additional number of hours of excess annual leave, or any portion thereof, equal to 10 percent of the number of hours in the employee's scheduled annual tour of duty.

(c) The time limits established under paragraphs (a) and (b) of this section for using restored annual leave accounts do not apply for the entire period during which an employee is subject to 5 U.S.C. 6304(d)(3). When coverage under 5 U.S.C. 6304(d)(3) ends, the agency must establish a new time limit under paragraph (b) of this section for all annual leave restored to an employee under 5 U.S.C. 6304(d).

§ 630.307 Time limit for using restored annual leave for a former missing employee.

Annual leave restored under 5 U.S.C. 5562 must be used within a time limit to be prescribed by OPM, in each case taking into consideration the amount of the restored leave and other relevant factors.

§ 630.308 Time limits for using restored annual leave in the event of an extended exigency of the public business.

(a) An employee must schedule and use annual leave restored under 5 U.S.C. 6304(d)(1)(B) because of an extended exigency, as defined in paragraph (b) of this section, within a time period that equals twice the number of full calendar years, or parts thereof, that the exigency existed. This time period begins at the beginning of the leave year following the leave year in which the exigency is declared to be ended.

(b) An *extended exigency* means an exigency of such significance as to—

(1) Threaten the national security, safety, or welfare;

(2) Last more than 3 calendar years;

(3) Affect a segment of an agency or occupational class; and

(4) Preclude subsequent use of both restored and accrued annual leave within the time limit specified in § 630.306.

§ 630.309 Restoring annual leave to employees determined necessary to respond to the "National Emergency by Reason of Certain Terrorist Attacks."

(a) OPM deemed the "National Emergency by Reason of Certain Terrorist Attacks" (Presidential Proclamation of September 14, 2001) to be an exigency of the public business for the purpose of restoring annual leave forfeited under 5 U.S.C. 6304.

(b) If an employee forfeits annual leave under 5 U.S.C. 6304 at the beginning of a leave year because his or her agency determines the employee's services are required in response to the national emergency, the forfeited annual leave is deemed to have been scheduled in advance for the purposes of 5 U.S.C. 6304(d)(1)(B) and § 630.304.

(c) An employee must schedule and use annual leave restored under 5 U.S.C. 6304(d) because of the national emergency within the following time limits:

(1) A full-time employee must schedule and use excess annual leave of 416 hours or less by the end of the leave year in progress 2 years after the date his or her services are no longer required by the national emergency. The agency must extend this period by 1 leave year for each additional 208 hours of excess annual leave or any portion thereof.

(2) A part-time employee must schedule and use excess annual leave in an amount equal to or less than 20 percent of the number of hours in his or her scheduled annual tour of duty by the end of the leave year in progress 2 years after the date the employee's services are no longer required by the

national emergency. The agency must extend this period by 1 leave year for each additional number of hours of excess annual leave, or any portion thereof, equal to 10 percent of the number of hours in the employee's scheduled annual tour of duty.

(d) The time limits established in paragraph (c) of this section for using restored annual leave accounts are suspended for the entire period during which an employee's services are required for the national emergency. When coverage under paragraphs (a) and (b) of this section ends, the agency must establish a new time limit under paragraph (c) of this section for all annual leave restored to an employee under 5 U.S.C. 6304(d).

(e) If an employee's services are determined essential during the national emergency, but he or she subsequently moves to a position not considered essential, the employee must make a reasonable effort to comply with the scheduling requirement in § 630.304(a). An authorized agency official may exempt such an employee from the advance scheduling requirement in § 630.304(a) if coverage under paragraphs (a) and (b) of this section terminated during the leave year and the employee can demonstrate that he or she was unable to comply with the advance scheduling requirement because of circumstances beyond his or her control.

Subpart D—Sick Leave

§ 630.401 Granting sick leave.

(a) Subject to paragraphs (b) through (e) of this section, an agency must grant sick leave to an employee when he or she—

(1) Receives medical, dental, or optical examination or treatment;

(2) Is incapacitated for the performance of his or her duties by physical or mental illness, injury, pregnancy, or childbirth;

(3)(i) Provides care for a family member who is incapacitated by a medical or mental condition or attends to a family member receiving medical, dental, or optical examination or treatment; or

(ii) Provides care for a family member with a serious health condition;

(4) Makes arrangements necessitated by the death of a family member or attends the funeral of a family member;

(5) Would, as determined by the health authorities having jurisdiction or by a health care provider, jeopardize the health of others by his or her presence on the job because of exposure to a communicable disease; or

(6) Must be absent from duty for purposes relating to his or her adoption of a child, including appointments with adoption agencies, social workers, and attorneys; court proceedings; required travel; and any other activities necessary to allow the adoption to proceed.

(b) The maximum amount of sick leave that may be granted to an employee during any leave year for the purposes described in paragraphs (a)(3)(i) and (4) of this section may not exceed a total of 104 hours (or, for a part-time employee or an employee with an uncommon tour of duty, the number of hours of sick leave he or she normally accrues during a leave year).

(c) The maximum amount of sick leave that may be granted to an employee during any leave year for the purposes described in paragraph (a)(3)(ii) of this section may not exceed a total of 480 hours (or, for a part-time employee or an employee with an uncommon tour of duty, an amount of sick leave equal to 12 times the average number of hours in his or her scheduled tour of duty each week), subject to the limitation found in paragraph (d) of this section.

(d) If, at the time an employee uses sick leave to care for a family member with a serious health condition under paragraph (c) of this section, he or she has used any portion of the sick leave authorized under paragraph (b) of this section during that leave year, the agency must subtract that amount from the maximum number of hours authorized under paragraph (c) of this section to determine the total amount of sick leave the employee may use during the remainder of the leave year to care for a family member with a serious health condition. If an employee has previously used the maximum amount of sick leave permitted under paragraph (c) of this section in a leave year, he or she is not entitled to use additional sick leave under paragraph (b) of this section.

(e) If the number of hours in the employee's tour of duty is changed during the leave year, his or her entitlement to use sick leave for the purposes described in paragraphs (a)(3) and (4) of this section must be recalculated based on the new tour of duty.

§ 630.402 Requesting sick leave.

An employee must file an application—written, oral, or electronic, as required by the agency—for sick leave within such time limits as the agency may require. The employee must request advance approval for sick leave for the purpose of receiving medical, dental, or optical examination or treatment and, to the extent possible, for the purposes described in § 630.401(a)(3), (4), and (6).

§ 630.403 Supporting evidence for the use of sick leave.

(a) An agency may grant sick leave only when the need for sick leave is supported by administratively acceptable evidence. An agency may consider an employee's self-certification as to the reason for his or her absence as administratively acceptable evidence, regardless of the duration of the absence. An agency may also require a medical certificate or other administratively acceptable evidence as to the reason for an absence for any of the purposes described in § 630.401(a) for an absence in excess of 3 workdays, or for a lesser period when the agency determines it is necessary.

(b) An employee must provide administratively acceptable evidence or medical certification for a request for sick leave within 15 days of his or her agency's request. An employee who does not provide the required evidence or medical certification within the 15 days is not entitled to sick leave.

(c) An agency may require an employee requesting sick leave to care for a family member under § 630.401(a)(3)(ii) to provide an additional written statement from the health care provider concerning the family member's need for psychological comfort and/or physical care. The statement must certify that —

(1) The family member requires psychological comfort and/or physical care;

(2) The family member would benefit from the employee's care or presence; and

(3) The employee is needed to care for the family member for a specified period of time.

§ 630.404 Use of sick leave during annual leave.

Subject to § 630.401(b) through (e), an agency may grant sick leave to an employee during a period of annual leave for any of the purposes described in § 630.401(a).

§ 630.405 Sick leave used in the computation of an annuity.

Sick leave used in the computation of an annuity is charged against an employee's sick leave account and may not thereafter be used, transferred, or recredited. All sick leave to the credit of an employee as of the date of his or her retirement (or death) and reported to OPM for credit towards the calculation of an annuity is considered to have been used.

§ 630.406 Records on the use of sick leave.

An agency must maintain records of the amount of sick leave used for family care purposes and to make arrangements for or attend the funeral of a family member under § 630.401(a)(3) and (4). The records must be sufficient to ensure that employees do not exceed the limitations in § 630.401(b) and (c).

Subpart E—Recredit of Leave

§ 630.501 Transferring annual and sick leave between agencies.

When an employee transfers between positions under 5 U.S.C., chapter 63, subchapter I, the agency from which the employee transfers must certify the employee's annual and sick leave accounts to the employing agency for credit or charge. When an employee transfers between positions under 5 U.S.C., chapter 63, subchapter I, the gaining agency must convert his or her leave into the minimum increments that can be accommodated by the gaining agency.

§ 630.502 Transferring annual leave between different leave systems.

(a) When annual leave is transferred between different leave systems under 5 U.S.C. 6308 or is recredited under a different leave system as the result of a refund under 5 U.S.C. 6306, 7 calendar days of annual leave are deemed equal to 5 workdays of annual leave.

(b) When an employee of the U.S. Postal Service transfers without a break in service to a position under 5 U.S.C. chapter 63, subchapter I, the employing agency must transfer and credit his or her accumulated annual leave to the employee's annual leave account. If the total amount of transferred annual leave exceeds the maximum amount of annual leave limitations under 5 U.S.C. 6304(a), (c), or (f), the maximum annual the leave that may be transferred is limited to the employee's former maximum annual leave limitation at the U.S. Postal Service. The employee's maximum annual leave limitation is subject to reduction in the same manner as provided in 5 U.S.C. 6304(c) until the employee's annual leave account is equal to or less than the limitations under 5 U.S.C. 6304(a), (b), or (f).

(c) The annual leave of an employee employed by the U.S. House of Representatives or Senate or both may not be transferred to an executive branch agency.

§ 630.503 Transferring sick leave between different leave systems.

(a) When sick leave is transferred between different leave systems under 5 U.S.C. 6308, 7 calendar days of sick leave are deemed equal to 5 workdays of sick leave.

(b) An employee who transfers to a position under a different leave system to which he or she may transfer only a part of his or her sick leave is entitled to a recredit of the untransferred sick leave (without regard to the date of the original transfer) if the employee returns to the leave system under which it was earned on or after December 2, 1994.

(c) An employee who transfers to a position to which he or she cannot transfer his or her sick leave is entitled to a recredit of the untransferred sick leave (without regard to the date of the original transfer) if the employee returns to the leave system under which it was earned on or after December 2, 1994.

(d) Except as provided in § 630.405, when an employee of the U.S. Postal Service transfers without a break in service to a position under 5 U.S.C. chapter 63, subchapter I, the employing agency must transfer and credit the employee's accumulated sick leave to his or her sick leave account. If the employee has a break in service, he or she is entitled to a recredit of sick leave if he or she is employed in a position under 5 U.S.C. chapter 63, subchapter I.

(e) The sick leave of an employee employed by the U.S. House of Representatives or Senate or both may not be transferred to an executive branch agency.

§ 630.504 Recrediting sick leave following a break in service.

(a) Except as provided in § 630.405 and in paragraph (b) of this section, an employee who has had a break in service is entitled to a recredit of sick leave (without regard to the date of his or her separation), if he or she returns to Federal employment on or after December 2, 1994, unless the sick leave was previously forfeited upon reemployment in the Federal Government before December 2, 1994.

(b) Except as provided in § 630.405, an employee of the government of the District of Columbia who was first employed by the government of the District of Columbia before October 1, 1987, who has had a break in service is entitled to a recredit of sick leave (without regard to the date of his or her separation) if he or she returns to Federal employment on or after December 2, 1994, unless the sick leave was previously forfeited upon reemployment in the Federal Government before December 2, 1994.

(c) The recredit of sick leave under this section must be supported by written documentation available to the employing agency in the employee's official personnel records, the official records of the former employing agency, copies of contemporaneous earnings and leave statements provided by the employee, or copies of other contemporaneous written documentation acceptable to the agency.

(d) The sick leave to be recredited under this section must have been accrued under 5 U.S.C. 6307 or transferred to an employee's sick leave account under 5 U.S.C. 6308 (or the corresponding provisions of prior statutes).

§ 630.505 Recrediting leave earned under a former leave system.

An employee who earned leave under another leave system that was merged under 5 U.S.C. chapter 63, subchapter I, is entitled to a recredit of that leave under subchapter I if he or she would have been entitled to recredit for it on reentering the leave system under which it was earned. However, this section does not revive leave already forfeited.

§ 630.506 Treatment of leave account when an employee goes on active military duty.

(a) When an employee leaves his or her civilian position to enter the military service, the employing agency must certify his or her annual and sick leave accounts for credit or charge. However, an employee entering the military service may choose to receive a lump-sum payment for unused annual leave under 5 CFR 550.1203(c).

(b) If the employee returns to a civilian position following military service, the agency to which the employee returns must reestablish the certified annual and sick leave accounts as a credit or charge (without regard to the date he or she left the civilian position) when the employee is—

(1) Restored in accordance with a right of restoration after separation from active military duty or hospitalization continuing thereafter as provided by law or in accordance with the mandatory provisions of a statute, Executive order, or regulation; or

(2) Reemployed in a position under 5 U.S.C. chapter 63, subchapter I, on or after December 2, 1994.

(c) For the purpose of documenting a returning employee's entitlement to a recredit of sick leave under this section, the employing agency must apply the documentation criteria established in § 630.504(c).

§ 630.507 Restoration of leave following an appeal.

When an employee is restored to duty as a result of an appeal, the agency must reestablish his or her leave account as a credit or charge as it was at the time of separation.

Subpart F—Home Leave

§ 630.601 Definitions.

In this subpart:

Home leave means leave authorized by 5 U.S.C. 6305(a) and earned by service abroad for use in the United States, the Commonwealth of Puerto Rico, or the territories or possessions of the United States.

Month means a period which runs from a given day in 1 month through the date preceding the numerically corresponding day in the next month.

Service abroad means service on and after September 6, 1960, by an employee at a post of duty outside the United States and outside the employee's place of residence if his place of residence is in the Commonwealth of Puerto Rico or a territory or possession of the United States.

§ 630.602 Coverage.

An employee who is stationed overseas and meets the requirements of 5 U.S.C. 6304(b) for the accumulation of a maximum of 45 days of annual leave earns and may be granted home leave in accordance with 5 U.S.C. 6305(a) and this subpart.

§ 630.603 Computation of service abroad.

(a) For the purpose of this subpart, service abroad—

(1) Begins on the date of the employee's arrival at a post of duty outside the United States or on the date of his or her entrance on duty, when recruited abroad;

(2) Ends on the date of the employee's departure from the post for separation or for assignment in the United States or on the date of his or her separation from duty, when separated abroad; and

(3) Includes any absence in a nonpay status up to a maximum of 2 workweeks within each 12 months of service abroad, authorized leave with pay, time spent in the Armed Forces of the United States which interrupts service abroad (but only for eligibility, not leave-earning, purposes), and any period on detail.

(b) In computing service abroad, full credit is given for the day of arrival and the day of departure.

§ 630.604 Earning rates.

(a) For each 12 months of service abroad, an employee earns home leave at the following rates:

(1) An employee who accepts an appointment to or occupies a position for which the agency has prescribed the requirement that the incumbent accept assignments anywhere in the world as the needs of the agency dictate earns 15 days.

(2) An employee who is serving with a U.S. mission to a public international organization earns 15 days.

(3) An employee who is serving at a post for which payment of a foreign or nonforeign (but not a tropical) differential of 20 percent or more is authorized by law or regulation earns 15 days.

(4) An employee who is not included in paragraph (a)(1), (2), or (3) of this section, but is serving at a post for which payment of a foreign or territorial (but not a tropical) differential of at least 10 percent, but less than 20 percent, is authorized by law or regulation, earns 10 days.

(5) An employee who is not included in paragraph (a)(1), (2), (3), or (4) of this section earns 5 days.

(6) An employee who is included in paragraph (a)(1) through (5) of this section and whose civilian service abroad is interrupted by a tour of duty in the Armed Forces of the United States does not earn home leave for the duration of such tour.

(b) An agency must credit home leave to an employee's leave account, as earned, in multiples of 1 day.

§ 630.605 Computing home leave.

(a) For each month of service abroad, an employee earns home leave at the rates fixed by § 630.604(a) in the amounts set forth in the following table:

HOME LEAVE-EARNING TABLE

[Days earned]

Months of service abroad	Earning rate (days for each 12 months)		
	15	10	5
1	1	0	0
2	2	1	0
3	3	2	1
4	5	3	1
5	6	4	2
6	7	5	2
7	8	5	2
8	10	6	3
9	11	7	3
10	12	8	4
11	13	9	4
12	15	10	5

(b) When an employee moves between different home leave-earning rates during a month of service abroad, or when a change in the differential during a month of service abroad results in a different home leave-earning rate, the agency must credit the employee with an amount of home leave for the month at the rate to which he or she was entitled before the change in his or her home leave-earning rate.

§ 630.606 Granting home leave.

(a) *Entitlement.* Except as otherwise authorized by statute, an employee is entitled to use home leave only when he or she has completed a basic service period of 24 months of continuous service abroad. If the employee has a break in service of 1 or more workdays or an assignment (other than a detail) to a position in which he or she is no longer subject to 5 U.S.C. 6305(a), he or she must complete another basic service period of 24 continuous months before becoming entitled to use home leave.

(b) *Agency authority.* Agencies have discretionary authority to grant home leave to an employee. An agency may grant home leave in combination with other leaves of absence in accordance with established agency policy.

(c) *Limitations.* An agency may grant home leave only—

(1) For use in the United States, the Commonwealth of Puerto Rico, or a

territory or possession of the United States; and

(2) During an employee's period of service abroad, or within a reasonable period after his or her return from service abroad when it is contemplated that the employee will return to service abroad immediately or on completion of an assignment in the United States. Home leave not granted during the period of service abroad or within a reasonable period after the employee's return from service abroad may be granted only after the employee has completed a further substantial period of service abroad. This further substantial period of service abroad may not be shorter than the tour of duty prescribed for the employee's post of assignment. However, an agency may determine in an individual case that an earlier grant of home leave is warranted.

(d) *Charging of home leave.* The minimum charge for home leave is 1 day, and additional charges are in multiples thereof.

(e) *Refund for home leave.* If an employee fails to return to service abroad after a period of home leave or after the completion of an assignment in the United States, he or she is indebted for the home leave he or she has used. However, an agency may not require a repayment of this debt for home leave when—

(1) The employee has completed at least 6 months of service in an assignment in the United States following the period of home leave;

(2) The agency determines that the employee's failure to return was due to compelling personal reasons of a humanitarian or compassionate nature, such as may involve physical or mental health or circumstances over which he or she has no control; or

(3) The agency that granted the home leave determines that it is in the public interest not to return the employee to his or her overseas assignment.

§ 630.607 Transfer or recredit of home leave.

An employee is entitled to have his or her home leave account transferred or recredited when he or she moves between agencies or is reemployed without a break in service of more than 90 days. An employee may not receive a lump-sum payment for unused home leave upon separation from Federal service.

Subpart G—Shore Leave

§ 630.701 Coverage.

An employee, as defined in 5 U.S.C. 6301, is eligible to accrue shore leave if he or she is regularly assigned to duties aboard an oceangoing vessel. An employee is considered to be regularly assigned when his or her continuing duties are such that all or a significant part of them require him or her to serve aboard an oceangoing vessel. Temporary assignments of a shore-based employee, such as for limited work projects or for training, do not constitute a regular assignment.

§ 630.702 Definitions.

Extended voyage means a voyage of not less than 7 consecutive calendar days duration.

Oceangoing vessel means a vessel in use on the high seas or the Great Lakes, but does not include a vessel that operates primarily on rivers, other lakes, bays, sounds or within the 3-nautical-mile limit of the coastal area of the 48 contiguous States, except when used in mapping, charting, or surveying operations or when in or sailing to or from foreign, territorial, Hawaiian, or Alaskan waters or waters outside its normal area of operation or outside the 3-nautical-mile limit.

Shore leave means leave authorized by 5 U.S.C. 6305(c) and this subpart.

Voyage means the sailing of an oceangoing vessel from one port and its return to that port or the final port of discharge.

§ 630.703 Earning shore leave.

(a) An employee earns shore leave at the rate of 1 day of shore leave for each 15 calendar days of absence on one or more extended voyages.

(b)(1) For an employee who is an officer or crewmember, a voyage begins on the date he or she assumes his or her duties aboard an oceangoing vessel to begin preparation for a voyage or on the date he or she comes aboard when a voyage is in progress. The voyage terminates on the date the employee ceases to be an officer or crewmember of the oceangoing vessel or on the date on which he or she is released from assigned duties relating to that voyage aboard the oceangoing vessel at the earlier of the employee's arrival at the port of origin or the port of final discharge.

(2) For an employee other than an officer or crewmember, a voyage begins on the date of sailing and terminates on the date the oceangoing vessel returns to a port at which the employee will disembark in completion of his or her assignment aboard the vessel or on the date the employee is released from assigned duties aboard the vessel, whichever is earlier.

(c) In computing days of absence, an agency must include—

(1) The beginning date of a voyage and the termination date of a voyage;

(2) The days an employee spends traveling to join an oceangoing vessel to which assigned when the vessel is at a place other than the port of origin;

(3) The days an employee spends traveling between oceangoing vessels when he or she is assigned from one vessel to another;

(4) The period representing the number of days within which an employee is reasonably expected to return to the port of origin when his or her oceangoing vessel's voyage is terminated, or the employee's employment as an officer or crewmember is terminated, at a port other than the port of origin;

(5) For an employee who is an officer or crewmember, the days on which the employee is on sick leave when he or she becomes sick during a voyage (whether or not continued as a member of the crew), but not beyond the earlier of the termination date of the voyage of the oceangoing vessel or the date of the employee's repatriation to the port of origin;

(6) For an employee who is other than an officer or crewmember, the days on which he or she is carried on sick leave, but not beyond the earlier of the date on which he or she returns to the port of origin or the termination date of the voyage; and

(7) The days of approved leave from a vessel (paid or unpaid) during a voyage.

§ 630.704 Granting shore leave.

(a) *Authority.* (1) An employee has an absolute right to use shore leave, subject to the right of the head of the agency to fix the time at which shore leave may be used.

(2) An agency may grant shore leave during a voyage only when requested by an employee.

(3) An employee must submit a written request to use shore leave. Whenever a request to use shore leave is denied, the agency must provide the employee with a written denial.

(b) *Accumulation.* Shore leave is in addition to annual leave, and an employee may accumulate shore leave for future use without limitation.

(c) *Charge for shore leave.* The minimum charge for shore leave is 1 day, and additional charges are in multiples thereof.

(d) *Lump sum payment.* An employee may not receive a lump-sum payment for unused shore leave when he or she separates from Federal service, except as provided in 5 U.S.C. 6305(c)(2).

(e) *Terminal leave.* (1) Except as provided by paragraph (e)(2) of this

section, an agency may not grant shore leave to an employee as terminal leave. For the purpose of this paragraph, terminal leave is an approved absence immediately before an employee's separation when the agency knows the employee will not return to duty before the date of his or her separation.

(2) An agency must grant shore leave as terminal leave when an employee's inability to use shore leave was because of circumstances beyond his or her control and not his or her own act or omission.

(f) *Forfeiture of shore leave.* Shore leave is forfeited if it is not granted before separation from Federal service or official assignment (other than by temporary detail) to a position in which an employee does not earn shore leave. When an official assignment will result in forfeiture of shore leave, the agency must, to the extent administratively practicable, give the employee an opportunity to use the shore leave to his or her credit before the reassignment or, when the agency is unable to grant the shore leave before the reassignment, not later than 6 months after the date of the employee's reassignment.

Subpart H—Funeral Leave

§ 630.801 Purpose.

This subpart and 5 U.S.C. 6326 authorize an agency to grant funeral leave to an employee in connection with the funeral of, or memorial service for, his or her immediate relative who died as a result of wounds, disease, or injury incurred while serving as a member of the Armed Forces in a combat zone.

§ 630.802 Coverage.

This subpart applies to an employee, as defined in 5 U.S.C. 2105, who is employed by an executive agency, as defined in 5 U.S.C. 105.

§ 630.803 Definitions.

In this subpart:

Armed Forces means the Army, Navy, Air Force, Marine Corps, and Coast Guard.

Combat zone means those areas determined by the President in accordance with section 112 of the Internal Revenue Code.

Funeral leave means leave authorized by 5 U.S.C. 6326 and this subpart.

Immediate relative means the following relatives of the deceased member of the armed forces:

(1) Spouse, and parents thereof;

(2) Children, including adopted children, and spouses thereof;

(3) Parents;

(4) Brothers and sisters, and spouses thereof; and

(5) Any individual related by blood or affinity whose close association with the deceased was the equivalent of a family relationship.

§ 630.804 Granting funeral leave.

(a) An agency must grant an employee up to 3 workdays of funeral leave without loss of pay, charge to leave to which the employee is otherwise entitled, or loss of credit for time or service and without adversely affecting his or her performance or efficiency rating. Funeral leave is granted to allow an employee to make arrangements for or to attend the funeral or memorial service for an immediate relative who died as the result of a wound, disease, or injury incurred while serving as a member of the Armed Forces in a combat zone. The 3 days need not be consecutive, but if not, the employee must furnish the approving authority with satisfactory reasons justifying a grant of funeral leave for nonconsecutive days.

(b) An agency may grant funeral leave only from an established tour of duty, including regularly scheduled overtime.

Subpart I—Voluntary Leave Transfer Program

§ 630.901 Purpose.

This subpart sets forth procedures and requirements for a voluntary leave transfer program under which the unused accrued annual leave of one agency employee or officer may be transferred for use by another agency employee or officer who needs such leave because of a medical emergency. This subpart implements the provisions of 5 U.S.C., chapter 63, subchapter III, and must be read together with those provisions of law.

§ 630.902 Coverage.

Employees and officers to whom the definition of *employee* under 5 U.S.C. 6301 applies are covered by the voluntary leave transfer program.

§ 630.903 Definitions.

In this subpart:

Agency means—

(a) An *executive agency,* as defined in 5 U.S.C. 105;

(b) A *military department,* as defined in 5 U.S.C. 102; or

(c) Any other entity of the Federal Government that employs officers or employees to whom the definition of *employee* under 5 U.S.C. 6301 applies. Except as provided in § 630.922, it does not include the Central Intelligence Agency; the Defense Intelligence Agency; the National Security Agency; the Federal Bureau of Investigation; or any other executive agency or unit thereof, as determined by the President, whose principal function is the conduct of foreign intelligence or counterintelligence activities.

Available paid leave means accrued or accumulated annual or sick leave under 5 U.S.C. 6302–6304 and 6307 and recredited and restored annual or sick leave under subpart C or E of this part. If the medical emergency involves a family member of the employee, his or her *available paid leave* includes that amount of sick leave which he or she is entitled to use to care for a family member under § 630.401. *Available paid leave* does not include annual or sick leave advanced to an employee under 5 U.S.C. 6302(d) or 6307(d) or any annual or sick leave accrued under § 630.915 that has not been transferred to the appropriate leave account under § 630.917.

Employee has the meaning given that term in 5 U.S.C. 6301(2), but does not include an individual employed by the government of the District of Columbia.

Family member means the following relatives of the employee:

(1) Spouse, and parents thereof;

(2) Children, including adopted children, and spouses thereof;

(3) Parents;

(4) Brothers and sisters, and spouses thereof; and

(5) Any individual related by blood or affinity whose close association with the employee is the equivalent of a family relationship.

Healthcare provider has the meaning given that term in § 630.1204.

Leave donor means an employee whose voluntary written request for transfer of annual leave to the annual leave account of a leave recipient is approved by his or her own employing agency.

Leave recipient means a current employee for whom the employing agency has approved an application to receive annual leave from the annual leave accounts of one or more leave donors.

Medical emergency means a serious health condition, as that term is defined in § 630.1204, which affects an employee or a family member of such employee and is likely to require the employee's absence from duty for a prolonged period of time and to result in a substantial loss of income to the employee because of the unavailability of paid leave.

Paid leave status means the administrative status of an employee while the employee is using annual or sick leave accrued or accumulated under 5 U.S.C. 6302–6304 and 6307.

Shared leave status means the administrative status of an employee

while the employee is using transferred leave under this subpart or leave transferred from a leave bank under subpart J of this part.

Transferred leave means donated annual leave credited to an approved leave recipient's annual leave account.

§ 630.904 Administration.

Each Federal agency must establish and administer procedures to permit the voluntary transfer of annual leave consistent with this subpart.

§ 630.905 Uncommon tour of duty.

An agency having employees who earn and use annual leave on the basis of an uncommon tour of duty, as that term is defined in § 630.201, must establish procedures for administering the transfer of annual leave to or from such employees under this subpart. Those procedures must be based on the "directly proportional" rules the agency uses to determine rates of leave accrual under 5 CFR 630.204.

§ 630.906 Application to become a leave recipient.

(a) An employee must make written application to his or her employing agency to become a leave recipient. If the employee is not capable of making application, a personal representative may make written application on his or her behalf. An agency may establish a time limit during which an employee must make a written application to become a leave recipient following the termination of a medical emergency.

(b) The following information must accompany an application for donated leave:

(1) The employee's name, position title, and grade or pay level;

(2) The reasons transferred leave is needed, including a brief description of the nature, severity, and anticipated duration of the medical emergency, and if it is a recurring one, the approximate frequency of the medical emergency affecting the employee;

(3) Certification from one or more healthcare providers, with respect to the medical emergency, if the employing agency so requires;

(4) The date the medical emergency terminated, if the employee is applying to become a leave recipient after the medical emergency has terminated; and

(5) Any additional information required by the employing agency.

(c) If an employee is required to obtain certification from two or more healthcare providers under paragraph (b)(3) of this section, the employing agency must ensure, by direct payment to the healthcare provider involved or by reimbursement, that the employee is not required to pay for the expenses associated with obtaining certification from more than one healthcare provider.

§ 630.907 Approval of an application to become a leave recipient.

(a) The potential leave recipient's employing agency must review an application to become a leave recipient under procedures established by the agency for the purpose of determining that the employee is or has been affected by a medical emergency.

(b) Before approving an employee's application to become a leave recipient, the employing agency must determine that his or her absence from duty without available paid leave because of the medical emergency is (or is expected to be) at least 24 hours (or, in the case of a part-time employee or an employee with an uncommon tour of duty, at least 30 percent of the average number of hours in the employee's biweekly scheduled tour of duty).

(c) In making a determination as to whether a medical emergency is likely to result in a substantial loss of income because of the unavailability of paid leave, an agency may not consider an employee's grade or pay level or financial status.

§ 630.908 Notification of approval of an application.

If an employee's application to become a leave recipient is approved, the employing agency must notify the employee (or the personal representative who made application on the employee's behalf) within 10 calendar days (excluding Saturdays, Sundays, and legal public holidays) after the date the application was received, that—

(a) The application has been approved; and

(b) Other employees of the employing agency may request the transfer of their annual leave to the employee's leave account.

§ 630.909 Disapproval of an application to become a leave recipient.

If an employee's application to become a leave recipient is not approved, the employing agency must notify the employee (or his or her personal representative who made application on the employee's behalf) within 10 calendar days (excluding Saturdays, Sundays, and legal public holidays) after the date the application was received, that—

(a) The application has not been approved, and

(b) The reasons for its disapproval.

§ 630.910 Donating annual leave through a leave transfer program.

(a) A leave donor may submit a voluntary written request to his or her employing agency that a specified number of hours of the donor's accrued annual leave, including annual leave restored under 5 U.S.C. 6304(d) and 5596(b)(1)(B)(i), but excluding annual leave advanced to the employee under 5 U.S.C. 6302(d) and § 630.210(a), be transferred from his or her annual leave account to the annual leave account of a specified leave recipient. Except as provided in § 630.911, annual leave may be transferred only to an approved leave recipient employed by the donor's employing agency.

(b) An employee who transfers to a position excepted from 5 U.S.C. chapter 63, subchapter I, by 5 U.S.C. 6301(2)(x)–(xii) may submit a voluntary written request to his or her employing agency that a specified number of hours of his or her accrued or accumulated annual leave that is being held in abeyance be transferred from his or her annual leave account to the annual leave account of a specified leave recipient. Except as provided in § 630.911, annual leave may be transferred only to a leave recipient employed by the leave donor's employing agency.

(c) Except as provided in § 630.913, and subject to the limitations on the amount of annual leave that may be donated by a leave donor under § 630.912, all or any portion of the annual leave the donor requested under paragraph (a) of this section may be transferred to the annual leave account of the specified leave recipient under procedures established by his or her employing agency.

§ 630.911 Donation of leave to an employee in a different agency.

(a) If a leave donor wishes to donate annual leave to an approved leave recipient in another agency, the donor's agency must verify the availability of annual leave in his or her annual leave account, determine that the amount of annual leave to be donated does not exceed the limitations in § 630.912, and ascertain that the leave recipient's employing agency has made the determination required by paragraph (b) of this section. Upon satisfying these requirements, the donor's agency must—

(1) Reduce the amount of annual leave credited to the donor's annual leave account, as appropriate; and

(2) Notify the approved leave recipient's employing agency in writing of the amount of annual leave to be credited to his or her annual leave account.

(b) The employing agency of an approved leave recipient must accept the transfer of annual leave from leave donors employed by one or more other agencies when—

(1) The leave recipient has a family member employed by another agency who requests the transfer of annual leave to him or her;

(2) In the judgment of the employing agency, the amount of annual leave transferred from leave donors employed by the employing agency may not be sufficient to meet the employee's needs; or

(3) In the judgment of the employing agency, acceptance of leave transferred from another agency would further the purpose of the voluntary leave transfer program.

§ 630.912 Limitations on the amount of annual leave that may be donated through a leave transfer program.

(a) In any one leave year, a leave donor may donate no more than a total of one-half of the amount of annual leave he or she would be entitled to accrue during the leave year in which the donation is made.

(b) If a leave donor is projected to have annual leave that otherwise would be subject to forfeiture at the end of the leave year under 5 U.S.C. 6304(a), the maximum amount of annual leave that may be donated during the leave year is the lesser of—

(1) One-half of the amount of annual leave the donor would be entitled to accrue during the leave year in which the donation is made; or

(2) The number of hours remaining in the leave year (as of the date of the transfer) for which the donor is scheduled to work and receive pay, excluding any period of paid or unpaid leave.

(c) In any one leave year, an employee who transfers to a position excepted from 5 U.S.C. chapter 63, subchapter I, by 5 U.S.C. 6301(2)(x)–(xii) may donate not more than a total of one-half of the amount of annual leave he or she was entitled to accrue in the leave year in effect prior to transfer to the excepted position.

(d) An agency may waive the limitations on donating annual leave in paragraphs (a), (b), and (c) of this section by establishing written criteria for such waivers. All waivers must be documented in writing.

(e) The limitations in this section apply to the total amount of annual leave donated or contributed under subparts I and J of this part (the voluntary leave transfer and leave bank programs).

§ 630.913 Prohibition against donation of leave to an immediate supervisor.

An employee may not donate annual leave to his or her immediate supervisor.

§ 630.914 Restrictions on the use of transferred annual leave by a leave recipient.

(a) A leave recipient may use annual leave transferred to his or her annual leave account only for the purpose of the medical emergency for which the recipient was approved. An approved leave recipient who has received an official notice of leave restriction from his or her agency is subject to the terms and conditions of the leave restriction notice when requesting and using donated annual leave under this subpart.

(b) Except as provided in § 630.915(b), in each biweekly pay period during which a leave recipient is affected by a medical emergency, he or she must use any accrued annual leave, and sick leave, if applicable, before using transferred annual leave.

(c) The approval and use of transferred annual leave is subject to all of the conditions and requirements imposed by 5 U.S.C. 6302–6304, this part, and the employing agency on the approval and use of annual leave accrued under 5 U.S.C. 6303, except that transferred annual leave may accumulate without regard to the limitation imposed by 5 U.S.C. 6304.

(d) A leave recipient may choose to substitute transferred annual leave retroactively for any period of leave without pay or use it to liquidate any indebtedness for any period of advanced annual or sick leave that began on or after the date fixed by the employing agency as the beginning of the medical emergency.

(e) A leave recipient may not—

(1) Transfer the leave he or she receives to another leave recipient;

(2) Receive a lump-sum payment for transferred leave under 5 U.S.C. 5551 or 5552; or

(3) Receive recredit under 5 U.S.C. 6306 for the transferred leave upon reemployment by a Federal agency.

(f) An agency may establish a maximum period of time, not less than 6 months, during which a qualified employee may continue to be an approved leave recipient under subparts I and J of this part (the voluntary leave transfer and leave bank programs) for any particular medical emergency. When an employee is approved as a leave transfer recipient, an agency which has established such a time limit must provide the leave recipient with written notification of the maximum period of time for which an employee may continue to be an approved leave recipient.

§ 630.915 Accrual of leave in set-aside accounts while using donated leave.

(a) An agency must credit any annual or sick leave a leave recipient accrues while using transferred leave under this section and § 630.1013 to a set-aside annual or sick leave account, as appropriate, that is separate from any leave account under 5 U.S.C. 6302–6304 and 6307.

(b) Any annual and sick leave an employee accrues in his or her set-aside accounts while using transferred leave may not become available for his or her use and may not otherwise be taken into account under 5 U.S.C. 6302–6304 until it is transferred to the appropriate annual and sick leave accounts under 5 U.S.C. 6303, as provided in § 630.917.

§ 630.916 Limitations on the accrual of annual and sick leave in set-aside accounts while using donated leave.

Except as otherwise provided in § 630.918, while an employee is in a shared leave status as a leave recipient, annual and sick leave must accrue to his or her credit at the same rate as if he or she were in a paid leave status under 5 U.S.C. 6303, 6304, and 6307, except that—

(a) The total amount of annual leave a leave recipient may accrue while in a shared leave status under §§ 630.915 and 630.1013 in connection with any particular medical emergency may not exceed 40 hours (or, in the case of a part-time employee or an employee with an uncommon tour of duty, the average number of hours in the employee's weekly scheduled tour of duty); and

(b) The total amount of sick leave a leave recipient may accrue while in a shared leave status under §§ 630.915 and 630.1013 in connection with any particular medical emergency may not exceed 40 hours (or, in the case of a part-time employee or an employee with an uncommon tour of duty, the average number of hours in the employee's weekly scheduled tour of duty).

§ 630.917 Using annual and sick leave in set-aside accounts.

Any annual or sick leave an employee accrues in his or her set-aside accounts as a leave recipient under subparts I and J of this part (the voluntary leave transfer and leave bank programs), must be transferred to the employee's annual or sick leave account, as appropriate, under 5 U.S.C. 6303 and 6307 and must become available for use—

(a) As of the beginning of the first pay period beginning on or after the date the

medical emergency terminates, as prescribed in § 630.920(a)(2) or (3); or

(b) Once the employee has exhausted all leave made available under 5 CFR subparts I or J (the voluntary leave transfer and leave bank programs), if the medical emergency has not yet terminated. If annual or sick leave accrued in the set-aside accounts under § 630.915 is transferred to the employee's appropriate leave account under 5 U.S.C. chapter 63, subchapter I, before the set-aside accounts have reached their maximum limits under § 630.916, annual leave and sick leave will continue to accrue in the set-aside accounts, in the event the leave recipient receives and uses additional donated leave, until the total amount accrued during the particular medical emergency has reached the maximum limit of 40 hours of annual leave and 40 hours of sick leave.

§ 630.918 Accrual of leave in set-aside accounts when annual and sick leave have been advanced at the beginning of a leave year.

If, at the beginning of a leave year, an employing agency advances the amount of annual leave an employee normally would accrue during the entire leave year under 5 U.S.C. 6302(d)—

(a) The employing agency must establish procedures to ensure that 40 hours (or, in the case of a part-time employee or an employee with an uncommon tour of duty, the average number of hours in his or her weekly scheduled tour of duty) of annual leave is placed in a separate set-aside annual leave account and made available for the leave recipient's use as described in § 630.917; and

(b) The leave recipient may continue to accrue annual leave while in a shared leave status to the extent necessary for the purpose of reducing any indebtedness caused by the use of annual leave advanced at the beginning of the leave year.

§ 630.919 Terminating set-aside accounts when a leave recipient is terminated from Federal service.

If a leave recipient is terminated from Federal service as described in § 630.920(a)(1) or § 630.1014(a), he or she may not receive credit or lump-sum payment for any leave accrued in the set-aside accounts under §§ 630.915 or 630.1013, and the employing agency must terminate the set-aside accounts.

§ 630.920 Termination of a medical emergency.

(a) A leave recipient's medical emergency terminates—

(1) When his or her Federal service terminates;

(2) At the end of the biweekly pay period in which the employing agency receives written notice from the employee or his or her personal representative that the employee is no longer affected by a medical emergency;

(3) At the end of the biweekly pay period in which the employing agency determines that the employee is no longer affected by a medical emergency, after giving the employee (or, if appropriate, his or her personal representative) written notice and giving the employee (or, if appropriate, his or her personal representative) an opportunity to answer orally or in writing; or

(4) At the end of the biweekly pay period in which the employing agency receives notice that OPM has approved the employee's application for disability retirement under the Civil Service Retirement System or the Federal Employees' Retirement System.

(b) The employing agency must continuously monitor the status of the medical emergency affecting a leave recipient to ensure that he or she continues to be affected by a medical emergency.

(c) When the medical emergency affecting an employee terminates, no further requests for transfer of annual leave to him or her may be granted, and any unused transferred annual leave remaining to the employee's credit must be restored to the leave donors under § 630.921.

(d) An agency may deem a medical emergency to continue for the purpose of providing an employee with an adequate period of time within which to receive donations of annual leave.

§ 630.921 Restoration of unused transferred annual leave to leave donors.

(a) When a medical emergency terminates, any transferred annual leave remaining to the credit of a leave recipient must be credited to the annual leave accounts of leave donors who, on the date leave restoration is made, are employed by a Federal agency and subject to 5 U.S.C. chapter 63. The employing agency must establish procedures for restoring such unused transferred leave (as provided in paragraphs (b) and (c) of this section and to the extent administratively feasible) by transfer to the annual leave accounts of the leave donors who, on the date leave restoration is made, are employed by a Federal agency and subject to 5 U.S.C. chapter 63.

(b) The amount of unused transferred annual leave to be restored to each leave donor must be determined as follows:

(1) Divide the number of hours of unused transferred annual leave by the total number of hours of annual leave transferred to the leave recipient;

(2) Multiply the ratio obtained in paragraph (b)(1) of this section by the number of hours of annual leave transferred by each leave donor eligible for restoration under paragraph (a) of this section; and

(3) Round the result obtained in paragraph (b)(2) of this section to the nearest increment of time, either one-tenth of an hour (6 minutes) or one-quarter of an hour (15 minutes), as established by the leave donor's employing agency to account for annual leave.

(c) If the total number of eligible leave donors exceeds the total number of hours of annual leave to be restored, no unused transferred annual leave may be restored. In no case may the amount of annual leave restored to a leave donor exceed the amount donated by the leave donor to the leave recipient.

(d) If the leave donor retires from Federal service, dies, or is otherwise separated from Federal service before the date unused transferred annual leave can be restored, the employing agency of the leave recipient may not restore the unused transferred annual leave.

(e) At the election of a leave donor, unused transferred annual leave restored under paragraph (a) of this section may be restored by—

(1) Crediting the restored annual leave to his or her annual leave account in the current leave year;

(2) Crediting the restored annual leave to his or her annual leave account effective as of the first day of the first leave year beginning after the date of election;

(3) Donating such leave in its entirety to another leave recipient; or

(4) Donating such leave in part to another leave recipient and electing to have the remaining unused transferred leave credited to his or her account under paragraphs (e)(1) or (e)(2) of this section.

(f) Transferred annual leave restored to a leave donor under paragraph (e)(1) or (e)(2) of this section is subject to the limitation imposed by 5 U.S.C. 6304(a) at the end of the leave year in which the restored leave is credited to the leave donor's annual leave account.

(g) If a leave recipient elects to buy back annual leave as a result of a claim for an employment-related injury approved by the Office of Workers' Compensation Programs under 20 CFR part 10, and the annual leave was leave transferred under § 630.910, the amount of annual leave bought back must be restored to the leave donor(s).

§ 630.922 Participation by an excepted agency.

(a) The head of an agency excepted from these regulations under 5 U.S.C. 6339(a)(1) may, at his or her sole discretion, establish a program under which an individual employed in or under such excepted agency may participate in a leave transfer program established under the provisions of this subpart, including provisions permitting the transfer of annual leave accrued or accumulated by such employee to, or permitting such employee to receive transferred leave from, an employee of any other agency (including another excepted agency having a program under this subpart).

(b) An excepted agency choosing to participate in a leave transfer program established under this subpart may develop a policy that includes provisions that protect the anonymity of its employees. Leave transferred to and from employees of such excepted agencies must be accepted by other agencies (including another excepted agency having a program under this subpart), regardless of whether the donating employee is identified.

§ 630.923 Records.

An agency must record the status of a current leave recipient under the voluntary leave transfer program when he or she transfers to another Federal agency without a break in service. The employing agency from which the leave recipient is transferring must document and forward the following information to the new employing agency:

(a) The dates the medical emergency began and terminated (if applicable);

(b) The date the employee was approved to become a leave recipient;

(c) The effective date of the transfer; and

(d) The hours of donated annual leave received, used, and remaining at the time the leave recipient transfers to the new employing agency.

Subpart J—Voluntary Leave Bank Program

§ 630.1001 Purpose.

This subpart establishes procedures and requirements for a voluntary leave bank program under which the unused accrued annual leave of an employee or officer may be contributed to a leave bank for use by a leave bank member who needs such leave because of a medical emergency. This subpart implements the provisions of 5 U.S.C., chapter 63, subchapter IV, and must be read together with those provisions of law.

§ 630.1002 Coverage.

This subpart applies to employees and officers—

(a) To whom the definition of *employee* under U.S.C. 6301 applies; and

(b) Who are employed in agencies and their organizational subunits operating a voluntary leave bank program under this subpart.

§ 630.1003 Definitions.

In this subpart:

Agency has the meaning given that term in § 630.903.

Available paid leave has the meaning given that term in § 630.903.

Employee has the meaning given that term in § 630.903.

Family member has the meaning given that term in § 630.903.

Healthcare provider has the meaning given that term in § 630.1204.

Leave bank means a pooled fund of annual leave established by an agency under § 630.1004.

Leave bank contributor means an employee who contributes annual leave to a leave bank under § 630.1008.

Leave bank member means a leave bank contributor who has contributed, in an open enrollment period (or individual enrollment period, as applicable) of the current leave year, at least the minimum amount of annual leave required by § 630.1007.

Leave recipient means a leave bank member whose application to receive contributions of annual leave from a leave bank has been approved under § 630.1011.

Medical emergency has the meaning given that term in § 630.903.

Paid leave status has the meaning given that term in § 630.903.

Shared leave status has the meaning given that term in § 630.903.

§ 630.1004 Establishing and operating leave banks.

(a) An agency participating in the voluntary leave bank program must—

(1) Develop written policies and procedures for establishing and administering leave banks and leave bank boards consistent with this subpart;

(2) Establish one or more leave bank boards to perform the duties authorized by this subpart; and

(3) Establish and begin operating one or more leave banks.

(b) Annual leave may not be borrowed, contributed, or otherwise transferred between leave banks, except as provided in § 630.1106.

§ 630.1005 Operation of a leave bank board.

(a) Each leave bank board must consist of three members. At least one member must represent a labor organization or employee group.

(b) Each leave bank board must—

(1) Establish its internal decision-making procedures;

(2) Review and approve or disapprove each application to become a leave contributor under §§ 630.1006 and 630.1008 and a leave recipient under §§ 630.1010 and 630.1011;

(3) Monitor the status of each leave recipient's medical emergency;

(4) Monitor the amount of leave in the leave bank and the number of applications to become a leave recipient;

(5) Maintain an adequate amount of annual leave in the leave bank to the greatest extent practicable in accordance with § 630.1007; and

(6) Perform other functions prescribed in this subpart.

(c) No more than one leave bank board may be established for each leave bank.

(d) An agency having employees who earn and use annual leave on the basis of an uncommon tour of duty must establish procedures for administering the contribution and withdrawal of annual leave by such employees under this subpart.

§ 630.1006 Application to become a leave bank member.

(a) An employee may become a leave bank member for a particular leave year if he or she submits an application that meets the requirements of this section and § 630.1007 during an open enrollment period established by the leave bank board under paragraphs (b) and (c) of this section (or, where applicable, during an individual enrollment period established under paragraph (d) of this section).

(b) A leave bank board must establish at least one open enrollment period for each leave year of leave bank operation.

(c) An open enrollment period must last at least 30 calendar days. An agency must take appropriate action to inform employees of each open enrollment period.

(d) If an employee is entering the agency or participating organizational subunit or returning from an extended absence outside an open enrollment period, he or she may become a leave bank member for the current leave year by submitting an application meeting the requirements of this section during an individual enrollment period lasting at least 30 calendar days, beginning on the date the employee entered or returned to the agency or organizational subunit.

§ 630.1007 Minimum contribution of a leave bank member.

(a) Except as provided in paragraph (b) of this section, the minimum contribution of annual leave required to become a leave bank member for a leave year is—

(1) Four hours of annual leave for an employee who has less than 3 years of service at the time he or she submits an application to contribute annual leave;

(2) Six hours of annual leave for an employee who has at least 3, but less than 15, years of service at the time he or she submits an application to contribute annual leave; and

(3) Eight hours of annual leave for an employee who has 15 or more years of service at the time he or she submits an application to contribute annual leave.

(b) A leave bank board may—

(1) Decrease the minimum contribution required by paragraph (a) of this section for the following leave year when the board determines that there is a surplus of leave in the bank;

(2) Increase the minimum contribution required by paragraph (a) of this section for the following leave year when the board determines that such action is necessary to maintain an adequate balance of annual leave in the leave bank; or

(3) Eliminate the requirement for a minimum contribution under paragraph (a) of this section when a leave bank member transfers within his or her employing agency to an organization covered by a different leave bank.

(c) If a leave recipient does not have sufficient available accrued annual leave to his or her credit to make the full minimum contribution required by this section, he or she must be deemed to have made the minimum contribution.

(d) A leave bank board must deposit all contributions of annual leave under this subpart in the leave bank.

(e) A leave bank member may apply to contribute additional annual leave at any time.

§ 630.1008 Application to become a leave bank contributor.

(a) An employee may make voluntary written application to the leave bank board to become a leave bank contributor at any time. The leave contributor must specify on the application the number of hours of his or her accrued annual leave, including annual leave restored under 5 U.S.C. 6304(d) and 5596(b)(1)(B)(i), but excluding annual leave advanced under 5 U.S.C. 6302(d) and 5 CFR 630.210(a), to be contributed and any other information the leave bank board may reasonably require.

(b) An employee may request that annual leave be contributed to a specified bank member other than his or her immediate supervisor.

(c) Except as provided in § 630.1019(c), a leave bank board may not return a contribution of annual leave to a leave contributor after deposit in the leave bank.

§ 630.1009 Maximum limitation on contribution of annual leave to a leave bank.

(a) In any one leave year, a leave contributor may contribute no more than a total of one-half of the amount of annual leave he or she would be entitled to accrue during the leave year in which the contribution is made.

(b) If a leave contributor is projected to have annual leave that otherwise would be subject to forfeiture at the end of the leave year under 5 U.S.C. 6304(a), the maximum amount of annual leave he or she may contribute during the leave year is the lesser of—

(1) One-half of the amount of annual leave the employee would be entitled to accrue during the leave year in which the contribution is made; or

(2) The number of hours remaining in the leave year (as of the date of the contribution) for which the employee is scheduled to work and receive pay (excluding any periods of paid or unpaid leave).

(c) An agency may waive the limitations on donating annual leave under paragraphs (a) and (b) of this section by establishing written criteria permitting the leave bank board to approve such waivers. All waivers must be documented in writing.

(d) The limitations in this section apply to the total amount of annual leave donated or contributed under subparts I and J of this part (the voluntary leave transfer and leave bank programs).

§ 630.1010 Application to become a leave recipient under a leave bank.

(a) A leave bank member may make written application to the leave bank board to become a leave recipient. If the leave bank member is not capable of making application on his or her own behalf, a personal representative may make written application on his or her behalf.

(b) For a medical emergency that has terminated, a leave bank board may establish a maximum period during which it will accept a leave bank member's written application to become a leave recipient following the termination of the medical emergency.

(c) A leave bank member's application to become a leave recipient must be accompanied by the following information:

(1) The leave bank member's name, position title, and grade or pay level;

(2) The reasons leave is needed, including a brief description of the nature, severity, anticipated duration, and if it is a recurring one, the approximate frequency of the medical emergency affecting the leave bank member;

(3) The date the medical emergency terminated if the leave bank member is applying to become a leave recipient after the medical emergency has terminated.

(4) Certification from one or more healthcare providers, with respect to the medical emergency, if the leave bank board so requires; and

(5) Any additional information that may be required by the leave bank board.

(d) If the leave bank board requires a leave bank member to submit certification from two or more sources under paragraph (c)(4) of this section, the agency must ensure, either by direct payment to the healthcare provider involved or by reimbursement, that the leave bank member is not required to pay for the expenses associated with obtaining certification from more than one source.

§ 630.1011 Approval of a leave recipient under a leave bank program.

(a) The leave bank board must review an employee's application to become a leave recipient under procedures established by the agency for the purpose of determining whether the employee is a leave bank member who is or has been affected by a medical emergency that is likely to result in a substantial loss of income.

(b) Before approving an application to become a leave recipient, the leave bank board must determine that the employee's absence from duty without available paid leave because of the medical emergency is (or is expected to be) at least 24 hours (or, in the case of a part-time employee or an employee with an uncommon tour of duty, at least 30 percent of the average number of hours in the employee's biweekly scheduled tour of duty).

(c) An agency may not consider an employee's grade or pay level or financial status in making a determination as to whether the medical emergency is likely to result in a substantial loss of income because of the unavailability of paid leave.

(d) The leave bank board must provide timely written notification to the applicant of the action taken on the application. If the leave bank board disapproves the application, notification

must include the reasons for disapproval.

§ 630.1012 Restrictions on the use of annual leave withdrawn from a leave bank.

(a) A leave recipient may use annual leave withdrawn from a leave bank only for the purpose of the medical emergency for which the leave recipient was approved. An approved leave recipient who has received an official notice of leave restriction from his or her agency is subject to the terms and conditions of the leave restriction notice when requesting and using donated annual leave under this subpart.

(b) Except as provided in § 630.1013, in each biweekly pay period during which a leave recipient is affected by a medical emergency, he or she must use any accrued annual leave (and sick leave, if applicable) before using annual leave withdrawn from a leave bank.

(c) The approval and use of annual leave withdrawn from a leave bank is subject to all of the conditions and requirements imposed by 5 U.S.C. 6302–6304, this part, and the agency on the approval and use of annual leave accrued under 5 U.S.C. 6303, except that annual leave withdrawn from a leave bank may accumulate without regard to any limitation imposed by 5 U.S.C. 6304(a).

(d) Annual leave withdrawn from a leave bank may be substituted retroactively for any period of leave without pay or used to liquidate an indebtedness for any period of advanced leave that began on or after the date fixed by the leave bank board as the beginning of the medical emergency.

(e) Annual leave withdrawn from a leave bank may not be—

(1) Transferred to another leave recipient;

(2) Included in a lump-sum payment under 5 U.S.C. 5551 or 5552; or

(3) Made available for recredit under 5 U.S.C. 6306 upon reemployment by a Federal agency.

(f) An agency may establish a maximum period of time, not less than 6 months, during which an employee may continue to be an approved leave recipient under subparts I and J of this part (the voluntary leave transfer and leave bank programs) for any particular medical emergency. An agency which has established such a time limitation must provide the leave recipient with written notification of the maximum continuous period of time for which an employee may continue to be an approved leave recipient.

§ 630.1013 Accrual and use of leave in set-aside accounts under a leave bank program.

When an employee is receiving donated leave from a leave bank, annual leave and sick leave will accrue to his or her credit as provided in §§ 630.915, 630.916, and 630.918 and will become available for his or her use as provided in §§ 630.917 and 630.919.

§ 630.1014 Termination of a medical emergency under the leave bank program.

A leave recipient's medical emergency terminates—

(a) When his or her Federal service terminates;

(b) When he or she leaves the agency or participating organizational subunit, if the bank board so determines;

(c) At the end of the biweekly pay period in which the leave bank board receives written notice from the leave recipient or his or her personal representative that the leave recipient is no longer affected by a medical emergency;

(d) At the end of the biweekly pay period in which the leave bank board determines, after written notice from the bank board and an opportunity for the leave recipient (or, if appropriate, his or her personal representative) to answer orally or in writing, that the leave recipient is no longer affected by a medical emergency; or

(e) At the end of the biweekly pay period in which the employing agency receives notice that OPM has approved the leave recipient's application for disability retirement under the Civil Service Retirement System or the Federal Employees' Retirement System.

§ 630.1015 Restoration of unused leave to a leave bank.

(a) A leave bank board must ensure that annual leave withdrawn from the leave bank and not used before the termination of the medical emergency is returned to the leave bank.

(b) A leave bank board may deem a medical emergency to continue for the purpose of providing the leave recipient with an adequate period of time within which to receive contributions of annual leave.

(c) If a leave recipient elects to buy back annual leave as a result of a claim for an employment-related injury approved by the Office of Workers' Compensation Programs under 20 CFR part 10, and the annual leave was leave withdrawn from a leave bank under § 630.1012, the amount of annual leave bought back must be restored to the leave bank.

§ 630.1016 Participation in both the voluntary leave transfer and leave bank programs.

(a) If an agency or organizational subunit establishes a voluntary leave bank program under this subpart—

(1) A covered employee may also participate in a voluntary leave transfer program under subpart I of this part;

(2) Any annual leave previously transferred to an employee under the voluntary leave transfer program must remain to his or her credit if the employee later becomes a leave recipient in a leave bank and must become subject to the agency's policies and procedures for administering this subpart, except as provided in paragraphs (b) and (c) of this section; and

(3) The agency or organizational subunit must establish policies or procedures governing the use of donated or transferred leave if an employee receives leave under both a voluntary leave transfer program and a voluntary leave bank program for the same medical emergency.

(b) Upon termination of a medical emergency, any annual leave previously transferred under the voluntary leave transfer program and remaining to the employee's credit must be restored under § 630.921(a) through (d).

(c) Transferred annual leave restored to the account of a leave donor under paragraph (b) of this section is subject to the limitation imposed by 5 U.S.C. 6304(a) and (b) at the end of the leave year in which the annual leave is restored.

§ 630.1017 Transferring to a new leave bank.

If an employee moves from an agency or organizational subunit operating a leave bank to an agency or organizational subunit operating a different leave bank, the following procedures apply:

(a) On the date of the leave recipient's transfer, he or she becomes subject to the policies and procedures of the voluntary leave bank program of the new agency or organizational subunit; and

(b) Nothing in §§ 630.1014(b) or 630.1015(a) may interfere with the employee's right to submit an application to become a leave contributor or leave recipient under the policies and procedures of the voluntary leave bank program of the new agency or organizational subunit.

§ 630.1018 Transferring to an agency that does not have a leave bank.

If an employee moves from an agency or organizational subunit covered by a

voluntary leave bank program under this subpart to an agency or organizational subunit covered only by a voluntary leave transfer program under subpart I of this part, the following procedures apply:

(a) On the date of the employee's transfer, he or she becomes subject to the policies and procedures of the voluntary leave transfer program of the new agency or organizational subunit; and

(b) Nothing in §§ 630.1014(b) or 630.1015(a) may interfere with the employee's right to submit an application to become a leave donor or leave recipient under the voluntary leave transfer program of the new agency or organizational subunit.

§ 630.1019 Termination of a voluntary leave bank program.

(a) An agency may terminate a voluntary leave bank program only after providing at least 30 calendar days advance written notice to current leave bank members.

(b) If an agency terminates a voluntary leave bank program before the termination of the medical emergency affecting a leave bank recipient, annual leave transferred to the leave recipient must remain available for use under the rules set forth in subpart I of this part.

(c) If an agency terminates a voluntary leave bank program, the agency must make provisions for the timely and equitable distribution of any leave remaining in the leave bank. The agency may allocate the leave to current leave recipients, recredit the leave to the accounts of current voluntary leave bank members, or a combination of both. The agency may distribute the leave immediately or may delay the distribution, in whole or part, until the beginning of the following leave year.

§ 630.1020 Records.

Each agency must maintain records concerning the administration of the voluntary leave bank program.

Subpart K—Emergency Leave Transfer Program

§ 630.1101 Purpose.

This subpart provides regulations to implement 5 U.S.C. 6391, which authorizes the President to direct OPM to establish an emergency leave transfer program under which an employee may donate unused annual leave for transfer to employees of his or her agency or to employees in other executive agencies who are adversely affected by a major disaster or emergency, as declared by the President.

§ 630.1102 Coverage.

This subpart applies to any individual who is defined as an *employee* in 5 U.S.C. 6331(1) and who is employed in an executive agency.

§ 630.1103 Administration.

The head of each agency having employees subject to this subpart is responsible for the proper administration of this subpart. Each Federal agency must establish and administer procedures to permit the voluntary transfer of annual leave consistent with this subpart.

§ 630.1104 Definitions.

In this subpart:

Agency means an *executive agency*, as defined in 5 U.S.C. 105.

Disaster or emergency means a major disaster or emergency, as declared by the President, that results in severe adverse effects for a substantial number of employees (*e.g.*, loss of life or property, serious injury, or mental illness as a result of a direct threat to life or health).

Emergency leave donor means a current employee whose voluntary written request for transfer of annual leave to an emergency leave transfer program is approved by his or her employing agency.

Emergency leave recipient means a current employee for whom the employing agency has approved an application to receive annual leave under an emergency leave transfer program.

Emergency leave transfer program means a program established by OPM that permits Federal employees to transfer their unused annual leave to other Federal employees adversely affected by a disaster or emergency, as declared by the President.

Employee has the meaning given that term in 5 U.S.C. 6331(1).

Family member has the meaning given that term in § 630.903.

Leave year has the meaning given that term in § 630.201.

Paid leave status has the meaning given that term in § 630.903.

Transferred leave means donated leave credited to an approved emergency leave recipient's annual leave account.

§ 630.1105 Establishment of an emergency leave transfer program.

(a) When directed by the President, OPM will establish an emergency leave transfer program that permits an employee to donate his or her accrued annual leave to employees of the same or other executive agencies who are adversely affected by a major disaster or emergency that results in severe adverse effects for a substantial number of employees. In certain situations, OPM may delegate to an agency the authority to establish an emergency leave transfer program.

(b) OPM will notify agencies of the establishment of an emergency leave transfer program for a specific disaster or emergency, as declared by the President. Once notified, an agency affected by the disaster or emergency is authorized to do the following:

(1) Determine whether, and how much, donated annual leave is needed by affected employees;

(2) Approve emergency leave donors and/or emergency leave recipients within the agency, as appropriate;

(3) Facilitate the distribution of donated annual leave from approved emergency leave donors to approved emergency leave recipients within the agency; and

(4) Determine the period of time for which donated annual leave may be accepted for distribution to approved emergency leave recipients.

§ 630.1106 Donations from a leave bank to an emergency leave transfer program.

A leave bank established under 5 U.S.C. 6362 and subpart J of this part may, with the concurrence of the leave bank board established under § 630.1004, donate annual leave to an emergency leave transfer program administered by the employing agency.

§ 630.1107 Application to become an emergency leave recipient.

(a) An employee who has been adversely affected by a disaster or emergency may make written application to his or her employing agency to become an emergency leave recipient. If an employee is not capable of making written application, a personal representative may make written application on behalf of the employee.

(b) An employee who has a family member who has been adversely affected by a disaster or emergency also may make written application to his or her employing agency to become an emergency leave recipient. An emergency leave recipient may use donated annual leave to assist an affected family member, provided such family member has no reasonable access to other forms of assistance.

(c) For the purpose of this subpart, an employee is considered to be adversely affected by a major disaster or emergency if the disaster or emergency has caused the employee or a family member of the employee severe hardship to such a degree that his or her absence from work is required.

(d) The employee's application must be accompanied by the following information:

(1) The name, position title, and grade or pay level of the potential leave recipient;

(2) A statement describing his or her need for leave from the emergency leave transfer program; and

(3) Any additional information that may be required by the potential leave recipient's employing agency.

(e) An agency may determine a time period by which employees must apply to become an emergency leave recipient after the occurrence of a major disaster or emergency.

§ 630.1108 Approval of an application to become an emergency leave recipient.

An agency must review an application to become an emergency leave recipient under procedures the agency has established for the purpose of determining that a potential leave recipient is or has been affected by a major disaster or emergency.

§ 630.1109 Notification of approval of an application.

If an employee's application to become an emergency leave recipient is approved, the agency must notify the employee (or his or her personal representative) within 10 calendar days (excluding Saturdays, Sundays, and legal public holidays) after the date the application was received (or the date established by the agency, if that date is later).

§ 630.1110 Disapproval of an application to become an emergency leave recipient.

If an employee's application to become an emergency leave recipient is not approved, the employing agency must notify the employee (or his or her personal representative who made application on the employee's behalf) within 10 calendar days (excluding Saturdays, Sundays, and legal public holidays) after the date the application was received (or the date established by the agency, if that date is later). The agency must give the reasons for its disapproval.

§ 630.1111 Use of available paid leave.

An approved emergency leave recipient is not required to exhaust his or her accrued annual and sick leave before receiving donated leave under the emergency leave transfer program.

§ 630.1112 Donating annual leave.

An employee may voluntarily submit a written request to his or her agency that a specified number of hours of his or her accrued annual leave, consistent with the limitations in § 630.1113, be transferred from his or her annual leave account to an emergency leave transfer program established under § 630.1105. An emergency leave donor may not donate annual leave for transfer to a specific emergency leave recipient under this subpart. Any donated leave not used by an emergency leave recipient may not be returned to the emergency leave donor(s), except as provided in § 630.1120(a).

§ 630.1113 Limitation on the amount of leave donated by an emergency leave donor.

(a) An emergency leave donor may not contribute less than 1 hour nor more than 104 hours of annual leave in a leave year to an emergency leave transfer program. Each agency may establish written criteria for waiving the 104-hour limitation on donating annual leave in a leave year.

(b) Annual leave donated to an emergency leave transfer program may not be applied against the limitations on the donation of annual leave under the voluntary leave transfer or leave bank programs established under 5 U.S.C. 6332 and 6362, respectively.

§ 630.1114 Limitation on the amount of leave received by an emergency leave recipient.

An emergency leave recipient may receive a maximum of 240 hours of donated annual leave at any one time from an emergency leave transfer program for each disaster or emergency.

§ 630.1115 Transferring donated leave between agencies.

(a) If an agency does not receive sufficient amounts of donated annual leave to meet the needs of approved emergency leave recipients within the agency, the agency may contact OPM to obtain assistance in receiving donated leave from other agencies. The agency must notify OPM of the total amount of donated annual leave needed for transfer to the agency's approved emergency leave recipients. OPM will solicit and coordinate the transfer of donated annual leave from other Federal agencies to affected agencies who may have a shortfall of donated annual leave. OPM will determine the period of time for which donations of accrued annual leave may be accepted for transfer to affected agencies.

(b) Each Federal agency OPM contacts for the purpose of providing donated annual leave to an agency in need must—

(1) Approve emergency leave donors under the conditions specified in §§ 630.1112 and 630.1113 and determine how much donated annual leave is available for transfer to an affected agency;

(2) Report the total amount of annual leave donated to the emergency leave transfer program to OPM; and

(3) When OPM has accepted the donated annual leave, debit the amount of annual leave donated to the emergency leave transfer program from each emergency leave donor's annual leave account.

(c) OPM will notify each affected agency of the aggregate amount of donated annual leave that will be credited to it for transfer to its approved emergency leave recipient(s). The affected agency will determine the amount of donated annual leave to be transferred to each emergency leave recipient (an amount that may vary according to individual needs).

(d) The affected agency must credit the annual leave account of each approved emergency leave recipient as soon as possible after the date OPM notifies the agency of the amount of donated annual leave that will be credited to the agency under paragraph (c) of this section.

§ 630.1116 Using donated annual leave.

(a) Any donated leave an emergency leave recipient receives from an emergency leave transfer program may be used only for purposes related to the disaster or emergency for which the emergency leave recipient was approved. Each agency is responsible for ensuring that leave donated under the emergency leave transfer program is used appropriately.

(b) Annual leave transferred under this subpart may be—

(1) Substituted retroactively for any period of leave without pay used because of the adverse effects of the disaster or emergency; or

(2) Used to liquidate an indebtedness incurred by the emergency leave recipient for advanced annual or sick leave used because of the adverse effects of the disaster or emergency. The agency may advance annual or sick leave, as appropriate (even if the employee has available annual and sick leave), so that the emergency leave recipient is not forced to use his or her accrued leave before donated annual leave becomes available.

§ 630.1117 Accrual of leave while using donated leave.

While an emergency leave recipient is using donated annual leave from an emergency leave transfer program, annual and sick leave continue to accrue to the credit of the employee at the same rate as if he or she were in a paid leave status under 5 U.S.C. chapter

63, subchapter I, and will be subject to the limitations imposed by 5 U.S.C. 6304(a), (b), (c), and (f) at the end of the leave year in which the transferred annual leave is received.

§ 630.1118 Purposes for which donated leave may not be credited.

An agency may not—

(a) Include annual leave transferred under this subpart in a lump-sum payment under 5 U.S.C. 5551 or 5552;

(b) Recredit the annual leave transferred under this subpart to an employee who is reemployed by a Federal agency under 5 U.S.C. 6306; or

(c) Use annual leave transferred under this subpart to establish initial eligibility for immediate retirement or acquire eligibility to continue health benefits into retirement under 5 U.S.C. 6302(g) and § 630.214.

§ 630.1119 Termination of a disaster or emergency.

The disaster or emergency affecting the employee as an emergency leave recipient terminates—

(a) When the employing agency determines that the disaster or emergency has terminated;

(b) When the employee's Federal service terminates;

(c) At the end of the biweekly pay period in which the employee, or his or her personal representative, notifies the emergency leave recipient's agency that he or she is no longer affected by such disaster or emergency;

(d) At the end of the biweekly pay period in which the employee's agency determines, after giving the employee or his or her personal representative written notice and an opportunity to answer orally or in writing, that the employee is no longer affected by such disaster or emergency; or

(e) At the end of the biweekly pay period in which the employee's agency receives notice that OPM has approved an application for disability retirement for the emergency leave recipient under the Civil Service Retirement System or the Federal Employees' Retirement System, as appropriate.

§ 630.1120 Procedures for returning unused leave to emergency leave donors.

(a) When a disaster or emergency is terminated, any unused annual leave donated to an emergency leave transfer program must be returned to the emergency leave donors. The amount of remaining annual leave to be returned to each emergency leave donor must be proportional to the amount of annual leave donated by the employee to the emergency leave transfer program for such disaster or emergency. Annual leave donated to an emergency leave transfer program for a specific disaster or emergency may not be transferred to another emergency leave transfer program established for a different disaster or emergency.

(b) Each agency must establish procedures to return unused donated annual leave to emergency leave donors. Each agency must determine the amount of annual leave to be restored to each of the emergency leave donors who, on the date leave restoration is made, is employed by a Federal agency. If the total number of eligible leave donors exceeds the total number of hours of annual leave to be restored, no unused transferred annual leave will be restored. At the election of the emergency leave donor, the agency may restore unused annual leave to the emergency leave donor by—

(1) Crediting the restored annual leave to the emergency leave donor's annual leave account in the current leave year; or

(2) Crediting the restored annual leave to the emergency leave donor's annual leave account effective as of the 1st day of the following leave year.

§ 630.1121 Protection against coercion.

(a) An employee may not directly or indirectly intimidate, threaten, or coerce, or attempt to intimidate, threaten, or coerce, any emergency leave donor or emergency leave recipient for the purpose of interfering with any right such employee may have with respect to donating, receiving, or using annual leave under this subpart.

(b) For the purpose of paragraph (a) of this section, the term *intimidate, threaten, or coerce* includes promising to confer or conferring any benefit (such as appointment or promotion or compensation) or effecting or threatening to effect any reprisal (such as deprivation of appointment, promotion, or compensation).

Subpart L—Family and Medical Leave

§ 630.1201 Purpose.

This subpart provides regulations to implement 5 U.S.C. 6381 through 6387 and must be read together with those sections of law. Sections 6381 through 6387 of title 5, United States Code, entitle most Federal employees to a total of up to 12 administrative workweeks of unpaid leave during any 12-month period for certain family and medical needs, as specified in § 630.1205.

§ 630.1202 Coverage.

(a) Except as otherwise provided in this paragraph, this subpart applies to any *employee* who—

(1) Is defined as an *employee* in 5 U.S.C. 6301(2), excluding employees covered by paragraph (b) of this section; and

(2) Has completed at least 12 months of service as—

(i) An *employee*, as defined in 5 U.S.C. 6301(2), excluding any service as an employee under paragraph (b) of this section;

(ii) An employee of the Veterans Health Administration appointed under title 38, United States Code, in occupations listed in 38 U.S.C. 7401(1);

(iii) A *teacher* or an individual holding a *teaching position*, as defined in 20 U.S.C. 901; or

(iv) An *employee* identified in 5 U.S.C. 2105(c) who is paid from nonappropriated funds.

(b) This subpart does not apply to—

(1) An individual employed by the government of the District of Columbia;

(2) An employee serving under a temporary appointment with a time limitation of 1 year or less;

(3) An employee on an intermittent work schedule as defined in § 630.201; or

(4) Any employee covered by Title I or Title V of the Family and Medical Leave Act of 1993 (Pub. L. 103–3, February 5, 1993). The Department of Labor has issued regulations implementing Title I at 29 CFR part 825.

(c) For the purpose of applying 5 U.S.C. 6381 through 6387—

(1) An employee of the Veterans Health Administration appointed under title 38, United States Code, in occupations listed in 38 U.S.C. 7401(1) must be governed by the terms and conditions of regulations prescribed by the Secretary of Veterans Affairs;

(2) A *teacher* or an individual holding a *teaching position*, as defined in 20 U.S.C. 901, must be governed by the terms and conditions of regulations prescribed by the Secretary of Defense; and

(3) An employee identified in 5 U.S.C. 2105(c) who is paid from nonappropriated funds must be governed by the terms and conditions of regulations prescribed by the Secretary of Defense or the Secretary of Transportation, as appropriate.

(d) The regulations prescribed by the Secretary of Veterans Affairs, the Secretary of Defense, or the Secretary of Transportation under paragraph (c) of this section must, to the extent appropriate, be consistent with the regulations prescribed in this subpart and the regulations prescribed by the Secretary of Labor to carry out Title I of the Family and Medical Leave Act of 1993 at 29 CFR part 825.

§ 630.1203 Administration.

The head of an agency having employees subject to this subpart is

responsible for the proper administration of family and medical leave.

§ 630.1204 Definitions.

In this subpart:

Accrued leave has the meaning given that term in § 630.201.

Accumulated leave has the meaning given that term in § 630.201.

Administrative workweek has the meaning given that term in 5 CFR 610.102.

Adoption refers to a legal process in which an individual becomes the legal parent of another's child. The source of an adopted child—*e.g.*, whether from a licensed placement agency or otherwise—is not a factor in determining eligibility for leave under this subpart.

Employee means an individual to whom this subpart applies.

Essential functions means the fundamental job duties of the employee's position, as defined in 29 CFR 1630.2(n). An employee who must be absent from work to receive medical treatment for a serious health condition is considered to be unable to perform the essential functions of the position during the absence for treatment.

Family and medical leave means an employee's entitlement to up to 12 administrative workweeks of unpaid leave for certain family and medical needs, as prescribed in 5 U.S.C. 6381 through 6387.

Foster care means 24-hour care for children in substitution for, and away from, their parent(s) or guardian. Such placement is made by or with the agreement of the State as a result of a voluntary agreement by the parent(s) or guardian that the child be removed from the home, or pursuant to a judicial determination of the necessity for foster care, and involves agreement between the State and foster family to take the child. Although foster care may be with relatives of the child, State action is involved in the removal of the child from parental custody.

Health care provider means—

(1) A licensed Doctor of Medicine or Doctor of Osteopathy or a physician who is serving on active duty in the uniformed services and is designated by the uniformed service to conduct examinations under this subpart;

(2) Any health care provider recognized by the Federal Employees Health Benefits Program or who is licensed or certified under Federal or State law to provide the service in question;

(3) A health care provider as defined in paragraph (2) of this definition who practices in a country other than the United States, who is authorized to practice in accordance with the laws of that country, and who is performing within the scope of his or her practice as defined under such law;

(4) A Christian Science practitioner listed with the First Church of Christ, Scientist, in Boston, Massachusetts; or

(5) A Native American, including an Eskimo, Aleut, and Native Hawaiian, who is recognized as a traditional healing practitioner by native traditional religious leaders and who practices traditional healing methods as believed, expressed, and exercised in Indian religions of the American Indian, Eskimo, Aleut, and Native Hawaiians, consistent with Public Law 95–341, August 11, 1978 (92 Stat. 469), as amended by Public Law 103–344, October 6, 1994 (108 Stat. 3125).

In loco parentis refers to the situation of an individual who has day-to-day responsibility for the care and financial support of a child or, in the case of an employee, who had such responsibility for the employee when the employee was a child. A biological or legal relationship is not necessary.

Incapacity means the inability to work, attend school, or perform other regular daily activities because of a serious health condition or treatment for or recovery from a serious health condition.

Intermittent leave or leave taken intermittently means leave taken in separate blocks of time, rather than for one continuous period of time, and may include leave periods of 1 hour to several weeks. Leave may be taken for a period of less than 1 hour if an agency policy provides for a minimum charge for leave of less than 1 hour under § 630.209.

Leave without pay means an absence from duty in a nonpay status. Leave without pay may be taken only for those hours of duty comprising an employee's basic workweek.

Parent means a biological parent or an individual who stands or stood *in loco parentis* to an employee when the employee was a son or daughter. This term does not include parents "in law."

Reduced leave schedule means a work schedule under which the usual number of hours of regularly scheduled work per workday or workweek of an employee is reduced. The number of hours by which the daily or weekly tour of duty is reduced are counted as leave for this purpose.

Regularly scheduled has the meaning given that term in 5 CFR 610.102.

Regularly scheduled administrative workweek has the meaning given that term in 5 CFR 610.102.

Serious health condition. (1) Serious health condition means an illness, injury, impairment, or physical or mental condition that involves—

(i) Inpatient care (*i.e.*, an overnight stay) in a hospital, hospice, or residential medical care facility, including any period of incapacity or any subsequent treatment in connection with such inpatient care; or

(ii) Continuing treatment by a health care provider that includes (but is not limited to) examinations to determine if there is a serious health condition and evaluations of such conditions if the examinations or evaluations determine that a serious health condition exists. Continuing treatment by a health care provider may include one or more of the following—

(A) A period of incapacity of more than 3 consecutive calendar days, including any subsequent treatment or period of incapacity relating to the same condition, that also involves—

(*1*) Treatment two or more times by a health care provider, by a health care provider under the direct supervision of the affected individual's health care provider, or by a provider of health care services under orders of, or on referral by, a health care provider; or

(*2*) Treatment by a health care provider on at least one occasion which results in a regimen of continuing treatment under the supervision of the health care provider (*e.g.*, a course of prescription medication or therapy requiring special equipment to resolve or alleviate the health condition).

(B) Any period of incapacity due to pregnancy or childbirth, or for prenatal care, even if the affected individual does not receive active treatment from a health care provider during the period of incapacity or the period of incapacity does not last more than 3 consecutive calendar days.

(C) Any period of incapacity or treatment for such incapacity due to a chronic serious health condition that—

(*1*) Requires periodic visits for treatment by a health care provider or by a health care provider under the direct supervision of the affected individual's health care provider,

(*2*) Continues over an extended period of time (including recurring episodes of a single underlying condition); and

(*3*) May cause episodic rather than a continuing period of incapacity (*e.g.*, asthma, diabetes, or epilepsy). The condition is covered even if the affected individual does not receive active treatment from a health care provider during the period of incapacity or the period of incapacity does not last more than 3 consecutive calendar days.

(D) A period of incapacity which is permanent or long-term because of a condition for which treatment may not be effective. The affected individual must be under the continuing supervision of, but need not be receiving active treatment by, a health care provider (*e.g.*, Alzheimer's disease, severe stroke, or the terminal stages of a disease).

(E) Any period of absence to receive multiple treatments (including any period of recovery) by a health care provider or by a provider of health care services under orders of, or on referral by, a health care provider, either for restorative surgery after an accident or other injury or for a condition that would likely result in a period of incapacity of more than 3 consecutive calendar days in the absence of medical intervention or treatment (*e.g.*, chemotherapy/radiation for cancer, physical therapy for severe arthritis, or dialysis for kidney disease).

(2) *A serious health condition* does not include routine physical, optical, or dental examinations; a regimen of continuing treatment that includes the taking of over-the-counter medications, bed-rest, exercise, and other similar activities that can be initiated without a visit to a health care provider; a condition for which cosmetic treatments are administered, unless inpatient hospital care is required or unless complications develop; or an absence because of an employee's use of an illegal substance, unless the employee is receiving treatment for substance abuse by a health care provider or by a provider of health care services on referral by a health care provider. Ordinarily, unless complications arise, the common cold, the flu, earaches, upset stomach, minor ulcers, headaches (other than migraines), routine dental or orthodontia problems, and periodontal disease are not serious health conditions. Allergies, restorative dental or plastic surgery after an injury, removal of a cancerous growth, or mental illness resulting from stress may be serious health conditions only if such conditions require inpatient care or continuing treatment by a health care provider.

Son or daughter means a biological, adopted, or foster child; a step child; a legal ward; or a child of a person standing *in loco parentis* who is—

(1) Under 18 years of age; or

(2) 18 years of age or older and incapable of self-care because of a mental or physical disability. A son or daughter incapable of self-care requires active assistance or supervision to provide daily self-care in three or more of the "activities of daily living" (ADLs) or "instrumental activities of daily living" (IADLs). Activities of daily living include adaptive activities such as caring appropriately for one's grooming and hygiene, bathing, dressing, and eating. Instrumental activities of daily living include cooking, cleaning, shopping, taking public transportation, paying bills, maintaining a residence, using the telephone and directories, and using a post office. A "physical or mental disability" refers to a physical or mental impairment that substantially limits one or more of the major life activities of an individual as defined in 29 CFR 1630.2 (h), (i) and (j).

Spouse means an individual who is a husband or wife pursuant to a marriage that is a legal union between one man and one woman, including common law marriage between one man and one woman in States where it is recognized.

Tour of duty has the meaning given that term in 5 CFR 610.102.

§ 630.1205 Entitlement to family and medical leave.

An employee is entitled to a total of up to 12 administrative workweeks of unpaid leave during any 12-month period for one or more of the following reasons:

(a) The birth of his or her son or daughter and the care of such son or daughter;

(b) The placement of a son or daughter with the employee for adoption or foster care;

(c) The care of a spouse, son or daughter, or parent, if such spouse, son or daughter, or parent has a serious health condition; or

(d) The employee's own serious health condition that makes him or her unable to perform any one or more of the essential functions of his or her position.

§ 630.1206 Procedures for invoking entitlement to family and medical leave.

An employee must invoke his or her entitlement to family and medical leave under § 630.1205, subject to the notification and medical certification requirements in §§ 630.1213 through 630.1216. An employee may not retroactively invoke his or her entitlement to family and medical leave. However, if the employee and his or her personal representative are physically or mentally incapable of invoking his or her entitlement to FMLA leave *during the entire period* in which the employee is absent from work for an FMLA-qualifying purpose under § 630.1205, the employee may retroactively invoke his or her entitlement to FMLA leave within 2 workdays after returning to work. In such cases, the employee's incapacity must be documented by a written medical certification from a health care provider. In addition, the employee must provide documentation acceptable to his or her agency explaining the inability of his or her personal representative to contact the agency and invoke his or her entitlement to FMLA leave during the entire period the employee was absent from work for an FMLA-qualifying purpose. An employee may take only the amount of family and medical leave necessary to manage the circumstances that prompted the need for leave under § 630.1205.

§ 630.1207 Calculating the 12-month period.

(a) An agency must calculate the 12-month period referred to in § 630.1205 beginning on the date the employee first takes leave for a family or medical need specified in § 630.1205 and continuing for 12 months. An employee is not entitled to 12 additional workweeks of leave until the previous 12-month period ends and an event or situation occurs that entitles him or her to another period of family or medical leave. (This may include a continuation of a previous situation or circumstance.)

(b) The entitlement to leave under § 630.1205(a) and (b) expires at the end of the 12-month period beginning on the date of birth or placement. Leave for a birth or placement must be concluded within this 12-month period. Leave taken under § 630.1205(a) and (b), may begin prior to or on the actual date of birth or placement for adoption or foster care, and the 12-month period referred to in paragraph (a) of this section begins on that date.

§ 630.1208 Calculating 12 administrative workweeks of family and medical leave.

(a) An agency must make available a total of up to 12 administrative workweeks equally for full-time or part-time employees in direct proportion to the number of hours in their regularly scheduled administrative workweeks. An agency must calculate the 12 administrative workweeks of leave on an hourly basis, and the 12 administrative workweeks must equal 12 times the average number of hours in the employee's regularly scheduled administrative workweek. If the number of hours in the employee's workweek varies from week to week, the agency must use a weekly average of the hours scheduled over the 12 weeks prior to the date leave commences for this calculation. An agency may not count toward the 12-week entitlement to family and medical leave any holidays

authorized under 5 U.S.C. 6103 or by Executive order or nonworkdays established by Federal statute, Executive order, or administrative order that occur during the period in which the employee is on family and medical leave.

(b) If the number of hours in an employee's regularly scheduled administrative workweek is changed during the 12-month period of family and medical leave, the agency must recalculate the employee's entitlement to any remaining family and medical leave based on the number of hours in the employee's current regularly scheduled administrative workweek.

§ 630.1209 Agency obligation.

An agency must inform all employees of their entitlements and responsibilities under this subpart, including the employees' requirements and obligations.

§ 630.1210 Involuntary placement on family and medical leave.

An agency may not place an employee on family and medical leave and may not subtract leave from his or her entitlement to leave under § 630.1205 unless the agency has obtained confirmation from the employee of his or her intent to invoke his or her entitlement to leave under § 630.1206. The employee's notice of his or her intent to take leave under § 630.1213 may suffice as his or her confirmation.

§ 630.1211 Intermittent use of family and medical leave.

(a) An employee may not take leave under § 630.1205(a) or (b) (leave for childbirth or adoption) intermittently or on a reduced leave schedule unless the employee and his or her agency agree to do so.

(b) An employee may take leave under § 630.1205(c) or (d) intermittently or on a reduced leave schedule when medically necessary, subject to the notification and medical certification requirements in §§ 630.1213 and 630.1215(f).

(c) If an employee takes leave under § 630.1205(c) or (d) intermittently or on a reduced leave schedule that is foreseeable based on planned medical treatment or recovery from a serious health condition, his or her agency may place the employee temporarily in an available alternative position for which he or she is qualified and which can better accommodate recurring periods of leave. Upon returning from leave, the employee is entitled to be returned to his or her permanent position or an equivalent position, as provided in § 630.1222.

(d) For the purpose of applying paragraph (c) of this section, an alternative position need not consist of equivalent duties, but must be in the same commuting area and must provide—

(1) An equivalent grade or pay level, including any applicable locality-based comparability payment under 5 U.S.C. 5304; special rate of pay for law enforcement officers or special pay adjustment for law enforcement officers under section 403 or 404 of the Federal Employees Pay Comparability Act of 1990 (Pub. L. 101–509), respectively; continued rate of pay under 5 CFR part 531; or special salary rate under 5 U.S.C. 5305 or similar provision of law;

(2) The same type of appointment, work schedule, status, and tenure; and

(3) The same employment benefits made available to the employee in his or her previous position (*e.g.*, life insurance, health benefits, retirement coverage, and leave accrual).

(e) An agency must determine the available alternative position that has equivalent pay and benefits consistent with Federal laws, including the Rehabilitation Act of 1973 (29 U.S.C. 701) and the Pregnancy Discrimination Act of 1978 (42 U.S.C. 2000e).

(f) Only the amount of leave taken intermittently or on a reduced leave schedule may be subtracted from the total amount of leave available to an employee under § 630.1208 (a) and (b).

§ 630.1212 Substitution of paid leave for unpaid family and medical leave.

(a) Except as provided in paragraph (b) of this section, leave taken under § 630.1205 must be leave without pay.

(b) An employee may elect to substitute the following paid leave for any or all of the period of leave without pay that may be taken under § 630.1205:

(1) Accrued or accumulated annual or sick leave under 5 U.S.C. 6302–6304 and 6307, consistent with current law and regulations governing the granting and use of annual or sick leave;

(2) Advanced annual or sick leave approved under the same terms and conditions that apply to any other agency employee who requests advanced annual or sick leave; and

(3) Leave made available to an employee under the voluntary leave transfer program or the voluntary leave bank program consistent with subparts I and J of this part.

(c) An agency may not deny an employee's right to substitute paid leave under paragraph (b) of this section for any or all of the period of leave without pay to be taken under § 630.1205, consistent with current laws and regulations governing the granting and use of annual and sick leave.

(d) An agency may not require an employee to substitute paid leave under paragraph (b) of this section for any or all of the period of leave without pay to be taken under § 630.1205.

(e) An employee must notify his or her agency of his or her intent to substitute paid leave under paragraph (b) of this section for the period of leave without pay to be taken under § 630.1205 prior to the date such paid leave begins. An employee may not retroactively substitute paid leave for leave without pay previously taken under § 630.1205, except as provided in §§ 630.914(d) and 630.1012(d).

§ 630.1213 Notification of intent to invoke entitlement to family and medical leave.

(a) If leave taken under § 630.1205 is foreseeable based on an expected birth, placement for adoption or foster care, or planned medical treatment, an employee must provide notice to the agency of his or her intent to take leave not less than 30 calendar days before the date the leave is to begin. If the date of birth or placement or planned medical treatment requires leave to begin within 30 calendar days, the employee must provide such notice as is practicable.

(b) If leave taken under § 630.1205(c) or (d) is foreseeable based on planned medical treatment, an employee must consult with his or her agency and make a reasonable effort to schedule medical treatment so as not to disrupt unduly the operations of his or her agency, subject to the approval of the health care provider. An employee's agency may, for justifiable cause, request that he or she reschedule medical treatment, subject to the approval of the health care provider.

(c) If the need for leave is not foreseeable—*e.g.*, because of a medical emergency or the unexpected availability of a child for adoption or foster care—and the employee cannot provide 30 calendar days' notice of his or her need for leave, the employee must provide notice within a reasonable period of time appropriate to the circumstances involved. If necessary, notice may be given by his or her personal representative (*e.g.*, a family member or other responsible party). If the need for leave is not foreseeable and the employee is unable, because of circumstances beyond his or her control, to provide notice of his or her need for leave, the agency may not delay or deny the requested leave.

(d) If the need for leave is foreseeable and an employee fails to give 30 calendar days' notice with no reasonable excuse for the delay of

notification, his or her agency may delay the taking of leave under § 630.1205 until at least 30 calendar days after the date the employee provides notice of his or her need for family and medical leave.

(e) An agency may waive the notification requirements under paragraph (a) of this section and instead impose the agency's usual and customary policies or procedures for providing notification of leave. The agency's policies or procedures for providing notification of leave must not be more stringent than the requirements of this section. However, an agency may not deny an employee's entitlement to leave under § 630.1205 if the employee fails to follow such agency policies or procedures.

(f) An agency may require that a request for leave under § 630.1205(a) and (b) (for childbirth or adoption) be supported by evidence that is administratively acceptable to the agency.

§ 630.1214 Medical certification of a serious health condition.

(a) An agency may require that a request for leave for a serious health condition under § 630.1205(c) or (d) be supported by written medical certification issued by the employee's health care provider or the health care provider of his or her spouse, son or daughter, or parent, as appropriate. An agency may waive the requirement for an initial medical certificate for a serious health condition in a subsequent 12-month period if the leave under § 630.1205(c) or (d) is for the same chronic or continuing condition.

(b) If an employee is unable to provide the requested medical certification before leave begins, or if the agency questions the validity of the original certification the employee provides and the medical treatment requires the leave to begin, the agency must grant provisional leave pending final written medical certification.

(c) If, after the leave has commenced, the employee fails to provide the requested medical certification, the agency may—

(1) Charge the employee as absent without leave (AWOL); or

(2) Allow the employee to request that the provisional leave be charged as leave without pay or charged to his or her annual and/or sick leave account, as appropriate.

§ 630.1215 Contents of a medical certification.

A written medical certification must include—

(a) The date the serious health condition commenced;

(b) The probable duration of the serious health condition or a specific indication that the serious health condition is a chronic or continuing condition with an unknown duration, including a finding that the patient is presently incapacitated, and the likely duration and frequency of episodes of incapacity;

(c) The appropriate medical facts within the knowledge of the health care provider regarding the serious health condition, including a general statement as to the incapacitation, examination, or treatment that may be required by a health care provider;

(d) If an employee is taking leave under § 630.1205(c)—

(1) A statement from the health care provider that the employee's spouse, son or daughter, or parent requires psychological comfort and/or physical care; needs assistance for basic medical, hygienic, nutritional, safety, or transportation needs or in making arrangements to meet such needs; and would benefit from his or her care or presence; and

(2) A statement from the employee on the care he or she will provide and an estimate of the amount of time needed to care for his or her spouse, son or daughter, or parent;

(e) If an employee is taking leave under § 630.1205(d), a statement that the employee requires medical treatment for a serious health condition or is unable to perform one or more of the essential functions of his or her position, based on written information provided by the employee's agency on the essential functions of his or her position or, if not provided, discussion with the employee about the essential functions of his or her position; and

(f) In the case of certification for intermittent leave or leave on a reduced leave schedule under § 630.1205(c) or (d) for planned medical treatment—

(1) A certification of the dates (actual or estimated) on which such treatment is expected to be given, the duration of such treatment, and the period of recovery, if any; or

(2) A certification that the serious health condition is a chronic or continuing condition with an unknown duration, specifying whether the patient is presently incapacitated and stating the likely duration and frequency of episodes of incapacity.

§ 630.1216 Limitations on the medical certification.

The information an employee must provide in the written medical certification must relate only to the serious health condition for which the current need for family and medical leave exists. An agency may not require any personal or confidential information in the written medical certification other than that required by § 630.1215. If an employee submits a completed medical certification signed by a health care provider, his or her agency may not request new information from the health care provider. However, a health care provider representing the agency, including a health care provider employed by the agency or under its administrative oversight, may contact the health care provider who completed the medical certification, with the employee's permission, for the purpose of clarifying the medical certification.

§ 630.1217 Second and third opinions on a serious health condition.

(a) If an agency questions the validity of the original medical certification that an employee provided under § 630.1214, the agency may require, at its expense, that the employee obtain the opinion of a second health care provider designated or approved by the agency concerning the information certified under §§ 630.1214 and 630.1215. The agency may not designate or approve any health care provider who is employed by the agency or is under its administrative oversight on a regular basis unless the agency is located in an area where access to health care is extremely limited—*e.g.*, a rural area or an overseas location where no more than one or two health care providers practice in the relevant specialty, or the only health care providers available are employed by the agency.

(b) If the opinion of the second health care provider differs from the original certification provided under § 630.1214, an agency may require, at its expense, that the employee obtain the opinion of a third health care provider designated or approved jointly by the employee and his or her agency concerning the information certified under § 630.1215. The opinion of the third health care provider is binding on the employee and the agency.

(c) To remain entitled to family and medical leave under § 630.1205(c) or (d), the employee or his or her spouse, son or daughter, or parent must comply with any requirement from the agency that the employee or his or her spouse, son or daughter, or parent submit to examination (though not treatment) to obtain a second or third medical certification from a health care provider other than the individual's health care provider.

§ 630.1218 Time limits for providing medical certification.

An employee must provide the written medical certification required by §§ 630.1214, 630.1215, and 630.1217, signed by the health care provider, no later than 15 calendar days after the date his or her agency requests such medical certification. If it is not practicable under the particular circumstances to provide the requested medical certification no later than 15 calendar days after the date requested by the agency despite the employee's diligent, good faith efforts, he or she must provide the medical certification within a reasonable period of time under the circumstances involved, but no later than 30 calendar days after the date the agency requests such medical certification.

§ 630.1219 Periodic recertification of a serious health condition.

An agency may require that an employee obtain subsequent medical recertification on a periodic basis, but not more than once every 30 calendar days, for leave taken for purposes relating to pregnancy, chronic conditions, or long-term conditions, as these terms are used in the definition of *serious health condition* in § 630.1204. For leave taken for all other serious health conditions, including leave taken on an intermittent or reduced leave schedule, if the health care provider has specified on the medical certification a minimum duration of the period of incapacity, his or her agency may not request recertification until that period has passed. However, the agency may require subsequent medical recertification more frequently than once every 30 calendar days, or more frequently than the minimum duration of the period of incapacity specified on the medical certification, if the employee requests that the original leave period be extended, the circumstances described in the original medical certification have changed significantly, or the agency receives information that casts doubt upon the continuing validity of the medical certification. The agency must pay for any periodic recertification it requires.

§ 630.1220 Protection of confidentiality.

To ensure the security and confidentiality of any written medical certification under §§ 630.1214, 630.1215, 630.1217 or 630.1224, the medical certification must be subject to the provisions for safeguarding information about individuals under 5 CFR part 293 or subpart A of this part.

§ 630.1221 Employee protections upon return to work.

If an employee takes family and medical leave under § 630.1205, he or she is entitled, upon return to his or her agency, to be returned to —

(a) The same position the employee held when the leave commenced; or

(b) An equivalent position with equivalent benefits, pay, status, and other terms and conditions of employment.

§ 630.1222 Equivalent position upon return to work.

(a) An equivalent position under § 630.1221(b) must be in the same commuting area and must carry or provide, at a minimum—

(1) The same or substantially similar duties and responsibilities, which must entail substantially equivalent skill, effort, responsibility, and authority;

(2) An equivalent grade or pay level, including any applicable locality-based comparability payment under 5 U.S.C. 5304; special rate of pay for law enforcement officers or special pay adjustment for law enforcement officers under section 403 or 404 of the Federal Employees Pay Comparability Act of 1990 (Pub. L. 101–509), respectively; continued rate of pay under 5 CFR part 531, subpart G; or special salary rate under 5 U.S.C. 5305 or similar provision of law;

(3) The same type of appointment, work schedule, status, and tenure;

(4) The same employment benefits made available to the employee in his or her previous position (*e.g.*, life insurance, health benefits, retirement coverage, and leave accrual);

(5) The same or equivalent opportunity for a within-grade increase, performance award, incentive award, or other similar discretionary and non-discretionary payments, consistent with applicable laws and regulations. However, the entitlement to be returned to an equivalent position does not extend to intangible or unmeasurable aspects of the job;

(6) The same or equivalent opportunity for premium pay consistent with applicable law and regulations under 5 CFR part 550, subpart A, or 5 CFR part 551, subpart E; and

(7) The same or equivalent opportunity for training or education benefits consistent with applicable laws and regulations, including any training the employee may be required to complete to qualify for his or her previous position.

(b) For the purpose of applying paragraph (c) of this section, the same entitlements and limitations in law and regulations that apply to the position, pay, benefits, status, and other terms and conditions of employment of an employee in a leave without pay status must apply when an employee is on leave without pay under this subpart, except where different entitlements and limitations are specifically provided in this subpart.

(c) An employee is not entitled to be returned to the same or equivalent position under paragraph (a) of this section if he or she would not otherwise have been employed in that position at the time he or she returns from leave.

(d) An agency may not return an employee to an equivalent position where written notification has been provided that the equivalent position will be affected by a reduction in force if the employee's previous position is not affected by a reduction in force.

§ 630.1223 Medical certification of fitness to return to work.

(a) An agency may establish, as a condition for returning to work for employees who take leave for a serious health condition under § 630.1205(d), a uniformly applied practice or policy that requires an employee, and all similarly-situated employees (*i.e.*, in the same occupation, with the same serious health condition), to obtain written medical certification from his or her health care provider that the employee is able to perform the essential functions of his or her position. An agency may delay an employee's return until the medical certification is provided. The same conditions for verifying the adequacy of a medical certification in § 630.1216 apply to the medical certification to return to work. An agency may not require a second or third opinion on the medical certification to return to work. An agency may not require a medical certification to return to work during the period the employee takes leave intermittently or under a reduced leave schedule under § 630.1211.

(b) If an agency requires an employee to obtain written medical certification under paragraph (a) of this section before he or she returns to work, the agency must notify the employee of this requirement before leave commences, or as soon as practicable in emergency medical situations, and pay the expenses for obtaining the written medical certification. An employee's refusal or failure to provide written medical certification under paragraph (a) of this section may be grounds for appropriate disciplinary or adverse action, as provided in 5 CFR part 752.

§ 630.1224 Intent to return to work.

An agency may require that an employee report periodically on his or her status and his or her intent to return to work. An agency's policy requiring such reports must take into account all of the relevant facts and circumstances of the employee's situation.

§ 630.1225 Adverse actions.

An employee's decision to invoke FMLA leave under § 630.1205 does not prohibit an agency from proceeding with appropriate actions under 5 CFR part 432 or 5 CFR part 752.

§ 630.1226 Denial of family and medical leave.

If an employee does not comply with the notification requirements in § 630.1213 and does not provide medical certification signed by the health care provider that includes all of the information required in § 630.1215 within the time limits prescribed in § 630.1218, he or she is not entitled to family and medical leave.

§ 630.1227 Continuation of health benefits.

If an employee is enrolled in a health benefits plan under the Federal Employees Health Benefits Program (established under 5 U.S.C. chapter 89) and is in a leave without pay status as a result of using his or her entitlement to family and medical leave under § 630.1205, he or she may continue his or her health benefits enrollment while in the leave without pay status and arrange to pay the appropriate employee contributions into the Employees Health Benefits Fund (established under 5 U.S.C. 8909). The employee must make such contributions consistent with 5 CFR 890.502.

§ 630.1228 Greater leave entitlements.

(a) An agency must comply with any collective bargaining agreement and any agency employment benefit program or plan that provides greater family or medical leave entitlements to an employee than those provided under this subpart. Nothing in this subpart prevents an agency from amending such policies, provided the policies comply with the requirements of this subpart.

(b) Any collective bargaining agreement or any employee benefit program or plan may not diminish the entitlements established for employees under this subpart.

(c) An agency may adopt leave policies more generous than those provided in this subpart, except that such policies may not provide entitlement to paid time off in an amount greater than that otherwise authorized by law or provide sick leave in any situation in which sick leave would not normally be allowed by law or regulation.

(d) The entitlements under 5 U.S.C. 6381 through 6387 and this subpart do not modify or affect any Federal law prohibiting discrimination. If the entitlements under 5 U.S.C. 6381 through 6387 and this subpart conflict with any Federal law prohibiting discrimination, an agency must comply with whichever statute provides greater entitlements to employees.

§ 630.1229 Records on the use of family and medical leave.

(a) An agency must maintain records of the amount of family and medical leave used by an employee under § 630.1205. The records must be sufficient to ensure that employees do not exceed the entitlement to 12 administrative workweeks within a 12 month period as described in § 630.1207.

(b) When an employee transfers to a different agency, the losing agency must provide the gaining agency with information on family and medical leave taken under § 630.1205 by the employee during the 12 months prior to the date of transfer. The losing agency must provide the following information:

(1) The beginning and ending dates of the employee's 12-month period, as determined under § 630.1207; and

(2) The number of hours of leave taken under § 630.1205 of the subpart during the employee's 12-month period.

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Part V

Department of Labor

Occupational Safety and Health Administration

29 CFR Parts 1910, 1915, and 1926
Standards Improvement Project-Phase II; Final Rule

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1910, 1915, and 1926

[Docket No. S–778–A]

RIN 1218–AB 81

Standards Improvement Project-Phase II

AGENCY: Occupational Safety and Health Administration, Labor.

ACTION: Final rule.

SUMMARY: The Occupational Safety and Health Administration (OSHA) through this final rule is continuing to remove and revise provisions of its standards that are outdated, duplicative, unnecessary, or inconsistent, or can be clarified or simplified by being written in plain language. The Agency completed Phase I of the Standards Improvement Project in June 1998. In this Phase II of the Standards Improvement Project, OSHA is again revising or removing a number of health provisions in its standards for general industry, shipyard employment, and construction. The Agency believes that the changes streamline and make more consistent the regulatory requirements in OSHA health and safety standards. In some cases, OSHA has made substantive revisions to requirements because they are outdated, duplicative, unnecessary, or inconsistent with more recently promulgated health standards. The Agency believes these revisions will reduce regulatory requirements for employers without reducing employee protection.

DATES: The final rule becomes effective March 7, 2005.

ADDRESSES: In accordance with 28 U.S.C. 2112(a), the Agency designates the Associate Solicitor of Labor for Occupational Safety and Health, Office of the Solicitor of Labor, Room S–4004, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, to receive petitions for review of the final rule.

FOR FURTHER INFORMATION CONTACT: Michael Seymour, Director, Office of Physical Hazards (202) 693–1950. For additional copies of this **Federal Register** document: OSHA, Office of Publications, Room N–3101, U. S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 (telephone: (202) 693–1888). Electronic copies of this **Federal Register** document, as well as news releases and other relevant documents, are available at OSHA's homepage at *http://www.osha.gov*.

SUPPLEMENTARY INFORMATION: References to comments and testimony in the rulemaking record are found throughout the text of the preamble. Comments are identified by an assigned exhibit number as follows: "Ex. 5–1" means Exhibit 5–1 in Docket S–778–A. For quoted material in the preamble, the page number where the quote can be located is included if other than page one. The transcript of the public hearing is cited by the page number as follows: Tr. 59. A list of the exhibits, copies of the exhibits and transcripts of the hearing are available in the OSHA Docket Office under Docket S–778–A and at OSHA's homepage.

I. Background

OSHA has made a continuing effort to eliminate confusing, outdated, and duplicative standards and regulations. In 1978, 1984, and again in 1996, the Agency conducted revocation and revision projects that resulted in the elimination of hundreds of unnecessary provisions.

In 1996, OSHA proposed Phase I of the Standards Improvement Project which set forth changes to a number of provisions in regulations and standards that were outdated, duplicative, unnecessary, inconsistent, or could be clarified or simplified by being rewritten in plain language (61 FR 37849, July 22, 1996). In 1998, OSHA published the final rule, Phase I of the Standards Improvement Project (63 FR 33450, June 19, 1998). Substantive changes were made under section 6(b) generally and under 6(b)(7) of the Occupational Safety and Health Act of 1970 which provides that:

> The Secretary, in consultation with the Secretary of Health, Education, and Welfare, may by rule promulgated pursuant to section 553 of title 5, United States Code, make appropriate modifications in the requirements relating to the use of labels or other forms of warning, monitoring or measuring, and medical examinations, as may be warranted by experience, information, or medical or technological developments acquired subsequent to the promulgation of the relevant standard.

The Agency believed that the revisions to its health and safety standards in that final rule reduce the regulatory burden of employers enhancing compliance while maintaining the safety and health protection afforded to employees.

In a related effort in 1996, OSHA published a proposal to revise Means of Egress, subpart E of part 1910 (61 FR 47712, September 10, 1996). OSHA proposed to rewrite the existing requirements in plain language so that the requirements would be easier to understand by employers, employees and others who use them. The proposal did not intend to change the regulatory obligations of employers or the safety and health protection provided to employees, only to simplify the standard. The final rule was published on November 7, 2002 (67 FR 67949). OSHA believed it accomplished the goals of maintaining the safety and health protections provided to employees without increasing the regulatory burden on employers, creating a regulation that is easily understood, and stating employers' obligations in performance-oriented language to the extent possible. As a consequence of these changes, the Agency believes it has made subpart E more user-friendly to employees and employers. Compliance is generally improved when employers and employees fully understand a regulation.

As a result of the Phase I Standards Improvement Project rulemaking, the Agency identified itself or through public comment other regulatory provisions that could be removed or revised to reduce regulatory burdens without diminishing employee safety and health. Those included amending provisions addressing notification of use, frequency of exposure monitoring and medical surveillance, and others that it believed were outdated, duplicative, unnecessary, inconsistent or could be clarified or simplified by being rewritten into plain language.

On October 31, 2002, OSHA published the proposed Phase II of the Standards Improvement Project which would remove or revise a number of health and safety standard provisions (67 FR 66494). Also, OSHA requested comment from the public on any other similar provisions to those in the proposal that interested parties believed to be outdated, duplicative or unnecessary that could be included in a subsequent Phase III Standards Improvement Project.

The Agency made a preliminary finding in the Phase II proposal that the proposed revision to the health standards would reduce the regulatory burden of employers without reducing the health protections the standards currently provide to employees and that some revisions would simplify and clarify requirements. These revisions would facilitate employer compliance and improve employee protection. OSHA also expressed its belief that the removal or revision of standards would in some cases reduce unnecessary

collection of information burdens (*e.g.*, paperwork burdens) on employers.

In addition to affecting part 1910 standards in general industry, the Phase II proposed rule also affected a number of standards included in parts 1915, shipyard employment, and 1926, construction. In accordance with Agency procedures and requirements, the Advisory Committee on Maritime Safety and Health and the Advisory Committee on Construction Safety and Health were advised of the revised standards that affected their industries prior to the publication of the proposed standard. This information was presented to the Advisory Committee on Construction on September 2, 2000, and the Advisory Committee on Maritime on December 6, 2000.

The comment period for the Phase II Standards Improvement Project proposal was to end on December 30, 2002. However, on January 6, 2003, in response to several requests the comment period was extended until January 30, 2003 (68 FR 1023). OSHA received 35 comments in response to the notice of proposed rulemaking. Also, in response to several requests to hold a public hearing to discuss the proposal, OSHA announced a public hearing on April 21, 2003 (68 FR 19472). OSHA held the public hearing on July 8 in Washington, D.C. OSHA staff testified and responded to questions and several members of the public testified. The administrative law judge scheduled the receipt of post hearing evidence on August 8, 2003, and post hearing briefs for September 10, 2003. The judge received the post hearing documents and closed the hearing record on February 26, 2004. The hearing resulted in 59 pages of testimony. No post-hearing comments or briefs were received. However, OSHA inserted some post-hearing material in response to questions asked at the hearing (Ex. 9).

II. Summary and Explanation of the Final Rule

This section contains an analysis of the record evidence and policy decisions pertaining to the various provisions of the final rule.

In the proposed rule, changes to provisions included: Methods of communicating illness outbreaks in the temporary labor camps standard (29 CFR 1910.142); first aid kits for general industry in the medical services and first aid standard (29 CFR 1910.151) and the telecommunications standard (29 CFR 1910.268); laboratory licensing in the vinyl chloride standard (29 CFR 1910.1017); periodic exposure monitoring in the vinyl chloride (29 CFR 1910.1017), 1,2-dibromo-3-chloropropane (DBCP) (29 CFR 1910.1044), and acrylonitrile (29 CFR 1910.1045) standards; reporting the use of alternative control methods in the asbestos standards for shipyards (29 CFR 1915.1001) and construction (1926.1101); evaluating chest x-rays for inorganic arsenic (29 CFR 1910.1018) and coke oven emissions (29 CFR 1910.1029) standards; signing medical opinions in the asbestos standard for general industry (29 CFR 1910.1001) and the cadmium standards for general industry (29 CFR 1910.1027) and construction (1926.1127); and semiannual medical examinations in the vinyl chloride, inorganic arsenic, and coke oven emissions standards.

Also included were proposed changes to the requirements to notify OSHA of certain events (*e.g.*, a substance specific release or emergency) in the standard for 13 carcinogens (29 CFR 1910.1003), the vinyl chloride, inorganic arsenic, DBCP, and acrylonitrile standards; semiannual updating of compliance plans in the standards for vinyl chloride, inorganic arsenic, lead for general industry (29 CFR 1910.1025) and construction (29 CFR 1926.62), DBCP, and acrylonitrile; and employee notification requirements in general industry standards for asbestos, vinyl chloride, inorganic arsenic, lead, cadmium, benzene (29 CFR 1910.1028), coke oven emissions, cotton dust (29 CFR 1910.1043), DBCP, acrylonitrile, ethylene oxide (29 CFR 1910.1047), formaldehyde (29 CFR 1910.1048), methylenedianiline (29 CFR 1910.1050), butadiene (29 CFR 1910.1051), and methylene chloride (29 CFR 1910.1052), and construction standards for methylenedianiline (29 CFR 1926.60), lead, asbestos, and cadmium.

Finally, although OSHA did not propose to delete the requirement to use social security numbers in a number of its exposure-monitoring and medical surveillance records, it requested comment on whether there was a need to continue to include an employee's social security number in these records.

In the proposal, OSHA emphasized that the scope of the rulemaking was limited to removing or revising provisions that were outdated, duplicative, unnecessary, or inconsistent with similar provisions in other standards. In regard to "inconsistent," the Agency specifically proposed to revise a number of OSHA's older standards (vinyl chloride, acrylonitrile, coke oven emissions, arsenic, and DBCP) to be consistent with the frequencies of exposure monitoring, medical surveillance, and compliance plan updates established in the majority of more recently promulgated standards. Comment was solicited on whether it would be appropriate to revise these older standards to be consistent with the newer standards.

OSHA also noted that certain sections in part 1910 that were being addressed in the proposal are incorporated by reference in parts 1915, shipyard employment, and 1926, construction. Therefore, any changes to referenced sections in part 1910 would also apply to parts 1915 and 1926.

Many commenters expressed their views on the approach taken by OSHA in its Phase II Standards Improvement Project. Most commenters supported OSHA's approach and its efforts to remove or revise standards because they are outdated, duplicative, unnecessary, or inconsistent (Exs. 3–5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 22, 24, 25, 26, 28, 29; 4–11, 12). For example, Phelps Dodge Corporation (Ex. 3–7) remarked that "We support OSHA's continuing effort to remove or revise provisions of its standards that are outdated, duplicative, unnecessary, or inconsistent, and we welcome the opportunity to share our comments and suggestions." The National Institute for Occupational Safety and Health (NIOSH) (Ex. 3–9) noted its support for OSHA's efforts to "reduce regulatory requirements for employers while maintaining worker safety and health by removing or revising provisions of standards that may be outdated, duplicative, or unnecessary." Another commenter, Organization Resources Counselors (Ex. 3–22), stated in its discussion regarding OSHA's elimination of collection of information (in this case, paperwork) requirements that:

> If OSHA no longer has need to collect the type of information required to be reported, or finds that the information provides no useful benefits for either enforcement of the standard or protection of employee health, the requirements should be deleted.

On the other hand, some commenters expressed their concern with the manner in which OSHA was streamlining standards and in some cases on the use of its resources for this type of project (Exs. 3–4, 16, 17, 18; 4–13; Tr. 38, 39, 46). The AFL–CIO (Tr. 29) observed that "Throughout this proposal, the Agency has consistently sought to streamline [standards] by reducing [them] to the lowest common denominator." The United Steelworkers of America (Ex. 3–16) stated that while "this may reduce some administrative burdens on OSHA and industry, it is hard to see how worker protection has been improved by any of the changes." The Union of Needletrades, Industrial

and Textile Employees (UNITE) (Ex. 3–18) remarked that it "strongly opposes expenditures of agency staff time and other resources on so-called 'improvements' to OSHA's standards when urgent action on clear regulatory gaps remain unattended."

However, based on the rulemaking record and experience from the Phase I Standards Improvement Project, OSHA continues to believe that the removal or revision of outdated, duplicative, unnecessary, or inconsistent requirements and rewriting requirements into plain language will simplify and clarify regulatory requirements, facilitate compliance, and will lead to improved safety and health. In finalizing the proposal, OSHA has been careful to ensure that the protections afforded employees are not weakened. With respect to these goals, the American Industrial Hygiene Association (AIHA) (Ex. 3–6) stated:

> AIHA applauds OSHA's latest decision to move forward with Phase II of the project through this proposed rulemaking. As was the case with the first phase of this process, completed in 1998, we are confident that the latest proposed health standard revisions will meet with success in terms of reducing the regulatory burden of employers without reducing the health protection that these standards currently provide to employees.
>
> AIHA wishes to publicly go on record as supportive of OSHA's efforts to modernize these standards using a common sense approach. Not only will the proposed revisions simplify and clarify the requirements of the current health standards, but they will also facilitate employer compliance, improved employee protection and reduced regulatory burden—a "win-win" situation for health and safety advocates, employers and employees.

Additionally, Dow Chemical Company (Ex. 3–13) observed:

> Dow supports OSHA's efforts to streamline its existing standards and to remove unnecessary or inconsistent provisions. Improvements in consistency and practicality not only assist the regulated community in its compliance efforts but also benefit OSHA and all employees as the rules are easier to enforce and because employers can better identify what they need to do to comply. Thus, Dow applauds OSHA's continuing efforts to improve their standards. Dow believes that this same philosophy of improvement for consistency and practicality without compromising safety or health protections can also be made in other areas of standards addressed in the proposed rule.

OSHA appreciates the time and effort expended by commenters in this rulemaking. The following is a provision by provision discussion of the changes OSHA has made in Phase II of the Standards Improvement Project.

A. Temporary Labor Camps, 29 CFR 1910.142.

Paragraph 1910.142(l)(2) of the temporary labor camp standard requires camp superintendents to report immediately to local health authorities "by telegram or telephone" the outbreak of specific illnesses and medical conditions among employees. With respect to this requirement, OSHA viewed the limitation to use a telegram or telephone to notify health authorities as too restrictive in this age of computers and the internet, and that other forms of communication should be permitted. In the notice of proposed rulemaking, OSHA proposed to delete the requirement to use a telegram or telephone for notification, but retain the requirement that camp superintendents immediately notify local health authorities of the outbreak any of the illnesses or medical conditions specified by the provision.

OSHA received six comments regarding this proposal. All of the commenters (Exs. 3–4, 16, 17, 22, 27; 4–11) agreed that telegrams and telephones unnecessarily limit the method of reporting. A few commenters (Exs. 3–17, 27) expressed concern, however, that if there was no specification of the means of communication, slower means of notification such as by mail might be used. For example, the United Automobile, Aerospace and Agricultural Implement Workers of America (UAW) (Ex. 3–17) opposed the removal for fear that employers would use fourth class mail for reporting. The AFL–CIO (Ex. 3–27) expressed a similar concern that the proposed change leaves the provision entirely too vague and that employers could even use mail.

In response to this concern, OSHA has decided rather than deleting the means of communication in the final rule, it would instead add additional language that would eliminate the possibility of using a slower means but permit equally fast means. OSHA concludes that any "fast method" is appropriate. The final rule now states "by telegram, telephone, electronic mail or any method that is equally fast."

B. Reference to First Aid Supplies in Appendix A to the Standard on Medical Services and First Aid, 29 CFR 1910.151

In the 1998 Phase I of the Standards Improvement Project (63 FR 33450), OSHA revised paragraph 1910.151(b) of OSHA's standard for medical services and first aid to require that adequate first aid supplies be readily available at the workplace. To assist employers in meeting this requirement for what would be adequate first aid supplies, OSHA added a nonmandatory Appendix A to 29 CFR 1910.151, entitled First Aid Kits, that references a national consensus standard, the American National Standards Institute (ANSI) Z308.1–1978 standard, "Minimum Requirements for Industrial Unit-Type First-aid Kits." The Agency believed that the information and reference to the ANSI standard in Appendix A to 29 CFR 1910.151 would provide employers with helpful information in selecting first aid supplies and containers appropriate to the medical emergencies and environmental conditions encountered in their workplaces.

OSHA pointed out in the Phase I Standards Improvement Project preamble that ANSI was developing a revision of the Z308.1–1978 consensus standard (63 FR 33461) and that OSHA planned to propose to revise Appendix A in Phase II to include the 1998 edition as long as the revision was as effective in protecting employees. In Phase II of the Standards Improvement Project, OSHA solicited comment and information on whether the revised ANSI Z308.1–1998, Minimum Requirements for Workplace First-aid Kits, consensus standard would provide equivalent or better protection to employees than the 1978 edition. OSHA also inquired whether there were any other consensus standards or guidelines available for first aid kits that might be included in Appendix A.

At the time of the Phase II of the Standards Improvement Project proposal, OSHA preliminarily found that the 1998 edition increased compliance flexibility by emphasizing performance-based requirements. OSHA also found that the 1998 edition provided employers with the information they needed to select first aid containers and fill items appropriate to the unique hazards in particular workplaces. OSHA believed that the ANSI 308.1–1998 edition would protect employees at least as well as the requirements of the 1978 edition.

OSHA received 13 comments regarding this proposed change (Exs. 3–3, 16, 17, 22, 24, 26, 27, 29; 4–6, 7, 8, 11, 13). Most commenters supported the Agency's updating of the ANSI 308.1–1978 edition to the 1998 edition in the nonmandatory Appendix A. For example, Verizon Communications, Inc. (Ex. 3–24) supported the revision to the 1998 edition because employers would have more flexibility and, therefore, would improve protection to employees. The Pinnacle West Capital Corp. (Ex. 4–7) observed that there have been changes in the medical profession since

1978, and agreed that the 1998 edition provides equivalent to better protection to employees. One commenter, the AFL–CIO (Ex. 3–27), even suggested that OSHA update the reference but make Appendix A mandatory or enforce the ANSI standard under the general duty clause.

In the final rule, the Agency has changed nonmandatory Appendix A to reference the ANSI 308.1–1998 standard. After reviewing the record evidence and based on OSHA's review of both the 1978 and 1998 editions, the Agency feels that the update to the 1998 edition will provide more compliance flexibility to employers while being as effective, or more effective, in the protection of employees. In its review of the 1998 edition, the Agency found that:

- Regarding container requirements, the 1998 edition permits more compliance flexibility than the 1978 edition. For example, the 1998 edition identifies three types of first-aid containers, types I, II, and III, designed for stationary indoor use, mobile indoor use, and mobile outdoor use, respectively, while the 1978 edition includes only two types of containers, (standard and special purpose, with special-purpose containers designed for use under extreme conditions such as example, corrosive, nonsparking, nonmagnetic, or dielectric conditions.
- Requirements for the three types of containers identified in the 1998 edition are performance based, while the 1978 edition provides extensive specifications for each type of container.
- Unlike the 1978 edition, the conditioning and drop-test procedures described in the 1998 edition for types II and III containers, and the procedures for testing type III containers for corrosion and moisture resistance, specify the minimum number of containers required for testing.
- The 1998 edition specifies that each type III container subjected to drop testing must also undergo corrosion and moisture-resistance testing to ensure the structural integrity of the container under severe moisture conditions. The 1978 edition appears to allow testing of different special-purpose containers under the drop- and moisture-testing conditions.
- Corrosion and moisture-resistance testing of type III containers under the 1998 edition requires exposure of the containers to simulated salt spray for 20 days in accordance with the provisions of American Society for Testing and Materials (ASTM) consensus standard B117 ("Operating salt spray (fog) operations"). The 1978 edition only requires exposure of a special-purpose container to fresh water for 15 minutes.
- Regarding the content (fill items) of the containers, the 1998 edition provides a short list of basic items needed to disinfect and cover wounds, including special items for treating burns. However, the 1998 edition lists optional fill items for use if an employer identifies workplace hazards that may inflict injuries not covered by the basic fill items. The 1978 edition has a single list of fill items, some of which are unnecessary for many emergencies (for example, forceps, metal splints, tourniquets). Additionally, the 1978 edition is missing several important fill items (for example, medical-examination gloves, cold packs).
- The 1998 edition requires color coding of unit packages that contain specific types of fill items (for example, yellow for bandages, blue for antiseptics), while the 1978 edition has no such requirement.
- The 1998 edition, more often than the 1978 edition, identifies fill items according to standardized testing and quality-control methods. For example, the 1998 edition requires that absorbent compresses meet the water-absorbency criteria of ASTM consensus standard D117 ("Nonwoven fabrics"), and that antiseptics conform to the requirements specified by the Food and Drug Administration in 21 CFR 333 ("Topical antimicrobial drug products for over-the-counter human use"). The 1978 edition provides no absorbency criteria for absorbent gauze compresses, while the antiseptic solution used for antiseptic swabs is required only to be "acceptable to the consulting physician."

The Agency's review of the two editions demonstrated that, compared with the 1978 edition, the 1998 edition: Increases compliance flexibility by emphasizing performance-based requirements, including a choice of three containers and a list of basic and optional fill items; improves the procedures for conditioning and testing first-aid containers; and ensures the reliability and efficacy of the fill items by basing the selection of these items on standardized testing and quality-control methods. Based on this review, OSHA preliminarily found that the provisions of the 1998 edition would provide employers with the information they needed to select first-aid containers and fill items appropriate to the hazards in their workplaces that could injure employees. Consequently, the 1998 edition would protect employees at least as well as the requirements of the 1978 edition.

The Agency believes that the 1998 edition of the ANSI standard is as protective to employees but increases compliance flexibility and, accordingly, has replaced the reference to the 1978 edition in Appendix A of § 1910.151 with a reference to the 1998 edition. OSHA believes that appropriate guidance is contained in the 1998 edition for a variety of workplaces with different needs.

Finally, although OSHA solicited information about other available consensus standards, no suggestions were received.

C. First Aid Supplies in the Telecommunications Standard, 29 CFR 1910.268

Paragraph 1910.268(b)(3) of OSHA's telecommunication standard requires an employer to: Provide first aid supplies (fill items) recommended by a consulting physician; ensure that the fill items are readily accessible and housed in weatherproof containers if used outdoors; and inspect the fill items at least once a month and replace expended items. In the proposal, OSHA proposed to revise paragraph 1910.268(b)(3) to read, "Employers must provide employees with readily accessible, and appropriate first aid supplies. An example of appropriate supplies is listed in non-mandatory Appendix A to § 1910.151."

In Phase I of the Standards Improvement Project, OSHA removed from paragraph 1910.151(b) of the medical services and first aid standard, the requirement that a consulting physician approve first aid supplies because it determined that commercial first aid kits are readily available and would meet the needs of most employers (61 FR 37850). OSHA noted that employers may have to enhance their first aid kits if unique or changing first aid needs exist in their workplaces. OSHA advised employers in Appendix A that if they had unique needs to consult with the local fire/rescue departments, appropriate medical professionals, or a local emergency room for help. Also, OSHA advised employers that they should assess the specific needs of their worksite periodically and augment the first aid kit accordingly.

In this proposal, the Agency preliminarily concluded that revising the telecommunication standard to reflect the general industry first aid requirements would be appropriate. The Agency received ten comments (Exs. 3–4, 16, 17, 22, 24, 27, 29; 4–6, 8, 11) concerning this proposed revision to the telecommunications standard. A few commenters (Exs. 3–4, 16, 17, 27) indicated that they believed the revision would reduce employee protection. For example, commenters believed that

deleting the requirement to inspect kits monthly to replace used items would increase the likelihood of deficient kits. Another commenter was concerned that there would no longer be a requirement for weatherproof kits.

However, other commenters supported the proposed changes (Exs. 3–22, 24, 29; 4–6, 8, 11). For example, the American Chemistry Council (Ex. 3–29) indicated that it supported the change to reflect present-day realities in the first aid supplies market and also supported the removal of the requirement for a physician's approval for supplies.

The Agency has concluded that substituting the guidance of nonmandatory Appendix A to 29 CFR 1910.151 for the requirements specified in paragraph 1910.268(b)(3) will reduce the regulatory burden on employers in the telecommunication industry by increasing their flexibility in meeting OSHA's requirements for first aid kits, allow employers to purchase off-the-shelf first aid kits, and will facilitate compliance by making the requirements to provide first aid kits consistent across the general industry standards. The Agency believes that the revision affords telecommunication employees at least the same level of protection they currently receive because Appendix A to 29 CFR 1910.151 provides more extensive guidelines for selecting appropriate medical first aid supplies than paragraph 1910.268(b)(3) and further, provides the recommendation that these supplies include personal protective equipment to prevent employee exposure to bloodborne pathogens. Finally, OSHA believes that deleting the requirement for a monthly inspection and weatherproof first aid kits does not reduce employee protection. First aid kits must be complete and contain the supplies necessary for the worksite. If upon inspection by an OSHA compliance officer, a first aid kit was found to be deficient because the supplies were depleted or water damaged, a citation could be issued because the first aid supplies would not be considered adequate or "appropriate." OSHA has concluded that the mandatory requirement to have appropriate and accessible first aid kits maintains employee protection.

D. 13 Carcinogens, 29 CFR 1910.1003

In the 13 Carcinogens standard, paragraph 1910.1003(f)(2) requires employers to provide the nearest OSHA Area Director with two separate reports on the occurrence of any incident that results in a release of any of the 13 carcinogens into any area where employees may be potentially exposed. The reports consist of (1) an abbreviated preliminary report submitted within 24 hours of the carcinogen release and (2) a detailed report submitted within 15 calendar days of the incident. In the proposal, OSHA expressed its belief that these reports were of little or no value to OSHA and were therefore creating an unnecessary burden on employers. More recent substance-specific standards including carcinogenic chemicals such as methylene chloride developed by the Agency do not contain any such reporting requirements. Because of these reasons, OSHA proposed to delete the requirement from the standard to reduce reporting requirements because the reports were unnecessary. OSHA requested comment on the extent to which the revision would reduce the reporting burden on employers and the effect the deletion would have on employee health.

OSHA received nine comments in response to the proposal to eliminate the carcinogen standard reporting requirements (Exs. 3–4, 16, 17, 18, 22, 27, 29; 4–11, 13). Three commenters agreed with the removal of the requirement (Exs. 3–22, 29; 4–11). The other commenters (Exs. 3–4, 16, 17, 18, 27; 4–13) objected to the removal of the reporting requirement. These commenters opposed the removal because: (1) The deletion would reduce worker protection because reporting gives useful information to OSHA by alerting it to workplace deficiencies; (2) the information helps management avoid future spills, and; (3) the information induces managers to take spills more seriously.

At the hearing OSHA was asked by a representative from the AFL–CIO (Tr. 16) about how many reports on spills OSHA had received under the current regulations. Responses from the OSHA regional offices indicated that few reports are received and those that are received are not used for inspection purposes (Ex. 9). Although a few OSHA staff believed that incidence reports might be useful, that has not been the case. Further, OSHA has a general requirement to report incidents that cause death or serious injury (29 CFR 1904.39). That provision is used by employers and OSHA and it does trigger compliance inspections.

The purpose for collecting these reports was to assist OSHA in identifying workplaces for inspection. OSHA has not used these reports over the years for this purpose and relies on other means to identify establishments to inspect. Further, the commenters provided no evidence that the reporting requirements serve to help management avoid future spills or to entice managers to take spills more seriously. In addition, the substances covered by this requirement are primarily chronic toxins and a single spill does not necessarily indicate a severe hazard requiring notification. Therefore, OSHA continues to believe that the reports have not proven to be useful and are an unnecessary employer burden since OSHA does not use them for identifying workplaces for inspection. In addition, under the Paperwork Reduction Act, agencies need to review their requirements to identify those that serve no purpose and if they do not serve any purpose, then consider removing them. Therefore, OSHA has eliminated the reporting requirements. OSHA is not aware of any reason that the elimination of the reports will reduce employee safety since OSHA does not use the reports.

E. Vinyl Chloride, 29 CFR 1910.1017

Paragraph 1910.1017(k)(6) of the vinyl chloride standard specifies that clinical laboratories licensed by the U.S. Public Health Service under 42 CFR part 74, must analyze biological samples collected during medical examinations. However, 42 CFR part 74 is outdated, and the Public Health Service now addresses laboratory-licensing requirements under 42 CFR part 493, laboratory requirements. Therefore, the Agency proposed to delete the reference to 42 CFR part 74 from the vinyl chloride standard. In the proposal, OSHA asked for comment on: (1) The need to specify a licensing or quality-control requirement; (2) the extent to which the requirements specified by 42 CFR part 493 would be a substitute for the outdated requirements; and (3) whether any other reference or criteria were available that could serve this purpose.

OSHA received eight comments on the proposed deletion of the requirement for a Public Health Service licensed laboratory to analyze biological samples collected during medical exams relative to vinyl chloride exposure (Exs. 3–4, 8, 16, 17, 27, 29; 4–11, 13). The Vinyl Institute (Ex. 3–8) supported the deletion of the provision entirely because they saw no current need for specifying licensing or quality-control of laboratories. The other seven commenters expressed their belief that paragraph 1910.1017(k)(6) should not be changed without either adding language offering equal or greater protection to workers or updating the reference to the new Public Health Service laboratory requirements (Exs. 3–4, 16, 17, 27, 29; 4–11, 13).

One commenter (Ex. 3–16) observed that this type of requirement, laboratory licensing, was an example of the kind of requirement that would be best dealt with by a generic medical monitoring standard which could address laboratory certification for all standards.

Based on the comments OSHA does not believe in this case that it is appropriate to reference outdated regulations, or that it would be appropriate to reference the new PHS standards. However, it is appropriate for OSHA to require employers use qualified laboratories for required medical tests. Other OSHA health standards have assured that qualified laboratories are used by requiring that employers use accredited laboratories. For example, the Bloodborne Pathogens standard [1910.1030(f)(iii)], the Benzene standard [1910.1028(i)(1)(ii)], the Cadmium standard [1910.1027(l)(1)(iv)] and the Lead standard for General Industry [1910.1025(j)(2)(iii)] require that medical tests be performed by accredited laboratories. There are several organizations that accredit laboratories. Each requires that laboratories implement quality control procedures to maintain accreditation. Therefore, OSHA has changed paragraph 1910.1017(k)(6)of the vinyl chloride standard to require the use of accredited laboratories for the medical tests required in paragraph (k)(1) of the standard.

F. Monthly and Quarterly Exposure Monitoring

Several of the Agency's older standards have provisions that require employers to monitor employee exposures either monthly or quarterly, depending on the level of a toxic substance found in the workplace.

Paragraphs 1910.1017(d)(2)(i) and (d)(2)(ii) of the vinyl chloride standard require employers to conduct exposure monitoring at least monthly if employee exposures are in excess of the permissible exposure limit (PEL) and not less than quarterly if employee exposures are above the action level (AL).

Paragraphs 1910.1044(f)(3)(i) and (f)(3)(ii) of the DBCP standard specify that employers perform exposure monitoring at least quarterly if employee exposures are below the PEL and no less than monthly if employee exposures exceed the PEL.

Paragraphs 1910.1045(e)(3)(ii) and (e)(3)(iii) of the acrylonitrile standard requires employers to conduct exposure monitoring at least quarterly for employees exposed at or above the AL, but below the PEL, and at least monthly for employees having exposures above the PEL.

The preambles to these older standards do not clearly explain the basis for adopting these monitoring frequencies. This absence of clear explanation suggests that OSHA likely relied on prevailing practice at the time for these older standards in establishing the frequencies. In substance-specific standards promulgated after these standards, exposure monitoring is required: (1) No more often than semiannually if employee exposures are at or above the AL and (2) no more than quarterly if employee exposures are above the PEL.

OSHA proposed to amend the exposure monitoring requirements specified in the vinyl chloride, acrylonitrile, and DBCP standards because they are inconsistent with the exposure monitoring protocols established by OSHA in its later substance-specific standards. OSHA believes that consistency among standards would increase compliance and because the Paperwork Reduction Act directs agencies to reduce paperwork burdens, OSHA therefore proposed to revise these paragraphs to make them consistent with the similar requirements pertaining to exposure monitoring in more recently promulgated health standards. That exposure monitoring is: (1) At least quarterly if the results of initial exposure monitoring show that employee exposures are above the PEL; and (2) no less than semiannually if the results indicate exposures that are at or above the AL. OSHA asked for comment on the extent, if any, to which the revision would reduce the protection afforded by the existing standards to employees exposed to vinyl chloride, acrylonitrile, and DBCP. OSHA also requested comment on the extent to which the proposed revisions would reduce employer burdens, including cost and collection of information (i.e., paperwork) reductions.

OSHA received 14 comments on modifying the exposure monitoring requirements (Exs. 3–4, 8, 10, 12, 13, 14, 16, 17, 18, 27, 29; 4–11, 12, 13). Seven commenters supported consistency in exposure monitoring for one or all of the substances (Exs. 3–8, 10, 13, 14, 29; 4–11, 12). Dow Chemical Company (Ex. 3–13) observed that "Consistency in monitoring requirements reduces employer burdens and enhances compliance while maintaining employee health protections." The American Chemical Council (Ex. 3–29) stated:

> ACC concurs that exposure monitoring should be consistent among the Agency's standards. The proposed revisions to § 1910.1044 and § 1910.1045 will help to unify the requirements for exposure monitoring. Further unification of the exposure monitoring requirements will enable employers to have one monitoring strategy that can be applied for all substances, rather than keeping track of the differences between the varying standards.

The American Society of Safety Engineers (Ex. 4–11) remarked that the "revision will assist companies in implementing more uniform industry hygiene programs. Also, there is no demonstrated need for more frequent exposure monitoring these substances."

The American Foundry Society (Ex. 3–12) expressed its view that the exposure monitoring change does not go far enough. The commenter stated:

> The proposed revision * * * to go from monthly to quarterly and from quarterly to semiannual does not go far enough. While monitoring of potential employee exposure is essential to maintain employee health and exposure monitoring as part of an engineering study may be necessary to determine the source and magnitude of exposure, periodic monitoring for its own sake imposes an unnecessary and possibly punitive burden on employers and employees unless there is some benefit to employee safety and health.
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> Once it has been determined that employees are exposed above an Action Level or Permissible Exposure Level, additional monitoring provides no additional useful information, unless it is part of an engineering study. Simply conducting exposure monitoring for its own sake wastes valuable health and safety resources and builds resentment among employees who must wear sampling equipment without justification.
>
> We strongly urge OSHA to modify the requirement in all health standards, now and in the future, to base the frequency of exposure monitoring on the need to establish employee exposure levels or to achieve some other useful safety and health objective. Of course, additional exposure monitoring should be conducted when work processes or practices change or there are good industrial hygiene or engineering reasons to conduct such monitoring.

Six commenters disagreed with the proposed changes (Exs. 3–4, 16, 17, 18, 27; 4–13). For example, the Paper Allied-Industrial, Chemical and Energy Workers Union (PACE) (Ex. 3–4) stated:

> * * * For these selected agents which have well-established toxicity, it is wholly inappropriate to ask employees whose exposure monitoring shows that they are exposed at levels above the permissible exposure limit to wait an addition 3 months to find out whether these exposures have been reduced. Likewise for employees whose exposures are above the action level, they should not have to wait six months to learn

whether their exposures have been reduced below that level.

The United Steel Workers of America (Ex. 3–16) remarked:

> When the three standards in question were written, it was assumed that most employers would come into compliance in a reasonable amount of time. Indeed, most have—by better controls in the case of vinyl chloride and acrylonitrile, by a phase-out of the chemical in the case of DBCP. Now OSHA proposes to reward those employers who have not achieved compliance. These changes will impair worker protection, and are not supported by evidence in the record.

Also, the International Chemical Workers Union (Ex. 4–13) observed:

> We do not believe that a change to these standards is justified. Each rule and requirement went through the rulemaking process at the time, weighing all available evidence. Again, just because later rules, for different chemicals with different hazards, controls and/or toxicities have different requirements, do not provide adequate justification for a change in monitoring frequencies. OSHA needs to provide additional information which gives a valid justification for change before proposing such changes.

The standards for vinyl chloride, acrylonitrile, and DBCB are among the oldest of OSHA health standards. As the United Steel Workers of America noted, most employers have come into compliance. Those employers who have not been able to achieve compliance through feasible engineering controls are required to protect their employees by using personal protective equipment. Those employers who have not been able to reduce worker exposures have collected hundreds of samples since the effective dates of these standards. Very high monitoring frequencies will not add appreciably to the statistical confidence an employer will have in the conclusion that employees' exposures exceed a permissible exposure limit or action level. Monitoring quarterly and semiannually will protect employees by allowing time to improve the workplace, while still producing suitably current information to employers and employees. When employers are over the action level or exposure limit, periodic monitoring is required to assure that proper respirators and personal protective equipment are worn.

Moreover, OSHA concludes, after reviewing the comments, that uniformity of monitoring frequency is beneficial for employers and employees (unless there are specific reasons for different frequency) because uniformity permits an employer to develop a more efficient and thus, better, industrial hygiene program and to increase compliance by improving understanding of health standards. In addition the Paperwork Reduction Act requires OSHA to consider reduction in paperwork burden when that will not interfere with worker protection.

OSHA notes that two of its standards, 29 CFR 1910.1028 and 1910.1051, benzene and 1,3-butadiene respectively, provide for exposure monitoring frequencies different from the quarterly and semiannual monitoring contained in other standards. The Agency is not revising benzene or 1,3-butadiene with respect to monitoring frequencies because the exposure monitoring provisions in those standards have specific bases in their rulemaking records that preclude changing them for consistency under this standards improvement action. (See e.g. 52 FR 34533–41, September 11, 1987.)

G. Alternative Control Methods for Class I Asbestos Removal

Provisions in OSHA's asbestos standards for shipyard employment and construction, paragraphs 1915.1001(g)(6)(iii) and 1926.1101(g)(6)(iii), respectively, address alternative control methods used to perform Class I asbestos work. Specifically, the paragraphs require an employer to send an evaluation and certification of alternative control methods to OSHA's Directorate of Technical Support before removing more than 25 linear feet or 10 square feet of thermal-system insulation or surfacing material respectively.

The purpose of this collection of information was for OSHA to develop a database of alternative control methods for use in future rulemaking. However, OSHA has not developed a database of alternative control methods nor does OSHA plan a future rulemaking to do so. Therefore, OSHA in the proposal said that these requirements are not useful and are not in keeping with the Paperwork Reduction Act. Current OSHA regulatory policy requires that paperwork provisions, such as this, be a benefit to employee health or serve some other useful regulatory purpose. Since certification of alternative control methods does not meet this requirement, the Agency proposed to delete it from the shipyard and construction asbestos standards. OSHA invited comment on any regulatory benefit or purpose that removal of this requirement would jeopardize.

Eight commenters addressed the removal of these paragraphs (Exs. 3–4, 16, 17, 24, 25, 27; 4–7, 11). Some commenters (Exs. 3–24; 4–7, 11) agreed with their deletion because OSHA has never used the information to develop a database. Other commenters (Exs. 3–4, 16, 17, 27) suggested rather than simply deleting the requirements, OSHA should enforce the requirement and start a database of alternative control methods which could be useful in rulemaking and to employers and employees seeking methods of abatement. Finally, the Associated General Contractors of America (Ex. 3–25) expressed concern that the change would eliminate contractors' abatement options and lead to increased delays to contractors and building owners because no simple substitution process would be available to submit alternatives. In response to this concern, OSHA would like to make it clear that the removal of these requirements does not disallow the use of alternative control methods since the submission of alternative control methods to OSHA did not constitute approval of the methods.

As stated, the intent of this collection of information was for OSHA to develop a database of alternative control methods, but no such database was developed. Further, OSHA has no future plans to expend its limited resources on developing a database. As to development or availability of alternative control methodologies, there are many competent asbestos abatement contractors and consultants available to employers so it is not necessary for OSHA to research these issues or collect information on them. Therefore, OSHA has deleted the requirement in the shipyard employment and construction standards, because it is an unnecessary and burdensome collection of information.

H. Evaluating Chest X-rays Using the ILO U/C Rating

OSHA proposed to amend paragraph 1910.1018(n)(2)(ii)(A) of the inorganic arsenic standard and paragraph 1910.1029(j)(2)(ii) of the coke oven emissions standard that require employees' chest x-rays receive an International Labor Office UICC/Cincinnati (ILO U/C) rating. Subsequent to the promulgation of these provisions, the Agency received information from two physicians that the ILO U/C rating is not suitable to evaluate chest x-rays for lung cancer, the possible outcome of exposure to these chemicals. Regarding the use of the ILO U/C ratings specified by the inorganic arsenic standard, Stephen Wood, MD, MSPH, Corporate Medical Director for the Kennecott Corporation, states in a letter to OSHA (Ex. 1–1):

> This method of x-ray interpretation was designed specifically for use in pneumoconiosis or dust related disease. Arsenic does not cause pneumoconiosis. This

classification system is unnecessary for cancer surveillance and represents a substantial cost and logistical burden to industry.

Later, Steven R. Smith, MD, Director of Occupational Health and Occupational Medicine, Community Hospitals Indianapolis, wrote to the Agency (Ex. 1–2) addressing the ILO U/C rating required by the coke oven emissions standard:

> I am sure you know that the main pulmonary problem with coke oven emission exposure is carcinoma of the lung and not pneumoconiosis. The main merit of the ILO U/C rating system is that it standardizes the reading of films where there are parenchymal opacities either round nodules or linear densities. For the problem of carcinoma of the lung this system really has little to add over the proper interpretation of films by skilled radiologists. I think it is of much more importance that the chest films done as part of the coke oven emissions exposure surveillance be interpreted by expert radiologists who are aware of the fact the films are being done primarily for pulmonary carcinoma. To require that an ILO U/C rating system be employed as well seems to me as though it is going to necessitate an additional expense as well as to greatly limit the number of radiologists who are able to interpret such films.

Based on these letters and on the opinion of OSHA's Office of Occupational Medicine, the Agency believed that the ILO U/C rating is not a suitable method to use in evaluating chest x-rays for lung cancer. Therefore, the Agency proposed to remove the ILO U/C rating requirements specified in the inorganic arsenic and coke oven emissions standards, thereby permitting the examining physician to determine the most effective procedure for evaluating the chest x-rays. This approach is similar to that taken in recent Agency standards that require the evaluation of chest x-rays for cancer (e.g., paragraph 1910.1027(l)(4)(ii)(C) of the cadmium standard). As part of the cadmium rulemaking, OSHA solicited comment and other information regarding the suitability of the ILO U/C ratings for evaluating chest x-rays for cancer, the identity of any other available method or procedure that could effectively substitute for ILO U/C ratings, and the safety and efficacy of the proposed elimination of the requirement.

OSHA received nine comments in response to this proposed change (Exs. 3–7, 9, 16, 17, 27, 28, 29; 4–7, 11). Some commenters agreed (Exs. 3–7, 28, 29; 4–7, 11) that the rating requirement should be deleted because the method was not appropriate to evaluating chest x-rays for lung cancer. The American Coke and Coal Chemical Institute (Ex. 3–28) stated:

> ACCCI concurs with the Agency's research and rationale that the ILO–U/C rating is not suitable for proper evaluation of standard posterior-anterior chest x-rays, as this designation does not promote proper lung cancer surveillance. In addition to the additional cost burden it imposes on employers, the requirement also delays the reading response time, due to the extremely limited number of radiologists qualified to render such an interpretation.

Pinnacle West Capital Corp (Ex. 4–7) indicated that its medical consultant saw no detriment to employee protection if the requirement was deleted.

Some commenters (Exs. 3–9, 16, 17, 27) whether they agreed with or opposed the removal of the rating, believed substitute language should be added and suggested what that language might be. For example, the United Steel Workers of America (Ex. 3–16) agreed that the rating is of little use for carcinogens but suggested that OSHA substitute the rating requirement with one that the radiologist be certified by the American Board of Radiologists to ensure qualified radiologists are used. The AFL–CIO (Ex. 3–27) observed that the use of the rating provided some quality control. To remedy the problem, the AFL–CIO suggested that x-rays be read by NIOSH certified B readers.

OSHA has decided to eliminate the part of the provisions in arsenic and coke oven emissions requiring the ILO U/C rating because the rating is appropriate only for pneumoconiosis and is not useful for lung cancer. OSHA agrees with commenters who noted that the rating method is not appropriate for diagnosing cancer, its intended purpose. First, it is clear that the specified rating method is inappropriate because it addresses dust inhalation and resulting pneumoconiosis, a problem unrelated to arsenic and coke oven emissions. The rating is not appropriate for identifying cancer, the primary concern with respect to these substances. Second, OSHA has no reason to believe that the elimination of an inappropriate rating method will result in the use of unqualified radiologists under the medical surveillance programs of employers and does not believe it is necessary to add any other language to the provision. OSHA has decided based on the rulemaking record, to delete the requirement and does not believe that the deletion will decrease employee health since the method is not even appropriate to diagnosing the substances' likely disease outcome, cancer.

I. Signed Medical Opinions

OSHA proposed to remove several requirements for medical opinions to be signed. (The requirement that a medical opinion be obtained by the employer was not affected by the proposed revision concerning a signature.) Paragraph 1910.1001(l)(7)(i) of the asbestos standard, and paragraphs 1910.1027(l)(10)(i) of the general industry cadmium standard and 1926.1127(l)(10)(i) of the construction industry cadmium standard, require that the examining physician sign the written medical opinion provided as part of the medical-surveillance requirements of these standards. The preamble to the cadmium standards states that the purpose of requiring the physician to sign the opinion is to ensure that the information that is given to the employer has been seen and read by the physician and that the physician has personally determined whether the employee may continue to work in cadmium-exposed jobs (57 FR 42366). No other substance-specific standards promulgated by OSHA requires that the physician sign the medical opinion.

The Agency expressed its belief in the proposal that the requirement for a physician to sign a medical opinion is unnecessary, precludes electronic transmission of the opinion from the physician to the employer, and provides no additional benefit to employees. Accordingly, OSHA proposed to remove the requirement from these standards. The Agency requested comment on whether a signed medical opinion is necessary to ensure that the examining physician has reviewed it prior to submitting it to the employer.

OSHA received 11 comments concerning the elimination of the requirement for a physician's signature on a medical opinion (Exs. 3–3, 4, 7, 16, 17, 22, 24, 26, 27; 4–7, 11). Seven commenters saw no need or reason for the signature (Exs. 3–3, 7, 22, 24, 26; 4–7, 11). For example, Phelps Dodge Corp. (Ex. 3–7) agreed that the requirements provide no added benefit and given current communication techniques, requiring signed medical opinions actually slows the process of completing the medical evaluation. The American Society of Safety Engineers (Ex. 4–11) stated that it "supports this change because it permits the use of new technology, which is generally accepted in the business and medical field, and will minimize paperwork burdens and reduce delays receiving such reports, thereby enhancing safety and health."

Four commenters objected to deleting the requirement for a physician's signature on the medical opinion (Exs.

3–4, 16, 17, 27). The views expressed by these commenters include: (1) Physicians should take responsibility for their opinions; (2) employees place greater weight on opinions signed by physicians; and (3) providing signed opinions requires minimal effort. These commenters generally agreed that if OSHA wanted to allow for electronic transmission, then the provision should be revised to allow electronic signatures.

OSHA does not believe that requiring a physician's signature on the required comprehensive medical opinion has any impact on the validity of the medical opinion. With or without a signature, the opinion is given by a physician through the physician's office leaving no doubt about responsibility for the opinion. Employees receiving the physician's opinions will see that the physician's name on his or her stationery sets forth the legitimacy of the report and the identify of the responsible physician. Further, OSHA believes that an actual physician's signature or a physician's electronic signature does not guarantee that the physician has read the opinion, making these signature requirements ineffective. The important part of the requirement is that a medical opinion is given. OSHA does not believe a signature establishes any greater validity to the medical opinion whether it is signed personally or electronically and has concluded that deleting the signature will not decrease employees' health protections.

J. Providing Semiannual Medical Examinations to Employees Experiencing Long-Term Toxic Exposures

Three of the Agency's oldest health standards specify that employers provide semiannual medical examinations to employees having long-term exposures to the toxic substances regulated by these standards. However, these standards, which regulate employee exposures to vinyl chloride, inorganic arsenic, and coke oven emissions (29 CFR 1910.1017, 1910.1019, and 1910.1029, respectively), require employees, exposed for lesser periods, be given annual medical examinations.

Under paragraph 1910.1017(k) of the vinyl chloride standard employers must institute a medical surveillance program including a physical examination for employees exposed in excess of the action level. For employees exposed above the action level and who have been employed in vinyl chloride or polyvinyl chloride manufacturing for 10 years or longer, employers must provide a semiannual medical examination (paragraph 1910.1017(k)(2)(i)). The preamble to this standard provides no rationale for this requirement.

Paragraph 1910.1018(n)(3)(i) of the inorganic arsenic standard requires that employers offer semiannual medical examinations to employees who are 45 years or older who have been exposed above the action level for 30 days per year or who have been exposed above the action level to inorganic arsenic for at least 10 years. In justifying this requirement, the Agency indicated in the preamble to this standard that:

> Long-term employees who have exposures now or in the near future below the action level, but have had exposure above the action level now or in the recent past, are quite likely to have had substantially greater exposures in the more distant past. The epidemiological studies indicate that risk increases with both degree and duration of exposure (43 FR 19620).

OSHA notes that this statement addressed high exposures that occurred prior to the 1970's.

Paragraphs 1910.1029(j)(3)(ii) and (j)(3)(iii) of the coke oven emissions standard require employers to provide semiannual medical examinations for employees who are at least 45 years of age, or have five or more years of employment in a regulated area, and for an employee in this age/experience group who transfers or is transferred from employment in a regulated area, for as long as that employee is employed by the same employer or a successor employer. In the preamble to this standard, the Agency explains this requirement by stating that the high risk population requires more frequent and more comprehensive testing than the remainder of the population (41 FR 46779, October 22, 1976).

OSHA believes that the available evidence does not support the requirements for semiannual medical examinations offered to employees with long-term exposures to vinyl chloride, inorganic arsenic, or coke oven emissions. Based on a review of the existing medical research literature in Phase I of the Standards Improvement Project, the Agency amended the inorganic arsenic and coke oven emissions standards by reducing the frequency of chest x-rays from semiannual to annual and by removing the requirement for sputum cytology entirely from these standards (63 FR 33450). This review indicated that semiannual chest x-rays and sputum cytology did not provide additional protection to employee health over and above that provided by an annual chest x-ray. Semi-annual medical exams provide little if any benefits when x-rays are only justified on an annual basis. Further, other health standards, promulgated by OSHA, *e.g.*, the 13 Carcinogens, benzene, ethylene oxide, etc., only require annual medical examinations.

Based on the available evidence, at the time of the proposal, the Agency believed that semiannual medical examinations for these three substances were unnecessary, and that annual medical examinations would be sufficient to detect cancer and other medical impairments caused by exposure to vinyl chloride, inorganic arsenic, or coke oven emissions. Also, aside from these three standards, no other substance-specific OSHA standard requires semiannual medical examinations. OSHA also believed that current medical practice with regard to employees occupationally exposed to toxic substances is to screen them annually. Therefore, the Agency proposed to revise these three standards to be consistent with its other substance-specific standards that require employers to provide annual medical examinations for covered employees regardless of the duration of their exposures. OSHA requested comment and other information on the effectiveness of annual versus semiannual medical examinations in detecting cancer and other medical impairments caused by exposure to vinyl chloride, inorganic arsenic, or coke oven emissions.

OSHA received 13 comments concerning semiannual versus annual medical examinations (Exs. 3–4, 7, 8, 10, 13, 14, 16, 17, 27, 28, 29; 4–7, 11). Most of these commenters supported the change from semiannual to annual medical examinations (Ex. 3–4, 7, 8, 10, 13, 14, 28, 29; 4–7, 11). OxyChem (Ex. 3–10) supported OSHA's rationale that semiannual medical examinations do not offer any more or better disease identification than annual examinations. Further, OxyChem noted that annual examination is the medical profession's standard, and is consistent with all recent OSHA medical examination requirements. The Vinyl Chloride Health Committee of the American Chemistry Council (Ex. 3–14) stated:

> OSHA recognizes in the preamble that semiannual examinations are not necessary, because annual medical examinations are sufficient to detect any material adverse health effect caused by vinyl chloride exposure. The Health Committee supports the proposal and notes that, more than any other proposed change, this will reduce significantly employer cost burdens without affecting worker health adversely.

Further, Pinnacle West Capital Corporation (Ex. 4–7) remarked:

These standards promulgated in the 70s took a very conservative view in regard to medical monitoring requirements. In view of today's knowledge and OSHA's mediating this ultra conservative stance, we agree that annual exams are adequate to protect employee health. We believe it will enhance compliance with OSHA standards by making these rules consistent in requiring annual exams for all substance specific standards.

Two commenters did not support eliminating the semiannual medical examinations (Ex. 3–17, 27). The UAW (Ex. 3–17) noted that increasing the frequency of examinations with increasing latency from first exposure to carcinogens is logical and based on science. The AFL–CIO (Ex. 3–27) expressed a similar opinion:

In the view of the AFL–CIO, the current language requiring semiannual exams should be retained. Workers with long term exposures to any of these three substances are likely to be at increased risk of developing lung and liver cancer. The time since first exposure is also increased among this subset of exposed workers. More frequent screenings will assist these workers in identifying or diagnosing their cancers earlier than with an annual examination frequency.

OSHA continues to believe based on available evidence resulting from its Phase I Standards Improvement Project, discussed above (that semiannual x-rays and sputum cytology do not improve survival rates), that annual medical examinations are sufficient to detect cancer and other medical impairments caused by exposure to vinyl chloride, inorganic arsenic, or coke oven emissions. The majority of commenters also believed that requiring annual medical examinations would be as effective as semiannual. OSHA finds that current medical practice to screen annually, makes it administratively advantageous especially when the medical examination may cover potential adverse health effects from other chemicals. Finally, OSHA's experience with other substance specific standards requiring annual medical examinations, persuades OSHA that the three standards can be changed without a decrease in employee health.

A second issue was raised in the proposal addressing the medical examination in the coke oven emissions standard. OSHA sought comment on whether the urinary cytology examination was a useful test. OSHA indicated it might include its removal in the final rule if warranted, based on comments. The coke oven emissions standard requires, in paragraph 1910.1029(j)(2)(vii), that employers provide urinary cytology examinations as part of the medical examination to exposed employees. OSHA had adopted this requirement based on its belief that the urinary cytology examination would serve as a useful tool in screening for bladder cancer for those exposed to coke oven emissions.

However, at the time of this proposal, the Agency believed that the use of urinary cytology in the coke oven emissions standard as a screening tool for cancer should be reexamined based on more recent scientific literature. OSHA's Office of Occupational Medicine (OOM) reviewed data pertaining to the benefits of urinary cytology in the detection of bladder cancer (Ex. 1–3). The literature indicates that the sensitivity of urine cytology, that is, its ability to detect bladder cancer, is not very powerful and, thus, not a particularly effective screening test for this disease. OOM recommends that urinary cytology testing be eliminated from the coke oven emissions standard. However, OOM does recommend retaining dipstick urinalysis as an inexpensive means of maintaining the urologic screening program until more effective technology is developed, despite its low sensitivity for detecting cancer. Comment was requested on the issue and on the OOM recommendation of retaining dipstick urinalysis.

OSHA received five comments on the urinary cytology examination in the coke oven emissions standard (Exs. 3–4, 16, 17, 27). None of the commenters believe that OSHA should eliminate the urinary cytology examination at this time. For example, the United Steel Workers of America (Ex. 3–16) remarked:

We agree with OSHA that urinary cytology should be thoroughly examined. While we have respect for OSHA's Office of Occupational Medicine, the evaluation should be based on more than their opinion. In addition, the Agency should consider newer methods for detecting overexposures, such as 2-hydroxypyrenol. Until that analysis is complete, the requirement for urinary cytology should be retained.

The AFL–CIO (Ex. 3–27) stated:

While we have no objection to OSHA reexamining the utility of using urinary cytology as a screen for cancer, we are opposed to removing it merely because the sensitivity of the screening tool "is not very powerful". If another screening method can be shown, with scientific substantiation, to be more powerful then it may be appropriate for the agency to require a different method to be used. Until such time as this analysis has been completed and a more powerful method identified, the AFL–CIO believes the requirement for urinary cytology should be retained. To eliminate the screening test altogether would weaken worker protection.

Based on comments, OSHA has been persuaded to retain the requirement to conduct urinary cytology testing as part of the medical examination required by the coke oven emissions standard until such time that the Agency more fully examines alternatives to the test. However, also based on the information in the record and comments, OSHA is requiring the test be conducted on an annual basis as part of the annual medical examination, the same time the other tests are required (urinalysis), rather than every 6 months. OSHA has found no compelling reason that the cytology test should be conducted more frequently than the other tests required as part of the medical examination and it is important to be consistent with the annual frequency of other required medical examinations and tests so that it can be reviewed by the physician.

K. Notifying OSHA Regarding the Use of DBCP or the Establishment of Regulated Areas for Certain Substances

The Agency proposed to delete paragraph 1910.1044(d) of the 1,2-dibromo-3-chloropropane (DBCP) standard. This standard is the only OSHA substance standard that requires employers to submit a report to the nearest OSHA Area Office that describes the employer's use of the chemical within 10 days of introducing the substance into the workplace. The preamble to the DBCP standard does not provide a rationale for the requirement. Further, OSHA has not found this requirement useful either for research or to assist in compliance activities.

OSHA believed that the provision had little use in practice and thus, it might be appropriate to remove this provision consistent with the Paperwork Reduction Act mandates. OSHA requested comment on the proposed deletion of paragraph 1910.1044(d) of the DBCP standard.

One commenter specifically disagreed with the deletion of paragraph (d) of the DBCP standard. The commenter, the United Steel Workers of America (Ex. 3–16) stated:

The DBCP standard requires employers to notify OSHA if they introduce the substance into the workplace. No known employers currently use or produce DBCP. If any do so in the future, it would be useful for the Agency to know it. Therefore, there is no reason to delete this provision. The deletion would not even reduce any current paperwork burdens.

At the request of the public, OSHA queried its regions on the notification of use and establishment of regulated area provisions. The regions said that very few notifications have been received with regard to any chemicals (*e.g.*, arsenic) and that the reports are not used for targeting inspections (Ex. 9–1–1). (For example, one region stated it has

received 2 to 3 reports over 28 years regarding reporting for vinyl chloride.) In any case, OSHA has other provisions for targeting inspections.

OSHA has decided to delete this requirement. It has not been used by OSHA and no other OSHA health standards have such provisions. At the time of this proposal, OSHA was aware that DBCP is no longer produced or used, and therefore no reduction in burden hours was projected for the deletion. Nonetheless, if DBCP was used again, OSHA still considers the provision an unnecessary burden under the Paper Work Reduction Act and unnecessary for purposes of targeting inspections. Moreover, if DBCP were to be used again, the standard would protect employees.

A number of other OSHA standards dating from the 1970s require employers to notify the nearest OSHA Area Director/Office if they are required to establish regulated areas in their workplaces. The following standards have such a requirement: Paragraph 1910.1003(f)(1) of the 13 carcinogens standard; paragraph 1910.1017(n)(1) of the vinyl chloride standard; paragraph 1910.1018(d)(1) of the inorganic arsenic standard; and, paragraph 1910.1045(d)(1) of the acrylonitrile standard.

The preamble to the vinyl chloride standard explains that the purpose of this notification requirement is to enable OSHA to obtain information on control technology (39 FR 35896, October 4, 1974). The preamble to the acrylonitrile standard notes that the requirement is designed to enable OSHA to be aware of facilities where substantial exposure exists (43 FR 45762).

In the years since these standards were promulgated, OSHA has not found the notification provision useful for the purposes described in the two preambles nor have these requirements been useful for compliance inspection targeting purposes. No other substance-specific standards promulgated by OSHA require such notification. The Agency proposed to delete the notification requirement from the standards to reduce unnecessary collections of information (paperwork burdens) required by OSHA but not used by OSHA. OSHA invited comment on the effect this deletion would have in general, and specifically on employee protection, employer burden, and paperwork reduction.

OSHA received 14 comments on the OSHA notification provision concerning regulated areas (Exs. 3–8, 10, 13, 14, 16, 17, 18, 22, 27, 29; 4–7, 11, 12, 13). Nine commenters supported deleting notifying OSHA of regulated areas (Exs. 3–8, 10, 13, 14, 22, 29; 4–7, 11, 12). Dow Chemical (Ex. 3–13) observed:

> Dow agrees with OSHA that it is appropriate to revise the requirement that an employer notify the Agency when it has established a "regulated area." OSHA does not find the information useful and we believe that the information serves no purpose and should be eliminated. The requirement to notify places a burden on the employer that does not appear to be necessary. Conditions in an area that might require reporting can change quickly. While these changes are being monitored, it does not appear to be a useful exercise to determine how many days the employer has to postmark a letter detailing the information to OSHA, particularly when OSHA does not utilize the information anyway. Further, there are many tasks that potentially might trigger establishing a regulated area, where other tasks involving the same chemical do not. Thus, it does not seem particularly helpful or necessary to notify OSHA when establishing a regulated area which only exists when certain tasks, done at a variety of different frequencies (rather than a permanent arrangement), exists. Dow supports OSHA's efforts to eliminate this unnecessary regulatory burden.

Organization Resources Counselors (Ex. 3–22) indicated it agreed with the elimination of the provisions on the principle that if OSHA no longer has a need to collect information or finds that the information provides no useful benefits for enforcement or protection, then the requirements should be deleted.

Five commenters did not agree that the regulated area notification provisions were unnecessary or should be deleted (Exs. 3–16, 17, 18, 27; 4–13). The UAW (Ex. 3–17) observed that the stronger argument would be to extend the requirement to other standards. This would enable OSHA to target health inspections more efficiently. The AFL–CIO (Ex. 3–27) stated:

> We are also opposed to removing the requirement to notify OSHA whenever regulated areas are established for the 16 carcinogens. This information can be extremely helpful in protecting worker health by identifying effective methods to control exposure and targeting OSHA inspections. Instead of eliminating this requirement, the agency should improve all its health standards by incorporating this provision into all of its health standards.

Also, the ICWU (Ex. 4–13) believes the rule at least encourages employers to investigate and institute corrective actions.

OSHA concludes that the notification requirements are not adding to worker protection and eliminating them will reduce the collection of information (paperwork) burden and overall improve compliance with OSHA health standards by making them more consistent. OSHA has not been using these reports for enforcement purposes. (See Ex. 9.) These are older standards with a high degree of compliance and where technology was long ago developed to achieve compliance. OSHA has other methods for targeting inspections. OSHA therefore has decided to eliminate these reporting requirements.

L. Reporting Emergencies to OSHA

Paragraph 1910.1017(n)(2) of the vinyl chloride standard and paragraph 1910.1045(d)(2) of the acrylonitrile standard require employers to report the occurrence of emergencies involving these substances to the nearest OSHA Area Director/Office. The preambles to these standards are silent on the reason for this reporting requirement and OSHA has not found such reporting, which has occurred only rarely, useful. In addition, other Agency substance-specific standards do not have such a requirement. Accordingly, OSHA proposed to delete these reporting provisions as unnecessary and a way to reduce unnecessary collections of information (paperwork burdens). OSHA asked for comment on the proposed deletions and for information on any impact such an action might have.

Thirteen commenters addressed the deletion of the provisions requiring notifying the OSHA Area Director/Office of an emergency (Exs. 3–4, 8, 10, 13, 14, 16, 17, 18, 22, 27, 29; 4–11, 13). Of those, seven commenters supported the modification (Exs. 3–8, 10, 13, 14, 22, 29; 4–11) and six commenters did not (Exs. 3–4, 16, 17, 18, 27; 4–13). Generally, commenters that supported the modification believed that if OSHA does not use the information, then it should not be collected.

The commenters who did not agree with the modification indicated that the information could be very useful to OSHA and employers if it was collected and evaluated properly. The AFL–CIO (Ex. 3–27) argued:

> The AFL–CIO is opposed to the deletion of this requirement because it will weaken worker protection. Information from emergencies can be used to identify hazards and inform other employers using these substances about control procedures that can eliminate similar emergencies from occurring in the future. The fact that such reporting has been rare is irrelevant and not sufficient justification to delete it from these two standards. Furthermore, it is our position that this emergency reporting requirement should be extended to all of OSHA's health standards. To do so, in our opinion, would genuinely result in the improvement of the

agency's standards and increase worker protection.

OSHA remains unconvinced by these arguments that it should retain the requirement to report emergencies for these two substances. OSHA regions have not been utilizing the few reports which have been filed, though several regional staff felt they conceivably could be useful. However, that the plans could be useful is not very persuasive when they have not been used. OSHA has other regulations for reporting deaths and serious injuries (see 29 CFR 1904.39).

Speculation that employees may be protected by these emergency reporting requirements does not outweigh the fact that emergency reports required by these standards are rare and OSHA has found them not to be useful. Finally, no evidence in the rulemaking records for OSHA's more recent health standards compelled the Agency to include emergency reporting requirements. Thus, OSHA had concluded that the requirements are unnecessary and create a needless paperwork burden. Therefore, the requirement to report emergencies to OSHA contained in these two standards is being deleted in this final rule.

M. Semiannual Updating of Compliance Plans

The Agency's substance-specific standards typically require employers to develop compliance plans to meet the exposure-control objectives of the standard. Most of these standards specify that employers must update these plans at least annually because OSHA believed that annual updating was sufficient to ensure the continued effectiveness of the plans. However, a few of the substance-specific standards promulgated by the Agency require semiannual updating. These standards include: the standard for vinyl chloride, paragraph 1910.1017(f)(3); the inorganic arsenic standard, paragraph 1910.1018(g)(2)(iv); the lead standard, paragraph 1910.1025(e)(3)(iv); the coke oven emissions standard, paragraph 1910.1029(f)(6)(iv); the DBCP standard, paragraph 1910.1044(g)(2)(ii); the acrylonitrile standard, paragraph 1910.1045(g)(2)(v); and, the lead in construction standard, paragraph 1926.62(e)(2)(v).

The preambles to these standards, vinyl chloride, inorganic arsenic, lead, coke oven emissions, DBCP, acrylonitrile and lead in construction, contained no evidence pointing to the need for a semiannual update of compliance plans in facilities handling these substances. Further, OSHA believed that current industry practice with respect to health issues is annual updating, which is consistent with other OSHA health standards. Based on these reasons, the Agency proposed to revise those substance-specific standards that contain semiannual updating to annual updating. The revision would make the compliance plan update requirements consistent across health standards without diminishing employee protection and would also reduce unnecessary paperwork. The Agency solicited comment on any impact, particularly on employee health, that the proposed revision might have.

Many commenters addressed the proposed change to an annual update of compliance plans (Exs. 3–4, 7, 8, 10, 13, 14, 15, 16, 17 18, 22, 27, 28, 29; 4–7, 11, 12, 13). Most of these commenters supported the revision as well as OSHA's reasons (Exs. 3–7, 8, 10, 13, 14, 15, 22, 28, 29; 4–7, 11, 12). However, some commenters disagreed with the proposed change (Exs. 3–4, 16, 17, 18, 27; 4–13).

Of those commenters that endorsed the change, OxyChem (Ex. 3–10) stated:

> The VCM standard requires a written compliance plan whenever employees' exposures exceed the Permissible Exposure Limit ("PEL"). The compliance plan is intended to help reduce employee exposures to or below the PEL through use of engineering and work practice controls. The written plan is required to be updated semi-annually. Like several other proposed revisions affecting the VCM standard, OSHA proposes to revise this regulation to require an annual update of the written plan. This will make these rules consistent with recent occupational health standards. While semi-annual plan updating may have been important when the VCM standard was published, it is no longer needed due to the reduced potential for exposure to VCM in the manufacturing and user industries. OxyChem supports this proposal.

Additionally, the American Coke and Coal Chemicals Institute (Ex. 3–28) noted:

> ACCCI supports this revision, as it would have no diminishing effect on employee safety and health. Engineering controls are well established and maintained throughout the industry, and work practice controls remain regimented within individual coke making facilities. Furthermore, employee protection is ensured through related compliance with other applicable standards such as Respiratory Protection (1910.134) and Personal Protective Equipment (1910.132).

Finally, the American Society of Safety Engineers (Ex. 4–11) recommended "this change to encourage uniformity in industrial health recordkeeping."

In contrast, the AFL–CIO (Ex. 3–27) remarked:

> The AFL–CIO is opposed to OSHA's proposed change. The semiannual requirement applies to a significant number of chemicals and is an important provision, particularly in circumstances where changes in the workplace occur that may increase the potential for worker exposures. Furthermore, in the interest of increasing worker protection, we believe this requirement needs to be added to all of the agency's health standards.

After reviewing the comments, OSHA concludes that annual updates are sufficient. Uniformity among standards is advantageous for improving compliance. Semi-annual updating of compliance plans was most useful in the years immediately following the promulgation of these standards. In those years, employers were installing engineering controls, evaluating their effectiveness and making modifications to increase their effectiveness. Now that many years have passed and engineering control strategies have been well established, the need to evaluate twice each year is diminished and does not outweigh the benefits of consistency among OSHA's health standards. Employees continue to be fully protected by the substantive provisions of these standards. Consequently the revisions will make compliance plan updates more consistent without diminishing employee protection. The revisions will also reduce employers' collection of information burdens (paperwork) which the Paperwork Reduction Act requires OSHA to consider. Therefore, OSHA is revising these standards to allow for an annual compliance program review.

N. Notifying Employees of Their Exposure Monitoring Results

Many of OSHA's substance-specific standards require employers to notify employees of their exposure monitoring results. The manner of notification varies. (See Table 1) Some standards require the employer to provide written notification to each employee in a monitoring program and also post the monitoring results. Other standards require the employer to only notify the individual of exposure monitoring results. Still other standards require that monitoring results be posted.

Obviously, the reason for employee notification of monitoring results is for employees to be aware of their exposures to regulated substances. However, the preambles to these standards do not identify the reasons for the differences in the manner in which employees are informed of their exposure results. Also, there was no evidence to suggest that the timing differences were based on effects on

employee health. Therefore, OSHA believed that making the notification and timing requirements consistent across standards would reduce regulatory confusion and facilitate compliance without diminishing employee protection.

The Agency proposed to allow employers to provide employees with their exposure monitoring results either individually in writing, or by posting the results in a readily accessible location, or by both. There were a number of considerations identified by OSHA with regard to the manner in which employees are notified. For example, individual notification gives employees a permanent record and they may take individual notification more seriously. Individual notification also avoids possible privacy concerns that may be associated with posting results. However, individual notification increases the paperwork burden on employers. On the other hand, posting monitoring has advantages. When monitoring results are posted, all employees, not just those monitored, will have knowledge of overall exposure related trends in their workplace. Posting monitoring results, however, might pose privacy issues that will be discussed under section O, Additional Issues for Comment. OSHA requested information on the impact the proposed revision might have on employee protection.

TABLE 1.—METHOD OF NOTIFICATION AND TIME PERIOD FOR NOTIFICATION OF EXPOSURE RESULTS

Standard	Method of notification	Maximum period for notification
Part 1910—General Industry		
Asbestos: Paragraph 1910.1001(d)(7)(i)	Individually in writing *or* posting	15 working days.
Vinyl Chloride: Paragraph 1910.1017(n)(3)	Individually in writing only	10 working days.
Inorganic Arsenic: Paragraph 1910.1018(e)(5)(i)	Individually in writing only	5 working days.
Lead: Paragraph 1910.1025(d)(8)(i)	Individually in writing only	5 working days.
Cadmium: Paragraph 1910.1027(d)(5)(i)	Individually in writing *and* posting	15 working days.
Benzene: Paragraph 1910.1028(e)(7)(i)	Individually in writing only	15 working days.
Coke Oven Emissions: Paragraph 1910.1029(e)(3)(i)	Individually in writing only	5 working days.
Cotton Dust: Paragraph 1910.1043(d)(4)(i)	Individually in writing only	20 working days.
1,2-Dibromo-3-Chloropropane: Paragraph 1910.1044(f)(5)(i)	Individually in writing only	5 working days.
Acrylonitrile: Paragraph 1910.1045(e)(5)(i)	Individually in writing only	5 working days.
Ethylene Oxide: Paragraph 1910.1047(d)(7)(i)	Individually in writing *or* posting	15 working days.
Formaldehyde: Paragraph 1910.1048(d)(6)	Individually in writing *or* posting	15 working days.
Methylenedianiline: Paragraph 1910.1050(e)(7)(i)	Individually in writing *or* posting	15 working days.
Butadiene: Paragraph 1910.1051(d)(7)(i)	Individually in writing *or* posting	5 working days.
Methylene Chloride: Paragraph 1910.1052(d)(5)(i)	Individually in writing *or* posting	15 working days.
Part 1915—Shipyard Employment		
Asbestos: Paragraphs 1915.1001(f)(5)(i) and (f)(5)(ii)	Individually in writing *or* posting	As soon as possible.
Part 1926—Construction		
Methylenedianiline: Paragraph 1926.60(f)(7)(i)	Individually in writing *or* posting	15 working days.
Lead: Paragraph 1926.62(d)(8)(i)	Individually in writing only	5 working days.
Asbestos: Paragraphs 1926.1101(f)(5)(i) and (f)(5)(ii)	Individually in writing *or* posting	As soon as possible.
Cadmium: Paragraph 1926.1127(d)(5)(i)	Individually in writing *and* posting	5 working days.

In addition to the notification requirements, these standards contain a variety of different time limits between receipt of employees' exposure monitoring results and notification of employees. Employee notification time for exposure results range from "as soon as possible," to 5, 10, 15 or 20 working days after the employer receives the monitoring results. See Table 1 for the amount of time permitted by 15 substance-specific standards for general industry, one for shipyard employment, and four for construction.

OSHA proposed to require employers regulated by the 15 substance-specific standards for general industry to notify employees of their exposure monitoring results within 15 working days of receiving the results. OSHA believed a consistent time-period would simplify employer compliance and found no reason to believe that 15 days is an unreasonable time frame or would in any way compromise employee protection.

For construction employers covered by the methylenedianiline, lead, asbestos, or cadmium standards, and shipyard employers covered by the asbestos standard, OSHA proposed to require notification as soon as possible but no later than five working days after the employer receives the results of exposure monitoring.

The asbestos and cadmium standards established different time periods for notification based on the industries affected. Although the general industry asbestos standard requires employee notification within 15 working days, both the construction and shipyard employment asbestos standards require notification "as soon as possible." Construction and shipyard employers were believed to have employees that were involved in more short-term and intermittent activities. Also, the general industry cadmium standard requires employee notification within 15 working days while the construction cadmium standard requires notification within five working days. Again, the preamble to the construction cadmium standard states that the five working-day notification period is appropriate because of the short term nature of many construction jobs (57 FR 42383).

OSHA requested comment on the appropriateness of the different notification time periods. The Agency believed that factors such as short-term or intermittent projects might justify retaining the shorter notification periods for construction and shipyard employment activities, although some health standards allow 15 working day time periods standards for these industries.

OSHA invited comment and information on the proposed revisions to the notification requirements in OSHA health standards, particularly on the differences proposed for employers in different industries and any reduction in employee protection that may result from the proposed revisions.

OSHA received 24 comments on the means of employee notification and the time period to inform employees the results of exposure monitoring (Exs. 3–1, 3, 4, 5, 7, 8, 10, 13, 14, 15, 16, 17, 18, 22, 23, 24, 26, 27, 28, 29; 4–7, 11, 12, 13). Of these comments, the majority addressed OSHA's proposal to allow informing employees of their exposure individually in writing, by posting the results, or by both (Exs. 3–1, 4, 7, 8, 10, 15, 16, 17, 22, 23, 26, 27, 28, 29; 4–12, 13) and most supported the proposal (Exs. 3–1, 7, 8, 10, 15, 16, 22, 23, 28, 29; 4–12, 13).

For example, Phelps Dodge Corporation (Ex. 3–7) remarked:

> We support OSHA's proposal to allow employers to provide employees with their exposure monitoring results either individually in writing or by posting the employees' results in a readily accessible location. We agree with OSHA's preliminary finding that the goal of ensuring that employees are aware of their exposures can effectively be met either by individual written notification or by posting results in a location that is readily accessible to all employees whose results are being posted. Posting results for general observation is efficient and provides a large number of people access to the exposure monitoring results. However, in some cases, individual written notification may be the preferred method of communication if the notification involves sensitive information. We ask OSHA to provide employers with the flexibility to choose the best method to notify employees and make this notification an effective communication tool.

The United Steelworkers of America (Ex. 3–16) stated that "We agree that these standards should be harmonized, and we agree that exposure results could be provided individually or by posting."

One commenter that supported employer choice of individual notification or posting, expressed concern about employee privacy with respect to posting monitoring results. OxyChem (Ex. 3–10) observed that "employers should not be forced to utilize employee identifiers that invoke privacy concerns when performing the notification of monitoring" such as social security numbers. OSHA absolutely agrees that employers should not use employee identifiers when posting monitoring results and does not require such identification and emphatically recommends that employers not use such identifiers.

Several commenters did not support allowing employers the latitude in choosing the method of informing employees about their exposures (Exs. 3–4, 17, 26, 27). The Paper, Allied-Industrial, Chemical & Energy Workers International Union (PACE) (Ex. 3–4) remarked:

> PACE sees no need or rationale for OSHA to change the requirement that employees receive their own test results on an individual basis. The proposed change is highly objectionable. In fact, OSHA should required that employers provide written notification of such results to individuals and, in addition, should require employers to post such results on an anonymous basis in a conspicuous place in the workplace. Many workers do not pay much attention to bulletin boards in the workplace and, therefore, use of such a communication method would likely not be effective. Also by being provided a written copy of exposure monitoring results, the employee has a record of exposures to toxic substances in a form that they can take with them, should they change employers.

OSHA concludes that its proposal to permit employers to either post or individually provide monitoring data to employees is justified. There is a substantial health benefit to employees to posting. They will be able to know exposures in all parts of the workplace, to know whether the employer is keeping exposures below the PEL, where in the workplace they need to wear a respirator and overall exposure trends. Individual notification may have some privacy benefits and employees may take the notification more seriously. Balancing these factors, and the reduced collection of information (paperwork) burden and increased flexibility at giving the employer the option, OSHA concludes that the proposal is justified. If an employee wants a copy of the record, then the employee can request the record under the 29 CFR 1910.1020, Access to Employee Exposure and Medical Records standard.

Of the 24 comments that addressed employee notification and the time limits for informing employees of exposure results, 21 commented on the number of days employers should have before notifying employees of exposure (Ex. 3–1, 3, 4, 5, 7, 8, 10, 13, 14, 15, 16, 23, 24, 26, 27, 28, 29; 4–1, 7, 11, 13). Although commenters generally agreed that it would be beneficial to have a consistent timeframe across standards, some commenters believed that 5 days should be the reporting time for general industry rather than the proposed 15 days (Exs. 3–4, 16, 26, 27; 4–13). For example, PACE (Ex. 3–4) remarked:

> OSHA's proposal to standardize the reporting period for employee monitoring results is fine, but the period should be a maximum of five days. There is really no need for a longer period of time. Providing for a longer period of time for notification communicates the lack of importance of such monitoring. In addition, use of a one week period will allow workers to remember what kinds of activities they were engaged in on the day of monitoring, which, in turn, may have lead to excessive exposure. Hence, the utility of exposure monitoring would be enhanced with a short notification period.

The United Steelworkers of America (Ex. 3–16) observed:

> We agree that these standards should be harmonized, and we agree that exposure results could be provided individually or by posting. But there is no reason for an employer to hold monitoring results for up to three weeks before passing them on to the employee, especially when the employer can do so by posting. These standards should be harmonized upwards, to a maximum notification period of five working days.

Finally, the AFL–CIO (Ex. 3–27) stated that:

> The AFL–CIO fully agrees that it is reasonable to establish consistency in the notification period. However, it is our position that, in order to be genuinely consistent in protecting workers from exposures to all of these substances, a 5 day notification period should be applicable across all industries and not just construction and shipyard industries. Again, OSHA's proposed 15 day period for general industry is the lowest common denominator. Reducing, uniformly, the notification period to 5 days increases worker protection by reducing the period of time between notification of the results and the subsequent implementation of responses to reduce worker exposure where overexposures have been identified.

On the other hand, the majority of commenters agreed with the 15 day uniform reporting proposal for general industry (Exs. 3–1, 3, 7, 8, 10, 13, 14, 15, 22, 28, 29; 4–1, 7, 11). A commenter from Phelps Dodge Corporation (Ex. 3–7) observed:

> We support OSHA's proposal to make the requirements for notifying employees of exposure monitoring results in the 15 general industry standards consistent at 15 working days. This time interval ensures timely communication of results to employees, while giving employers sufficient time to adequately evaluate and communicate exposure-monitoring results. In addition, many standards require that the employer communicate a corrective action plan to the employee when exposures exceed the Permissible Exposures Limit. It is often impossible to develop an effective and realistic plan in less than 15 working days.

Dow Chemical Company (Ex. 13) remarked:

> Having consistency in this area will greatly reduce administrative burden as well as

regulatory confusion. This, in turn, will facilitate better compliance without diminishing employee protection.

The American Coke and Coal Chemicals Institute (ACCCI) (Ex. 3–28) also supported the proposal by stating:

ACCCI is in agreement with the proposal revisions, as they would facilitate regulatory compliance without adversely affecting employee health. By increasing the notification period to 15 days, it not only provides consistency with other standards but also provides employers with the leeway to work through periods when employees may be away from work and to coordinate any remedial testing that may be warranted by the initial results.

Finally, the American Chemistry Council (Ex. 3–29) noted:

The wide variety of existing requirements creates confusion and an unnecessary burden on employers to keep detailed records on individual employees' different potential exposures. ACC recommends OSHA establish a uniform reporting timeframe (*e.g.* fifteen days).

A few commenters urged OSHA not to limit the maritime shipyard proposal (Ex. 3–1) or the construction proposals (Exs. 3–5, 7, 13, 24; 4–7) to a 5-day notification rather than a 15 day notification. Northrop Grumman Newport News (Ex. 3–1) indicated that it:

Does not agree with the proposal to require notification "as soon as possible but no later than five working days" after shipyard employers receive exposure-monitoring results. The shipyard employee population is as non-transitory as general industry in spite of short-term and intermittent projects and that those employees will receive exposure notification as effectively as in general industry.

With respect to the construction industry, Phelps Dodge Corporation (Ex. 3–7) stated:

We believe that the construction industry should also be allowed 15 working days to communicate the results of exposure monitoring. While some employees in these fields are employed for only short periods of time, the employer would still be able to reach them to communicate their results in the vast majority of cases. Interaction between employers and transient employees continues to take place when paychecks or tax documents are mailed. We believe that the proposed five-day time limit in the construction standard effectively prohibits any meaningful employee involvement in developing action plans.

Dow Chemical Company (Ex. 3–13) remarked:

While we understand the premise for the difference in report times (namely, that the transient nature of construction work and the construction workers may lead to difficulty in communicating results), this has not been our experience. Construction workers must still provide addresses to their employer and this information can still be channeled to the individuals accordingly. Moreover, employees in general industry as well as construction are advised of their rights to access this information. To have inconsistent notification requirements will be confusing for General Industry employers that may have extensive construction work on their sites, as they may have to comply with both standards. Dow believes that both the General Industry and Construction Standards should follow the proposed 15 working day requirement for employee notification.

Finally, Pinnacle West Capital Corporation (Ex. 4–7) observed:

We see no reason to have a shorter period for construction workers. Our experience is that when we monitor a contractor's employee, we provide notice to the construction company, who is then required to provide it to their employee. The 15 working day period would allow enough time to complete the notification. Even when the worker has left the construction company's employment, they usually have either his/her home address or know for which union he/she works. This notification can be made to either place. Less than 15 working days almost make this almost impossible.

OSHA has concluded that a uniform time limit for notifying employees in general industry has substantial benefits. It will improve employer understanding of standards and improve compliance. As a practical matter it will reduce employers paperwork burdens because their compliance program will be simpler and uniform. There will be no reduction in employee protection and probably improvement because of improved compliance. The 15 working day period is a reasonable time for notification in general industry with its more stable workforce and is the time frame OSHA adopted in most of its health standards for general industry.

Employment at a particular location is often brief in construction and sometimes brief in shipyards. Therefore OSHA is finalizing the proposal "as soon as possible but not more than 5 working days" requirement for asbestos in shipyards and MDA, lead, asbestos, and cadmium in construction.

O. Additional Issue for Comment

Social Security Numbers

OSHA's substance-specific standards require that exposure monitoring and medical-surveillance records that the employer is required to retain, include the employee's social security number (SSN). In the preamble to the final methylene chloride standard (62 FR 1598, January 10, 1997), OSHA justified the requirement for employers to document social security numbers by observing that the numbers are correlated to employee identity in other types of records and that they are a more useful differentiation among employees since each number is unique to an individual for a lifetime and does not change as an employee changes employers. In a letter of interpretation regarding the use of social security numbers in the asbestos standard for construction (April 16, 1999), the Agency provided the following response. Many employees have identical or similar names and that identifying employees solely by name makes it difficult to determine to which employee a particular record pertains. The use of SSNs avoids this problem because they are unique to an individual.

In addition, epidemiologic studies of employee health from workplace exposures to toxic substances require that social security numbers be attached to employee medical and monitoring records. Only in that way can employee health end points be compared to employee exposures over many years, over changes in employers and ultimately be compared to death certificates.

However, OSHA has examined alternatives to requiring SSNs in its requirements for employee identification due to growing concerns about individual privacy. In Phase II of the Standards Improvement Project, OSHA requested public comments on: the necessity, usefulness, and effectiveness of SSNs as a means of identifying employee records in exposure monitoring and medical-surveillance records. Further, OSHA asked whether there were privacy concerns or issues raised by this requirement. Finally, the Agency inquired about the existence of other equally effective methods of uniquely identifying employees for OSHA exposure and medical-surveillance records.

The Agency received 14 comments with respect to OSHA's requirements to use employee SSNs in records (Exs. 3–1, 7, 9, 16, 17, 24, 26, 27, 28, 29; 4–6, 7, 11, 13). Seven commenters believed that SSNs needed to be retained in OSHA standards (Exs. 3–9, 16, 17, 24, 27; 4–6, 13). NIOSH (Ex. 9) strongly believes in the use of SSNs. NIOSH stated:

In NIOSH's experience, the SSN is the most practical identifier when studying large workplace populations. Any other unique and unchanging individual identifier that would accompany a worker throughout his or her life would essentially serve as an SSN surrogate. This alternative identifier would also have to be a unique personal identifier

and would thus share any privacy concerns associated with the use of SSNs.

NIOSH listed a number of shortcomings concerning the use of employer-generated identifiers. They include:

1. Use of non-unique identification numbers or codes across employers;
2. Re-issuance of previously used identification codes to different individuals;
3. Periodic changes in identification codes with changes in company ownership or organization;
4. Introduction of new or revised data management systems;
5. Changes in product lines;
6. Elimination of functions or activities;
7. Implementation of new payroll or other administrative systems;
8. Revision of job titles;
9. Abbreviations following personal names (*e.g.*, Jr., Sr., Esq.)
10. Variations in spelling of names or name changes (for example, through marriage).

The United Steel Workers of America (Ex. 3–16) remarked:

> Employers currently use social security numbers on virtually all employee records. Almost all health care institutions and insurance companies identity individuals by social security number. We understand OMB's privacy concerns, but employee exposure records are an insignificant part of the problem of workplace privacy. Deleting requirements for social security numbers would complicate record handling. It would also complicate epidemiological studies, which depend on social security numbers to ascertain vital status.

Also, Verizon Communications, Inc. (Ex. 3–24) offered its opinion on why SSNs should be retained in OSHA health standards:

> Anytime a SSN is used as an identifier on paperwork, one might raise the issue of privacy. However, one should try to balance these privacy issues against the need to have a unique identifier that can be used to track individuals. Certainly, a SSN is unique and follows the person for a lifetime. There is no ambiguity when such an exclusive number is used. In work-related exposure situations, it is desirable to track individuals for the short term and the long term. There is a strong emphasis within the public health arena to follow and protect workers, especially over a working lifetime with multiple employers. Verizon believes that this need outweighs the potential privacy issues involved in using a SSN for tracking purposes. Verizon is not aware of anything comparable to a SSN that could serve a similar purpose. Even if there were, privacy issues might also be raised with its use. In summary, it is Verizon's opinion that if one balances the uniqueness of SSN and the strong public health policy to follow and protect these individuals employees against the public's interest in maintaining adequate privacy, the scales are tipped in favor of retaining the current system.

Four commenters disagreed with continuing the use of SSNs (Exs. 3–1, 7, 28; 4–7) and suggested that some other identification system should be developed to identify employees for the purposes of exposure monitoring or medical-surveillance. Northrup Grumman Newport News (Ex. 3–1) expressed:

> OSHA should not continue to require that social security numbers be used as identifiers in employee exposure records. Widespread personal security concern associated with using them to identify individuals and records makes this practice unpopular and unnecessary in today's environment.
>
> Many companies, including Northrop Grumman Newport News, have already implemented alternative employee identification systems to allay employee security concerns and are in the process of phasing-out routine use of social security numbers as identifiers. If OSHA were to continue to require the use of social security numbers, employers using alternative numbering systems would be forced to maintain redundant and more secure social security number systems. This would be unnecessarily cumbersome, would not provide added benefit to OSHA, employers or employees and would be a continued concern to employees worried about personal security issues.

Another commenter, Pinnacle West Capital Corporation (Ex. 4–7), stated:

> We see no value in requiring monitoring records to include the social security number (SSN). Most employees, either ours or contractors are reluctant to give their SSN for privacy reasons. The only reason we were ever told that SSNs were necessary was for use in future epidemiological studies. We use our unique employee numbers for our workers. If needed for an epidemiological study, we could cross-reference the SSN from our employee numbers. That should be adequate to meet this need.

Finally, a few commenters recognized the need to identify employees for exposure monitoring and medical-surveillance but suggested that some other identification system might be developed in the future (Ex. 3–26, 29; 4–13). The American Chemistry Council (Ex. 3–29) indicated that it believed SSNs are the most effective means of tracking lifetime exposures to employees. "However, we also recognize potential privacy concerns within individual companies that may warrant further discussion and consideration. ACC would be interested in discussing alternatives with other stakeholders should OSHA convene such a group." The International Chemical Workers Union (Ex. 4–13) indicated that it is concerned about identity theft and that a means must be found to both protect employees privacy and ensure continuity of records across time and across employers.

Finally, the American Society of Safety Engineers (Ex. 4–11) remarked that employers should have the flexibility to use any system that enables accurate identification and tracking of employees for medical purposes.

OSHA health standards require employers to keep social security numbers with monitoring and medical records which employers are required to retain. All employers have access to employee social security numbers for tax purposes. OSHA's Access to Employee Exposure and Medical Records standard, 29 CFR 1910.1020, grants access to employee medical records only to the employee, those who the employee authorizes in writing to have access and to OSHA in circumstances requiring OSHA to rigorously protect the employee's privacy. So there is no additional privacy concern created by having social security numbers included in the medical records beyond that already existing in the employers use of the social security numbers for payroll and tax purposes.

Access to employee exposure records is similar except that a collective bargaining agent for an employee does have access to the monitoring data for employees. That assists collective bargaining agents to negotiate on employee health protection issues.

However, there is no requirement and no need for an employer to attach social security numbers to employee exposure records it intends to post or provide to anyone other than the employee whose record it is.

OSHA is not taking action in this final rule concerning the use of SSNs in the various health standards. OSHA believes that all commenters have raised significant concerns and that it will need to investigate this issue in greater detail.

First Aid

One commenter (Ex. 3–20), the American Heart Association, responded to the proposal with a request to eliminate or revise the OSHA Directive CPL–2–2.53, Guidelines for First Aid Training Programs. The request to revise the OSHA Directive is not a part of rulemaking and therefore has not been considered in this final rule.

III. Legal Considerations

The Agency concludes that the final rule does not reduce the employee protections put into place by the rules being revised. There is no change in exposure limits or action levels. There

are no reductions in respiratory protection, personal protective equipment or industrial hygiene provisions. There is therefore no change in risk and no need to determine significant risk, or the extent to which the proposed rule would reduce or increase that risk, as would be required by *Industrial Union Department, AFL–CIO* v. *American Petroleum Institute*, 448 U.S. 607 (1980), the Supreme Court ruling applying to standards addressing new hazards, setting more stringent standards, or reducing employee protection. Accordingly, no further analysis of significant risk is necessary as that has already been determined when OSHA issued the underlying standards.

A number of the amendments made by this rule change medical and monitoring provisions. These changes are covered by Sect. 6(b)(7) of the OSH Act.

IV. Final Economic Analysis

OSHA has determined that this final rule is not an economically significant regulatory action under Executive Order (E.O.) 12866. E.O. 12866 requires regulatory agencies to conduct an economic analysis for rules that meet certain criteria. The most frequently used criterion under E.O. 12866 is that the rule will impose annual costs on the economy of $100 million or more. Neither the benefits nor the costs of this rule exceed $100 million. OSHA has provided OMB's Office of Information and Regulatory Affairs with this assessment of the costs, benefits and alternatives, as required by section 6(a)(3)(C) of E.O. 12866.

OSHA has also determined that the final rule is not a major rule under the Congressional Review provisions of the Small Business Regulatory Enforcement Fairness Act. The Regulatory Flexibility Act of 1980 (RFA), as amended in 1996, requires OSHA to determine whether the Agency's regulatory actions will have a significant impact on a substantial number of small entities. OSHA's analysis, based on the analysis in this section of the preamble as well as the later section "OMB Review Under the Paperwork Reduction Act" below, indicates that the final rule will not have significant impacts on a substantial number of small entities. Indeed, the final standard reduces the costs and paperwork on all affected entities, including small businesses. The rule benefits small entities by reducing costs and paperwork.

The final standard deletes or revises a number of provisions in existing OSHA standards. The reasons for these changes are presented and discussed in subsections A through N in the Summary and Explanation of this preamble above. Most of the provisions delete requirements that the Agency has concluded are unnecessary to protect employee health. Some of the provisions provide greater flexibility in complying with requirements or reduce reporting requirements that have proved to have little if any value in protecting worker health. One provision updates a reference to a current consensus standard (for first aid kits) and another corrects a technical error in requirements for evaluating x-rays for lung cancer.

The final rule is technologically feasible because it reduces or eliminates current requirements on employers. The Agency considered regulatory and non-regulatory alternatives to the final rule. Because every final provision reduces requirements or provides flexibility to employers by revising current standards, non-regulatory alternatives are not an appropriate remedy to affect those changes. As discussed in the Summary and Explanation section above, the Agency considered alternatives to amending the several ancillary provisions. In most cases, the Agency chose to revise older ancillary provisions to make them consistent with standards more recently promulgated by the Agency. In some cases, the final standard provided more flexibility in the way information is communicated to employees or the Agency. All of the final provisions were intended to reduce burden on employers—or provide flexibility—while maintaining necessary protections for employee health.

This Final Economic Analysis provides estimates of the cost savings resulting from the final standard. All of the changes OSHA is making are expected to reduce employers' costs of compliance. The revised standard eliminates or reduces requirements for many "ancillary" provisions, provides greater flexibility for compliance for others, or reduces paperwork/reporting requirements. For most of these changes, economic benefits can be quantified. Where revisions have only provided greater flexibility for compliance, the Agency has not calculated any cost savings.

The Agency received several comments in response to the proposal that asserted that the proposed standards would weaken employee protection (*e.g.*, AFL–CIO, Ex. 3–27). However, as discussed above in the Summary and Explanation section, the Agency has concluded that the final standards do not reduce protection for employees. Amending the ancillary provisions of older standards will make them consistent with the industrial hygiene and surveillance practices of more recent standards.

The Agency received only a few comments on the estimates of cost savings from the proposed standards. A comment from the International Chemical Workers Union (Ex. 4–13) asserted that some cost savings were "minimal" or that some of the provisions were only a "minimal burden on employers," but did not offer any corrections to the Agency's estimates or provide new estimates.

The AN [Acrylonitrile] Group said that the Agency had "grossly underestimated the time and cost-burden [savings]" resulting from the final standard. As an example, the AN Group cites the costs of reporting an emergency to OSHA [29 CFR 1910.1045(d)(2)]. OSHA estimates the cost that will be saved by the final standard as an hour's time each for a manager and a secretary to prepare the notification of an emergency. But the AN Group suggests that actual paperwork costs should include assessing whether an event qualifies as an emergency, including time for groups of professionals to meet. The Agency has concluded that its existing regulation does not require such a complex determination. Although that saving may be real for some employers, it is not required or necessarily implied by the standard and the Agency is not revising the cost saving estimate for that provision in the final standard.

Dow Chemical (Ex. 3–13) stated that the Agency's estimates of cost savings for reduced sampling frequencies was underestimated. According to Dow, the Agency should include the cost of "pre-work time" it takes for exposure monitoring. Pre-work time would include: identifying employees at work that day; setting up times for monitoring; determining the number of samples to be taken; ordering badges (for vinyl chloride, in this instance); internal analysis of the sampling results; and written reports. Accordingly, the Agency has revised the model in "Provision F" below, which estimates the cost [savings] for exposure monitoring for vinyl chloride and acrylonitrile.

The Agency estimates that the final standard will result in total annual cost savings of $6.8 million (see table below). (The estimates in this Final Economic Analysis may differ slightly from the estimates in the Paperwork Reduction Analysis below because of rounding.) Because this rule provides only cost savings, and no new costs on employers, it is economically feasible.

The following paragraphs discuss the methodology of the analysis and the estimates of cost (saving) for specific provisions.

ESTIMATED ANNUAL COST SAVINGS DUE TO THE STANDARDS IMPROVEMENT PROJECT—PHASE 2

Provisions A through N (as set out in the Summary and Explanation)	Annual cost savings ($)
A § 1910.42, Temporary Labor Camps	0
B § 1910.151(b), Reference to First Aid Supplies in Appendix A	0
C § 1910.268, First Aid Supplies Telecom	5,618
D § 1910.1003(f)(2) Incident Reports, 13 Carcinogens	27,286
E § 1910.1017(k)(6), Vinyl Chloride	0
F:	
§ 1910.1017(d)(2)(i), Exposure Monitoring, Vinyl Chloride	66,024
§ 1910.1017(d)(2)(ii), Exposure Monitoring, Vinyl Chloride	17,554
§ 1910.1044(f)(3)(i) & f(3)(ii), Exposure Monitoring, 1,2–DBCP	0
§ 1910.1045(e)(3)(ii), Exposure Monitoring, Acrylonitrile	160,455
F Subtotal	244,033
G:	
§ 1915.1001(g)(6)(iii), Alt. Control Methods, Asbestos Removal	39
§ 1926.1101(g)(6)(iii), Alt. Control Methods, Asbestos Removal	39
G Subtotal	78
H:	
§ 1910.1018(n)(2)(ii)(A), ILO/UC Rating, Inorganic Arsenic	0
§ 1910.1029(j)(2)(ii), ILO/UC Rating, Coke Oven Emissions	0
I:	
§ 1910.1001(1)(7)(i), Signed Opinion, Asbestos.	0
§ 1910.1027(1)(10)(i), Signed Opinion, Cadmium Gen. Industry	0
§ 1926.1127(1)(10)(i), Signed Opinion, Cadmium Con. Industry	0
J:	
§ 1910.1017(k)(2)(i), Semiannual Medical Exams, Vinyl Chloride	31,064
§ 1910.1018(n)(3)(ii), Semiannual Medical Exams, Inorganic Arsenic	157,005
§ 1910.1029(j)(3)(ii–iii), Semiannual Medical Exams, Coke Oven emissions	621,053
J Subtotal	809,122
K:	
§ 1910.1044(d), Notifying OSHA Regarding Regulated Areas, 1,2–DBCP	0
§ 1910.1003(f)(1) Notifying OSHA Regarding Regulated Areas, 13 Carcinogens	5,457
§ 1910.1017(n)(1) Notifying OSHA Regarding Regulated Areas, Vinyl Chloride	671
§ 1910.1018(d)(1) Notifying OSHA Regarding Regulated Areas, Inorganic Arsenic	117
§ 1910.1045(d)(1) Notifying OSHA Regarding Regulated Areas, Acrylonitrile	647
K Subtotal	6,892
L:	
§ 1910.1017(n)(2) Reporting Emergencies, Vinyl Chloride	22,504
§ 1910.1045(d)(2) Reporting Emergencies, Acrylonitrile	2,588
L Subtotal	25,091
M:	
§ 1910.1017(f)(3) Semiannual Updating Compliance Plans, Vinyl Chloride	7,614
§ 1910.1018(g)(2)(iv), Semiannual Updating Compliance Plans, Inorganic Arsenic	2,284
§ 1910.1029(f)(6)(iv), Semiannual Updating Compliance Plans, Coke Oven Emissions	1,332
§ 1910.1044(e)(3)(iv), Semiannual Updating Compliance Plans, 1,2–DCBP	0
§ 1910.1045(g)(2)(ii), Semiannual Updating Compliance Plans, Acrylonitrile	448
§ 1926.1025(e)(2)(v), Semiannual Updating Compliance Plans, Lead, Con	4,210,054
M Subtotal	4,221,732
N:	
§ 1910.1017(n)(3) Notify Employees of Expos. Monitoring Results, Vinyl Chloride	2,741
§ 1910.1018(e)(5)(i) Notify Employees of Expos. Monitoring Results, Inorganic Arsenic	9,393
§ 1910.1025(d)(8)(i) Notify Employees of Expos. Monitoring Results, Lead, Gen Ind	891,293
§ 1910.1027(d)(5)(i) Notify Employees of Expos. Monitoring Results, Cadmium, Gen Ind	50,341
§ 1910.1029(e)(3)(i) Notify Employees of Expos. Monitoring Results, Coke Oven	25,765
§ 1910.1043(d)(4)(i) Notify Employees of Expos. Monitoring Results, Cotton Dust	68,102
§ 1910.1044(f)(5)(i) Notify Employees of Expos. Monitoring Results, 1,2–DBCP	0
§ 1910.1045(e)(5)(i) Notify Employees of Expos. Monitoring Results, Acryonitrile	8,255
§ 1926.62(d)(8)(i) Notify Employees of Expos. Monitoring Results, Lead Construction	494,063
§ 1926.1127(d)(5)(i) Notify Employees of Expos. Monitoring Results, Cadmium, Con	27,189
N Subtotal	1,454,431
Total	6,794,283

Methodology

This section describes OSHA's development of the annual cost (savings) for the provisions of the final standard. For the purposes of this Final Economic Analysis, one-time or intermittent costs have been annualized using a discount rate of 7 percent, as required by the U.S. Office of Management and Budget (OMB) [Reference 1], over a specified period of time using the formula:

a = (i × (1 + i)\n\)/((1 + i)\n\ − 1), ["\n\" in the formula means raised to the nth power], where

a = annualization factor,

i = discount rate, and

n = economic life of the one-time or intermittent investment

OSHA uses average hourly earnings, including benefits, to represent the cost of employee time. For the relevant occupational categories, mean hourly earnings from the Year 2000 National Compensation Survey by the Bureau of Labor Statistics have been adjusted to reflect the fact that fringe benefits comprise about 27.1 percent of total employee compensation in the private sector (Reference 2). (Straight-line hourly wages and salaries were estimated to be 72.9 percent of total compensation in 2000. Total compensation including benefits for workers with hourly wages of $13.41 would be $13.41/.729 = $18.40). The costs of labor used in this analysis are therefore estimates of total hourly compensation. These average hourly costs are: $38.92 for managers; $27.39 for production supervisors; $24.68 for chemical technicians; $18.40 for production workers; and $17.34 for clerical workers.

Estimates of the number of establishments and the number of employees affected by the final standard are from a statement in support of information collection requirements (ICR) or from an economic analysis. The number of employees affected and their hourly total wages are used to calculate costs. The changes in existing standards made by the final Standards Improvement Project-Phase II pertain to approval of equipment, reporting incidents, exposure monitoring, laboratory analysis, medical examinations, and employee notification requirements.

Most of the provisions in the final standard reduce costs related to a percentage of affected employees in the industry and the number of labor hours required to monitor a specific activity. Usually, the frequency of an activity, the number of employees requiring the activity, and the cost of the activity per employee were used to arrive at the estimated costs. In some instances, the costs of the activity were calculated according to the number of affected establishments.

A. Temporary Labor Camps

Paragraph 1910.142(l)(2) requires that the camp superintendent immediately report the outbreak of certain diseases to the local health authority "by telegram or telephone." OSHA believes that because other forms of communication are readily available, the requirement for notification via "telegram or telephone" is unnecessarily restrictive. Thus, the Agency proposed deleting the requirements specifying notification by telegram or telephone. The final standard does not delete the language as proposed, but allows other means, thus permitting more flexibility in reporting. The Agency has not calculated the value of such savings.

B. Reference to First Aid Supplies in Appendix A to the Standard on Medical Services and First Aid

Paragraph 1910.151(b) in the Agency's standard regulating medical services and first aid supplies, requires employers to ensure that adequate first aid supplies be readily available in the workplace. OSHA added a non-mandatory appendix to this standard in a recent rulemaking (63 FR 33460) to help employers meet this requirement. OSHA proposed to update this appendix. OSHA has updated the appendix in the final rule. This revision would not impose any additional cost on employers because Appendix A is non-mandatory.

C. First Aid Supplies in the Telecommunications Standard

The final rule revises paragraph 1910.268(b)(3) of OSHA's telecommunications standard that requires an employer to: provide first aid supplies recommended by a consulting physician; ensure that the items are readily accessible and housed in weatherproof containers if used outdoors; and inspect the items at least once a month and replace expended items. The Agency is revising the paragraph to read, "Employers must provide employees with readily accessible, adequate, and appropriate first aid supplies. A non-mandatory example of appropriate supplies is listed in Appendix A to 29 CFR 1910.151."

The final rule eliminates the existing requirements in paragraph 1910.268(b)(3) that employers must have certain first aid supplies approved by a consulting physician before they are used. This requirement applied only in cases where no infirmary, clinic, or hospital was in close proximity to the worksite and the employer intended to treat first-aid injuries at the site. OSHA's analysis here relies on the assumptions in the Final Economic Analysis in an earlier rulemaking (63 FR 33461). Based on the ICR to that rulemaking, the Agency estimates that 10 percent of the establishments would meet these criteria. OSHA also estimates that 5 minutes of a physician's time, valued at $100/hr ($8.33 for five minutes), would be required to approve the contents of the first aid kit at these establishments. The opportunity cost is estimated by the market price for occupational physical exams; i.e. at the rate of about $100 per hour.

OSHA assumes that the physician would need to approve the first aid supplies once every 10 years, considering the possibility of the development of new kinds of medical supplies and of new hazards at the worksite. The cost of 5 minutes of a physician's time annualized over a 10-year period at 7 percent interest is $1.19 per year (5/60 × $100 × annualization factor of 0.1424). The Agency estimates that there were approximately 47,217 employers in the telecommunications industry in 1998 [County Business Patterns, 1998]. The major sector in the telecommunications industry is telephone communications, which consists of establishments that operate both wireline and wireless networks. The wireline networks use wires and cables to connect customers' premises to central offices maintained by the telecommunications companies. The wireless networks on the other hand operate through the transmission of signals over networks of radio towers and communications satellites [Career Guide to Industries 2000–01 Edition, Telecommunications (SIC's 481, 482, 489)]. Since first aid supplies have to be approved once every 10 years, each year approximately 10 percent of the establishments incur costs to comply with the current requirement. Thus, current annualized cost is approximately $5,618 ((47,217 × 10 percent) × $1.19). Eliminating the requirement for a physician's approval of an establishment's first aid kit would eliminate this annual burden of $5,603.

D. 13 Carcinogens

The final rule deletes paragraph 1910.1003(f)(2) that requires reporting of releases of a regulated carcinogen to the nearest OSHA Area Director. Deleting this provision results in a savings in burden hours and associated costs.

Based on the ICR, the Agency estimates that reportable incidents occur once per year at each facility and that about 97 employers fall under OSHA jurisdiction and will be affected by the rule. A manager and a clerical worker will each take 5 hours to collect information and to report a release of a regulated carcinogen to the nearest OSHA Area Director, for a total of 10 hours per employer. Thus, 970 burden hours are attributed to this provision (485 burden hours each by a manager and a clerk), at an annual cost of $27,286. Annual cost savings are obtained by multiplying 485 burden hours by each wage rate and adding the products [485 hours × ($38.92 + $17.34 per hour)]. By eliminating the requirement to report releases of a regulated carcinogen to the nearest OSHA Area Director, OSHA will eliminate annual cost burdens to employers of $27,286.

E. Vinyl Chloride

Paragraph 1910.1017(k)(6) of the vinyl chloride standard specifies that laboratories licensed by the U.S. Public Health Service (PHS) under 42 CFR part 74 ("Clinical laboratories") must analyze biological samples collected during medical examinations. However, 42 CFR part 74 is outdated, and the PHS now addresses laboratory licensing requirements under 42 CFR part 493 ("Laboratory requirements"). The Agency proposed to delete the reference to 42 CFR part 74 from paragraph (k)(6) of this standard. However, the Agency is replacing this outdated requirement with a requirement that employers use accredited laboratories for the medical tests required under the vinyl chloride standard. This change should provide employers with greater choice in laboratories while ensuring that qualified laboratories are used for required medical tests. The Agency had made no estimates of cost savings for this revision in the existing standards.

F. Monthly and Quarterly Exposure Monitoring

Several of the Agency's older standards retain provisions that require employers to monitor employee exposures either monthly or quarterly, depending on the concentration of the toxic substance found in the workplace. These include: paragraphs 1910.1017(d)(2)(i) and (d)(2)(ii) of the vinyl chloride standard, requiring employers to conduct exposure monitoring each month if employees' exposure are above the permissible exposure limit (PEL), and quarterly if employee exposures are above the action level (AL); paragraphs 1910.1044(f)(3)(i) and (f)(3)(ii) of the 1,2-dibromo-3-chloropropane (DBCP) standard, requiring exposure monitoring quarterly if employee exposures are below the PEL, and monthly if employee exposures exceed the PEL; and paragraphs 1910.1045(e)(3)(ii) and (e)(3)(iii) of the acrylonitrile standard, requiring quarterly monitoring for employees exposed at or above the AL, but below the PEL, and each month for employees exposed above the PEL.

For substance-specific standards published more recently by the Agency subsequent to these three standards, the most frequent exposure monitoring requirement is semiannually if employee exposures are at or above the AL, and quarterly if they are above the PEL. OSHA is amending the exposure monitoring requirements in the older standards because they are inconsistent with the exposure monitoring protocols established by OSHA in its later substance-specific standards. OSHA believes consistency among standards will improve compliance levels thereby improving worker protection. OSHA is requiring that employers conduct exposure monitoring quarterly if the results of initial exposure monitoring show that the employee exposures are above the PEL, and semiannually if these results are at or above the AL.

OSHA has concluded that revision of paragraphs 1910.1044(f)(3)(i) and (f)(3)(ii) of the standard regulating DBCP, would have no effect on cost or burden hours since no U.S. employers currently produce DBCP-based end products.

For purposes of the below analysis, the Agency assumes that exposure monitoring is done with an active sampling method; that is, with typical industrial hygiene sampling pumps and collection tubes. Passive vapor badges are available for the two substances in question, and the PEA referred to sampling with them, but the Agency has not been able to ascertain that passive monitoring meets the standards' requirements for accuracy for single samples. To be conservative—to not underestimate the potential burden—the Agency assumes sampling with a method whose accuracy is known. This economic analysis relies on the following assumptions of employee exposure to vinyl chloride and acrylonitrile: the Agency estimates, based on OSHA sampling data in its IMIS database, that 1 percent of all employees are exposed between the AL and the permissible exposure level (PEL), and another 1 percent are exposed above the PEL; sampling of employee exposures is conducted with active sampling methods, i.e. personal air pumps and cassettes with appropriate collection media for the substance; and laboratory analysis of collected samples is performed by a commercial laboratory.

In its Preliminary Economic Analysis (PEA), the Agency estimated that a supervisor, who earns $27.39 per hour, will spend 5 minutes to administer, and 5 minutes to collect, each vapor badge, for a total of 0.17 hour; and a clerical worker, earning $17:34 per hour, will spend 5 minutes (.08 hour) to maintain each record of a monitoring event. In a written comment on this rulemaking, Dow Chemical (Ex. 3–13) pointed out that there are significant other activities needed to perform exposure monitoring besides these identified by the Agency. In addition, the Agency, in concurrence with the Office of Management and Budget, currently includes all costs of exposure monitoring as paperwork costs, viewing the entire activity as a "collection of information"—not just the function of recordkeeping. The existing paperwork burden is based only on gathering the information to form a permanent record, as noted at the beginning of this paragraph. In contrast, the new estimate here includes an average of 1 hour for a technician to collect, process, and record sampling data.

The final rule revises paragraph 1910.1017(d)(2)(i) of the vinyl chloride standard to require quarterly rather than monthly exposure monitoring if past employee exposures have been above the PEL. In the PEA, the Agency estimated that there are 131 employees who are currently monitored monthly who will now be monitored quarterly. The Agency estimates that a technician spends, on average, 60 minutes for each employee sampled, which includes planning activities, affixing pumps, gathering sample cassettes, sending tubes or cassettes for laboratory analysis, and recording the results into a permanent record. The Agency doesn't believe there is any significant loss of employee time from production activities. Thus, for each employee sampled, the cost of the collection media and analysis and technician's time is about $67 ($43 for the collection media and lab analysis, about $24 in technician's time). When an estimated 131 employees are sampled monthly the annual cost is $105,324. When sampled quarterly the estimated annual cost is $39,300. The final standard will reduce annual employer costs by $66,024.

The final rule also revises paragraph 1910.1017(d)(2)(ii) of the vinyl chloride standard to require semiannual rather than quarterly exposure monitoring if exposure is at or above the AL. In the

PEA the Agency estimated that there are 131 employees who must be monitored twice a year rather than 4 times. Under the existing standard, using the same unit cost and time estimates from the paragraph above, employers currently expend an estimated $31,618 on quarterly exposure monitoring that would be reduced by one-half to $17,554 under the final standard. Cost savings would also be $17,554.

The final paragraphs 1910.1045(e)(3)(ii) and (e)(3)(iii) of the acrylonitrile standard parallel the changes in exposure monitoring requirements to vinyl chloride, above. The final standard requires semiannual monitoring if employee exposures were at or above the AL, and quarterly monitoring if these exposures were above the PEL. The existing standard requires monthly monitoring if above the PEL and quarterly monitoring if above the AL. In the PEA, the Agency estimated that there are 314 employees who require monitoring and that each exposure monitoring sample represents the exposures of 2 employees (i.e. on average, there are 2 employees involved in the same or similar tasks). These estimates are based on the Supporting Statement for the Information Collection Requirements of the Acrylonitrile (AN) Standard (29 CFR 1910.1045), OMB #1218–0126 (2000), p. 16. The Agency estimates that a technician (wage $24.68) spends, on average, 60 minutes for each employee sampled, which includes planning activities, affixing pumps and cassettes, gathering and sending cassettes for analysis, and recording the results into a permanent record. The Agency doesn't believe there is any significant loss of employee time from production activities. Tubes or cassettes and laboratory analysis cost $64 each. (The Agency neglected to include the costs of collection media and laboratory analysis for acrylonitrile in the PEA.) Thus, for each employee sampled, the cost is estimated to be about $88 (tube and laboratory analysis $64 and technician's wage $24.68). When one-half of the estimated 314 employees are sampled monthly, the cost is $165,792; when sampled quarterly the estimated cost is $55,264. The final standard will thus reduce employer costs by $110,528 by requiring quarterly rather than monthly sampling where employee exposures are over the PEL.

Where the final standard reduces exposure monitoring from quarterly to semi-annually for employees above the AL but below the PEL, the Agency estimates that the current burden for 563 employees to be sampled is $99,854 and will be reduced to $49,927, thereby reducing the current burden by $49,927. The total reduction in burden due to the final acrylonitrile standard is $160,455.

G. Alternative Control Methods for Class I Asbestos Removal

OSHA is deleting provisions in OSHA's asbestos standards for shipyard employment and for construction (paragraphs 1915.1001(g)(6)(iii) and 1926.1101(g)(6)(iii), respectively) that require that employers submit, to the Directorate of Technical Support, alternative control methods used to perform Class I asbestos work. OSHA has concluded that this requirement is unnecessary because it has not been used and that both the private sector and OSHA have substantial expertise in this area. Current OSHA regulatory policy requires that paperwork provisions such as this requirement, demonstrate a benefit to employees or serve some other useful regulatory purpose.

To submit alternative control methods to the Directorate of Technical Support, OSHA estimates would require 1 hour and cost $39. These estimates are based on the assumption that OSHA would receive 7 notifications from employers who choose new or modified control technology to reduce exposure in Class I asbestos for shipyards. A manager, earning $38.92 per hour, would spend on average 10 minutes to develop and transmit the information to the Agency for each employer. Thus removing this requirement would result in annual cost savings of $39.

For the construction asbestos standard, OSHA again assumes the Agency would receive 7 notifications from employers who choose new or modified control technology to reduce exposures in Class I asbestos work. OSHA estimates a manager, earning $38.92 an hour, would need 10 minutes to develop and transmit the information to OSHA. Thus, 1 burden hour would be spent, at a cost of $39, to submit alternative method information to OSHA.

H. Evaluating Chest X-rays Using the ILO U/C Rating

OSHA is amending paragraph 1910.1018(n)(2)(ii)(A) of the inorganic arsenic standard and paragraph 1910.1029(j)(2)(ii) of the coke oven emissions standard. These provisions require that employees' chest x-rays receive an International Labor Office UICC/Cincinnati (ILO U/C) rating. Subsequent to the promulgation of these provisions, the Agency received information from two physicians that the ILO U/C rating is not the most appropriate standard for evaluating chest x-rays for lung cancer (discussed above). Based on this information, OSHA believes that the ILO U/C rating is not a suitable method to use in evaluating chest x-rays for lung cancer. Therefore, the Agency is removing the ILO U/C rating requirements specified in the inorganic arsenic and coke oven emissions standards, thereby permitting the examining physician to determine the most effective procedure for evaluating these chest x-rays. Deleting the ILO/UC rating would provide cost savings since it allows the examining physician to determine the most effective procedure for evaluating chest x-rays. However, the Agency has not calculated the value of such savings.

I. Signed Medical Opinions

Paragraph 1910.1001(l)(7)(i) of the asbestos standard and paragraphs (l)(10)(i) of the cadmium standard for general industry, 29 CFR 1910.1027, and for construction, 29 CFR 1926.1127, require that the examining physician sign the written medical opinion provided as part of the medical surveillance requirements of these standards. The preamble to the cadmium standards states that "the requirement that the physician sign the opinion is to ensure that the information that is given to the employer has been seen and read by the physician and that the physician has personally determined whether the employee may continue to work in cadmium-exposed jobs" (57 FR 42366). No other substance-specific standard promulgated by OSHA requires a signed medical opinion.

The Agency believes that the requirement to sign a medical opinion written by a physician is unnecessary, precludes electronic transmission of the opinion from the physician to the employer, and provides no benefit to employees. Accordingly, OSHA is removing this requirement from these paragraphs.

Removal of the requirement that a physician sign the written medical opinion provided as part of the medical surveillance requirement of these standards provides more flexibility. OSHA has not estimated the cost savings.

J. Semiannual Medical Examinations

The Agency's final standard replaces a requirement for semiannual medical exams in three standards (vinyl chloride, arsenic, and coke ovens) with a requirement for an annual medical examination. This analysis presents the burden hours and costs associated with the current provisions and the estimates of cost savings of the final standard.

The final standard's revision of a semiannual requirement for medical examinations to annual one would generate annual cost savings from several sources: less employee time; fewer medical examinations; and less clerical time providing the physicians' opinions to the affected employees and maintaining medical records.

Based on estimates in the vinyl chloride ICR of the number of facilities, the number of employees per facility, and the distribution of employee exposures, OSHA estimates that 890 burden hours are incurred for medical surveillance under the semiannual examination requirement, with 183 employees monitored twice a year for 2 hours and 79 employees once a year for 2 hours at a cost of $16,376 (890 hours × $18.40, the wage rate of a production worker). With annual examinations, OSHA estimates that 324 burden hours would be required, as 262 employees would be monitored only once a year, taking 2 hours. The cost would be $9,642 (524 hours × $18.40). Annual savings of $6,734 would result.

The revision from semiannual to annual medical examinations would result in annual savings of $23,790 in the cost of the medical examinations themselves, at $130 per examination, as 183 employees would have only one, as opposed to two, medical examinations per year. The change in frequency from semiannual to annual medical examinations also reduces the number of hours of clerical time required from 76 to 45, resulting in annual savings of $539.

When annual savings are summed for the cost of employees' time ($6,734), medical examinations ($23,790), and clerical costs of medical records ($539), the revision of the vinyl chloride standard generates annual savings of $31,064.

The final rule revises the semiannual medical examination to an annual requirement in the arsenic standard, paragraph 1910.1018(n)(3)(ii), for employees who are 45 years old or older with 10 or more years of exposure to inorganic arsenic above the AL. OSHA assumes each examination would take one hour and forty minutes and that 50 percent of the 1,900 employees who now would require two examinations per year would undergo only one. Requiring only one annual medical examination would save about 1,587 hours in employee time away from the job. Thus, replacing semiannual medical examinations with annual medical examinations would result in annual savings of about 1,662 burden hours and $29,192 (about 1,587 burden hours at $18.40/per hour).

The change in frequency from semiannual to annual contributes $123,500 in annual cost savings for the medical examinations themselves, at $130 per exam. Semiannual medical examinations cost $413,920 while annual medical examinations would cost an estimated $284,570. In addition, the clerical costs of medical records would drop by $4,313 (from $13,803 to $9,489). Total annual savings resulting from revision of the inorganic arsenic standard would be $157,005 ($123,500 + $29,192 + $4,313) and would consist of savings in costs of employees' time, medical examinations, and clerical time for medical records.

The final rule revises the semiannual medical examinations requirement to annual medical examinations in the coke oven standard, paragraph 1910.1029(j)(3)(i), for employees who are 45 years of age or older with five or more years of exposure in regulated areas. Employees will receive annual urinary cytology examinations as part of the annual examination. The final standard would generate annual cost savings in employees' time, medical examinations, and physicians' medical opinions. Based on the ICR, medical examinations currently require 14,903 burden hours as 84 percent of the 4,600 employees who work in regulated areas require semiannual medical examinations, 16 percent require an annual medical examination, and 10 percent require an additional medical examination per year. Each examination requires an employee to be away from his or her job for 1 hour and 40 minutes, at $18.40 per hour, for a total annual cost of $274,217. Under the final standard, annual medical examinations would require 8,450 burden hours at a cost of $155,484. Cost savings in employees' time would thus be $118,733.

At a cost of $130 per medical examination and $50 for urinary cytology examinations per employee, replacing semiannual medical examinations (estimated cost of $1,425,384) with annual medical examinations (estimated cost of $933,064) would result in annual cost savings of $502,320. There would be no savings in clerical costs of medical records. OSHA estimates that revision of the coke oven standard would result in annual cost savings of $621,053.

K. Notification of Regulated Areas

The final rule deletes the "13 carcinogens" provision, paragraph 1910.1003(f)(1), that requires employers to notify the nearest OSHA Area Director of newly established regulated areas. Deleting this provision results in savings in burden hours and associated costs. As in the ICR, OSHA assumes that changes in operations requiring a report to the nearest OSHA Area Director currently occur once a year per facility and require 1 hour each of managerial and clerical time, a total of 2 hours per employer, to report the necessary information. OSHA estimates that 97 employers would be affected. Burden hours are thus estimated to total 194 hours to report the information. The cost is estimated to be $5,457 (97 employers × ($38.92 × 1 hour + $17.34 × 1 hour)), where $38.92 is the wage rate of a manager and $17.34 is the wage rate of a clerical worker. Thus, savings due to deleting this provision are estimated to be 194 burden hours and $5,457.

The final rule would eliminate the vinyl chloride provision, paragraph 1910.1017(n)(1), that requires employers to notify the nearest OSHA Area Director of the establishment of regulated areas. Based on the ICR, the Agency estimates that 13 new regulated areas are established each year and that a manager, at an hourly rate of $38.92, takes 15 minutes (0.25 hour) to notify the Area Director of the address of the establishment and the number of employees in a new regulated area. Thus, for new regulated areas, OSHA estimates a current burden of 3.25 hours at a cost of $126.

For existing facilities, OSHA assumes that each employer experiences one change in a regulated area each year, and that a supervisor requires 10 minutes (0.17 hour) to inform the Area Director of this change. OSHA estimates that there are 80 affected facilities, resulting in 14 burden hours and a cost of $545 (14 burden hours × $38.92). Total burden of the current rules, for new and existing facilities, is 17 hours, costing $671.

The final rule deletes the requirement in the inorganic arsenic standard, paragraph 1910.1018(d)(1), that employers notify the nearest OSHA Area Director of the establishment of regulated areas. An OSHA report titled "Sampling Activity by Substance" determined that 14.1 percent of establishments had inorganic arsenic exposures that exceeded the PEL. Based on the Agency's estimate that 42 facilities are covered by the standard, six facilities would have employees with inorganic arsenic exposures that exceed the PEL (14.1% × 42 = 6). OSHA assumes that these six employers have already notified the Agency about establishing regulated areas; therefore, only significant changes to existing regulated areas or establishments of new regulated areas must be reported to OSHA. The Agency assumes that one

significant change occurs in, or a new regulated area is added to, each of these facilities annually, and that a manager, earning $38.92 an hour, will take 30 minutes (0.5 hours) to notify the Agency of the significant change or addition. Thus, OSHA estimates it would require three burden hours for six employers to notify the Area Director about establishment of regulated areas. Estimated cost would be $117 (three burden hours × $38.92 an hour). By deleting this provision, savings of three burden hours and $117 would be realized.

The final rule deletes the provision in the acrylonitrile standard, paragraph 1910.1045(d)(1), that requires employers to notify the nearest OSHA Area Director of the establishment of regulated areas. Since there are no new establishments, OSHA assumes that employers will not establish new regulated areas during this clearance period, and estimates that each of the 23 facilities will make 1 significant change annually in a regulated area. The Agency estimates that reporting a significant change to the nearest OSHA Area Office currently takes a manager 0.5 hour and a clerical worker 0.5 hour each, for a total of 1 hour for each of the 23 facilities. Thus, it costs $647 for the 23 facilities to report a significant change, at $38.92 an hour for a manager and $17.34 an hour for a clerical. Savings due to deleting this provision would thus be 23 burden hours and $647.

L. Reporting Emergencies and Incidents

The final rule deletes the provision in the vinyl chloride standard, paragraph 1910.1017(n)(2), that requires employers to report emergencies and available facts regarding each emergency to the nearest OSHA Area Director. On request of the Area Director, the employer must submit additional information in writing describing the nature and extent of employee exposures and measures taken to prevent similar emergencies in the future. OSHA estimates that each employer experiences one reportable emergency per year and that a manager and a secretary will each spend five hours, for a total of 10 hours, reporting the emergency. OSHA assumes there are 80 affected employers; a manager and a secretary would each spend 5 hours to report an emergency for a total of 800 burden hours. The cost to the employers would be $22,504 (80 employees × ($38.92 × 5 hours + $17.34 × 5 hours)), since a manager earns $38.92 an hour and a secretary earns $17.34 an hour. Hence, there would be savings of 800 burden hours and $22,504 by deleting this provision.

The final rule deletes the provision in the acrylonitrile standard, paragraph 1910.1045(d)(2), that requires employers to report an emergency to OSHA within 72 hours and to provide additional information in writing to the nearest OSHA Area Office if requested to do so. OSHA estimates that 2 emergencies will occur in each facility annually, and that a professional and a secretary each require 1 hour for a total of 2 hours to compile and report the necessary information for each emergency. OSHA estimates 92 burden hours would be attributed to this provision because 23 facilities would report two emergencies per year and a manager and a secretary would each spend 1 hour to compile and report the necessary information. The cost of this provision would be $2,588, since a manager earns $38.92 per hour and a secretary earns $17.34 an hour. Savings due to deleting this requirement would be 92 burden hours, worth $2,588.

M. Semiannual Updating of Compliance Plans

The Agency's substance-specific standards typically require employers to develop compliance plans to meet the exposure-control objectives of the standard. Most of these standards specify that employers must update these plans at least annually, and OSHA believes that annual updating is sufficient to ensure the continued effectiveness of the plans. However, several older substance-specific standards promulgated by the Agency require semiannual updating, including: vinyl chloride, paragraph 1910.1017(f)(3); inorganic arsenic, paragraph 1910.1018(g)(2)(iv); lead, paragraph 1910.1025(e)(3)(iv); coke oven emissions, paragraph 1910.1029(f)(6)(iv); 1,2-dibromo-3-chloropropane (DBCP), paragraph 1910.1044(g)(2)(ii); acrylonitrile, paragraph 1910.1045(g)(2)(v); and lead in the construction industry, paragraph 1926.62(e)(2)(v).

OSHA has concluded that for those older standards with a high degree of compliance, updating compliance plans semi-annually does not increase worker protection. Therefore, the Agency is revising its older substance-specific standards to require annual, instead of semiannual, updating of compliance plans. OSHA believes that making this requirement consistent across its standards, will further improve employer compliance. Accordingly, the final standard eliminates a significant paperwork requirement without reducing employee protection. The following discussion estimates the cost savings of this amendment.

The final rule revises the vinyl chloride standard to require that employers update compliance plans at least annually, instead of semiannually. As in the ICR, the Agency estimates that semiannual updates require 480 burden hours (20 facilities, each needing eight hours from a manager and four hours from a secretary) to update the compliance plans, at a cost of $15,229. On average, a manager earns $38.92 an hour while a secretary earns $17.34 an hour. Annual updates on the other hand, would require 240 burden hours at a cost of $7,614. Thus, revising the standard to allow for annual updates of compliance plans instead of semiannual updates would result in savings of $7,614.

Modifying the inorganic arsenic standard, 29 CFR 1910.1018, to require that employers update compliance plans at least annually likewise would reduce burden hours and cost. OSHA estimates there are six employers affected by this standard and that a manager and a secretary need 8 hours and 4 hours, respectively, to update the compliance plans. With semiannual updates, the standard would require 144 burden hours at a cost of $4,569. Revising the standard to require annual compliance updates would entail 72 burden hours at a cost of $2,284, thereby resulting in savings of $2,284.

The final revision of the lead standard for general industry, paragraph 1910.1025(e)(3)(iv), would reduce the frequency for updating the compliance plan from semiannually to annually for areas with exposures over the PEL. OSHA's information on areas over the PEL in general industry is relatively old and the standard is almost 25 years old. Therefore, a substantial amount of time has gone by to achieve exposures below the PEL. Accordingly, OSHA has not assigned a cost saving for this provision at this time. Instead, OSHA requested comments on the approximate number of general industry lead facilities that still have areas over the PEL, but received none in the record. OSHA's estimate of the cost savings from this provision remains unchanged from the PEA.

Revision of the coke oven standard, paragraph 1910.1029(f)(6)(iv), would allow employers to update their compliance plans annually instead of semiannually. OSHA estimates that each of the 14 plants takes 3 hours to review and update its compliance plan semiannually for a total of 84 burden hours. OSHA estimates that a manager earning $32.92 takes 2 hours to update the compliance semiannually; and that a clerk earning $17.34 will take 1 hour semiannually to update the plans.

Therefore the cost for the 14 plants to update their compliance plans semiannually is $2,665. Revising semiannual updating to annual the 14 plants would take 42 hours annually costing a total of $1,333. The burden hour savings would be 42 hours and cost saving would be $1,332.

The final revision of the 1,2-dibromo-3-chloropropane (DBCP) standard, 29 CFR 1910.1044, would have no cost or burden hours to employers since no U.S. employers currently produce DBCP-based end products.

Revision of the acrylonitrile standard, paragraph 1910.1045(g)(2)(v), would require that employers update compliance plans annually instead of semiannually. OSHA assumes that a manager earning $38.92 an hour would devote 0.5 hour to update a compliance plan at each facility. With semiannual updating of compliance plans, employers would require 23 burden hours at a cost of $895 (23 hours × $38.92). Revision of the standard to require annual updates would lower this to 11.5 burden hours at a cost of $448 (11.5 × $38.92). Savings due to this revision would thus be $448.

The revision of the lead in construction standard, paragraph 1926.62(e)(2)(v), requires employers to update compliance plans annually instead of semiannually. Based on the Lead in Construction Paperwork Package, which in turn drew upon the Economic Analysis for that standard, OSHA estimates the standard now requires 216,344 employer burden hours at a cost of $8,420,108 (216,344 hours × $38.92) to update compliance plans semiannually. The Agency estimates that the revision of the standard to require annual updates would simply cut the burden in half, to 108,172 hours at a cost of $4,210,054 (108,172 hours × $38.92). Thus, the savings due to changing from semiannual to annual compliance updates would be $4,209,657. Although the burden reduction from this revised standard is the largest among the standards being revised in this rulemaking, the Agency has consistently applied simple adjustments to its current paperwork model of burden on employers for each of its calculations. The Agency did not receive any comment about either the number of affected employers or unit costs for estimating the burden. The Agency's final estimate of the reduction in paperwork burden for this standard is thus unchanged from the proposal.

N. Notifying Employees of Their Exposure Monitoring Results

Many of OSHA's substance-specific standards require employers to notify employees of their exposure monitoring results. However, the standards specify several different methods for providing this notice. The standards state that an employer must provide such notification to employees individually in writing or by posting the results in a readily accessible location, or both. In addition, the maximum period for notifying employees of their exposure monitoring results after the employer receives them varies across the standards. These periods range from "as soon as possible" to 20 working days after receipt of the monitoring results.

A review of the preambles to each of the above standards indicates that the final choice of notification method and maximum period for notification was a matter of convenience; none of the preambles provided objective evidence that the final requirements were the only effective or even most effective in protecting employees. The record developed during this rulemaking supports this view. OSHA has concluded that making the requirements consistent among the standards would reduce confusion and facilitate compliance without diminishing employee protection. As a result, the Agency is revising the standards by requiring employers to provide employees with their exposure monitoring results individually in writing or by posting the employees' results in a readily accessible location. Although the posting option would reduce employers' paperwork burden to some extent, they must still maintain individual exposure monitoring records for employees under §§ 1910.1020, 1915.1020, and 1926.33—OSHA's records-access standards for general industry, shipyard employment, and construction, respectively. Thus, employees could still get subsequent access to their exposure monitoring results.

OSHA proposed to standardize the period of time for notifying employees of their exposure monitoring results after the employer receives them across 20 pertinent standards. Currently, the notification period ranges from "as soon as possible" to 20 working days after receipt of the monitoring results. The Agency proposed to standardize the notification period to 15 days for general industry and 5 days for one shipyard and several construction standards on which OSHA made specific findings. Making these requirements consistent will reduce confusion and facilitate compliance with the provisions. However, it will not result in any significant cost savings.

OSHA assumes that the employers will choose to post the employees' results in a readily accessible location for all the standards that give the option of providing the results individually in writing or by posting. This would generate savings in burden hours and costs.

The final rule would revise the vinyl chloride standard, paragraph 1910.1017(n)(3), to require employers to provide employees with their exposure monitoring results individually in writing or by posting the employees' results in a readily accessible location. Based on the ICR, under the present standard for exposure above the AL, but below the PEL, 42 burden hours are required at a cost of $727 as 131 employees would be notified quarterly by a secretary earning $17.34 an hour who would spend 5 minutes per notification. For exposures above the PEL, 126 burden hours at a cost of $2,181 are required, as the same number of employees would be notified monthly by the secretary. Additional monitoring involves another 6 burden hours, at a cost of $111. Thus, the present vinyl chloride standard requires a total of 174 burden hours and a cost of $3,019.

With the revised standard, for exposure above the AL but below the PEL, 3 burden hours at a cost of $55 would be incurred as a secretary of each of 20 employers would post monitoring results semiannually at a readily accessible location. For exposure above the PEL, a secretary would quarterly post monitoring results at 20 facilities in a readily accessible location, requiring 6 burden hours at a cost of $111. Additional monitoring would require 6 burden hours at a cost of $111. Thus, the revised standard would require 15 burden hours at a cost of $277. Cost savings would amount to $2,741.

The final rule revises the inorganic arsenic standard, paragraph 1910.1018(e)(5)(i), to require employers to provide employees with their exposure monitoring results individually in writing or by posting the employees' results in a readily accessible location. OSHA assumes the employers would prefer to post the employees' results in a readily accessible location as that would be less costly.

The present inorganic arsenic standard requires employers to notify employees individually in writing of their exposure monitoring results. As in the Inorganic Arsenic Paperwork Package, OSHA estimates that 7,400 employees are exposed to inorganic arsenic, 14.1 percent or 1,043 of these are exposed above the PEL and will be monitored quarterly, 12.8 percent or 947

of these employees are exposed above the AL but below the PEL and will receive semiannual monitoring, while the employers must provide 10 percent or 740 of these employees with the results obtained to meet the additional monitoring requirement. OSHA estimates that a secretary, earning $17.34 per hour, will take 5 minutes (.08 hour) to prepare each notification. Thus, 545 burden hours estimated to cost $9,444 are attributed to the present inorganic arsenic standard.

With the revised standard, employers would be allowed to post monitoring results in a readily accessible location, which is cheaper than writing to employees individually. For estimating the burden, the assumptions would remain the same as under the present standard except employers or facilities would post monitoring results. OSHA estimates there are 42 facilities: 14.1 percent or 6 of these have employees exposed above the PEL and will be monitored quarterly; 12.8 percent or 5 of these have employees that are exposed above the AL but below the PEL and will be monitored semiannually, and an additional 10 percent or 4 facilities will be monitored yearly. Thus, the revised standard would require 3 burden hours at a cost of $51. Cost savings due to changing from writing employees individually to employers posting monitoring results in a readily accessible location would amount to $9,393.

The final rule revises the lead standard for general industry, paragraph 1910.1025(d)(8)(i), to require employers to provide employees with their exposure monitoring results individually in writing or by posting the employees' results in a readily accessible location. OSHA assumes the employers would post the employees' results in a readily accessible location.

Currently, monitoring is required initially to determine if any employees are exposed to lead at or above the action level, and every 6 months if employees are exposed above the AL but below the PEL and quarterly if employees are exposed to lead above the PEL. OSHA assumes zero burden hours for quarterly monitoring based on the assumption in the paperwork burden analysis that no industry sectors have working conditions in which employees are being exposed above the PEL. The Agency has estimated that about 11,508 employees would receive initial monitoring and 377,859 employees may be exposed to lead at levels between the AL and the PEL, which would require periodic monitoring at 6-month intervals. OSHA estimates that a secretary earning $17.34 an hour will require 5 minutes (.08 hour) to prepare each of 767,226 employee notifications (11,508 initial notifications and 377,859 employees × 2 semiannual notifications).

The paperwork burden for employee notification of monitoring results under the existing standard is as follows: 11,508 employees are notified once annually of initial monitoring results and 377,589 employees receive results twice a year. Notifying employees of 767,226 sampling results requires 0.08 hours each for a total of 61,378 hours, which, at an hourly secretarial wage of $17.34, costs $1,064,296. Employee notification under the revised standard will reduce the paperwork burden considerably: 62,357 employers will post sampling results twice a year, taking 0.08 hours for each, or 9,977 burden hours, which will cost $173,001 at the same secretarial wage. Cost savings would amount to 51,401 burden hours, or $891,293.

The final rule revises the cadmium standard for general industry, paragraph 1910.1027(d)(5)(i), to require employers to provide employees with their exposure monitoring results individually in writing or by posting the employees' results in a readily accessible location. As posting the monitoring results is cheaper than individually writing employees, OSHA assumes the employers would prefer to post the monitoring results.

The present standard requires employers to notify employees individually in writing and to post in a centralized location their exposure monitoring results. As in the Cadmium General Industry Paperwork Package, the Agency estimates that 71,306 employees may need periodic monitoring when exposed to cadmium above the AL. Under the existing standard, OSHA estimates that a secretary, earning $17.34 per hour, will take 5 minutes (.08 hour) semiannually to individually inform the employees in writing of exposure monitoring results and to also post a copy of the results in a centralized location. The Agency also estimates that 143 additional samples will be taken in 143 plants when raw materials, process, personnel, or work practices change. Thus, under the existing standard, 11,420 burden hours would be required at a cost of $198,030 as 71,306 employees are notified individually in writing and 143 plants post notices of the employees' exposure monitoring results in centralized locations.

Under the final standard, 8,517 burden hours at a cost of $147,685 would be required (secretaries at each of the 53,161 employers, and for posting 143 additional samples spending five minutes, at $17.34 per hour, to post monitoring results). Cost savings due to changing from individually writing employees and posting notices in centralized location to employers posting notices in a readily accessible location would amount to $50,341.

The final rule revises the coke oven emissions standard, paragraph 1910.1029(e)(3)(i), to require employers to provide employees with their monitoring results individually in writing or by posting the employees' results in a readily accessible location. OSHA assumes the employees would prefer to post the employees' results in a readily accessible location.

The present standard requires employers to notify employees individually in writing of their exposure monitoring results. As in the ICR, the Agency estimates that 4,600 employees receive exposure measurements (*i.e.*, are "covered employees" because they work in regulated areas). These measurements include 18,400 quarterly measurements (4,600 employees × 4 measurements) and 230 resamplings (5% of 4,600 employees), for a total of 18,630 samples. The Agency also assumes that a secretary, at a wage rate of $17.34 per hour, will take 5 minutes (.08 hour) to notify each employee of his or her sampling results. Thus, 1,490 burden hours would be required at a cost of $25,844 as 4,830 employees would be notified individually in writing of their exposure monitoring results.

With the final standard, 5 burden hours at a cost of $79 would be attributed to secretaries, who earn $17.34 per hour, at each of the 14 employers and would spend 5 minutes each to post monitoring results at a readily accessible location. Cost savings would amount to $25,765.

The final rule revises the cotton dust standard, paragraph 1910.1043(d)(4)(i), to require employers to provide employees with their exposure monitoring results individually in writing or by posting the employees' results in a readily accessible location. OSHA assumes the employers would prefer to post the employees' results in a readily accessible location.

OSHA estimated the numbers of exposed employees and the number of facilities in the industry by utilizing data from Employment and Earnings and County Business Patterns. The Agency estimates that 49,628 employees would be notified in writing of their exposure monitoring results. OSHA estimates that a secretary, earning $17.34 per hour, will take 5 minutes (.08 hour) to prepare each notification. Thus, 3,970 burden hours are required at a

cost of $68,844 as 53,938 employees are notified individually in writing of their exposure monitoring results.

Under the final standard, 43 burden hours at a cost of $742 would be required (a secretary at each of the 535 plants, earning $17.34 per hour, would spend 5 minutes (.08 hour) to post monitoring results). Cost savings would amount to $68,102.

The final rule would revise the 1,2-dibro-3-chloropropane, paragraph 1910.1044(f)(5)(i), to require employers to provide employees with their exposure monitoring results individually in writing or by posting the employees' results in a readily accessible location. No cost or burden hours accrue to employers under this standard since OSHA has determined that no U.S. employers currently produce DBCP or DBCP-based end-use products.

The final rule would revise the acrylonitrile standard, paragraph 1910.1045(e)(5)(i), to require employers to provide employees with their exposure monitoring results individually in writing or by posting the employees' results in a readily accessible location. OSHA assumes the employers would prefer to post the employees' results in a readily accessible location.

The Agency estimates that under the present standard, 923 employees must be informed of sampling results in writing. OSHA estimates that a secretary, earning $17.34 per hour, will take 5 minutes (.08 hour) to prepare each notification. Thus, 485 burden hours are required at a cost of $8,415.

Under the revision, 9 burden hours at a cost of $160 would be attributed to secretaries at each of the 23 plants, earning $17.34 per hour, spending 5 minutes (.08 hour) each to post quarterly monitoring results and one additional monitoring result. Cost savings would amount to $8,255.

The final rule would revise the lead standard for the construction industry, paragraph 1926.62(d)(8)(i), to require employers to provide employees with their exposure monitoring results individually in writing or by posting the employees' results in a readily accessible location. OSHA assumes the employers would prefer to post the employees' results in a readily accessible location.

As in the Lead in Construction Paperwork Package, the Agency estimates that under the present standard, 177,194 employees are notified two times a year in writing of their exposure monitoring results. OSHA estimates that a secretary, earning $17.34 per hour, will take six minutes (.10 hour) to prepare each notification. Thus, 38,678 burden hours are required at a cost of $670,671.

The revised standard would require that employers post monitoring results at readily accessible locations at each facility. Thus, 10,185 burden hours at a cost of $176,608 would be required in the lead standard for construction as secretaries of each of 147,073 firms, earning $17.34 per hour, would spend six minutes (.10 hour) to post monitoring results two times a year. Cost savings would amount to $494,063.

The final rule revises the cadmium standard for the construction industry, paragraph 1926.1127(d)(5)(i), to require employers to provide employees with their exposure monitoring results individually in writing or by posting the employees' results in a readily accessible location. OSHA assumes the employers would prefer to post the employees' results in a readily accessible location.

The Agency estimates that under the present standard 7,500 employees need monitoring when exposed to cadmium above the AL three times per year. OSHA estimates that a secretary, earning $17.34 per hour, will take 5 minutes (.08 hour) to individually inform the employees in writing of exposure monitoring results and to also post a copy of the results in a centralized location. The Agency assumes that the time associated with posting a copy of the result is minimal after already completing the individual notification; thus no additional time is assumed. Included in this 5 minutes is the time to maintain the record as required in paragraph (n)(1). The present standard requires 1,720 burden hours at a cost of $32,044.

With the final standard, 280 burden hours at a cost of $4,855 would be required (secretaries at 1,000 employers, earning $17.34 per hour, would spend 5 minutes each to post monitoring results). The revision would result in cost savings of $27,189.

References

1. Office of Management and Budget, "Guidelines and Discount Rates for Benefit-Cost Analysis of Federal Programs," Circular No. A–94 Revised (Transmittal Memo No. 64). October 29, 1992.

2. U.S. Dept. of Labor, Bureau of Labor Statistics, "Employer Costs for Employees."

V. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* (as amended), OSHA examined the regulatory requirements of the proposed rule to determine if they would have a significant economic impact on a substantial number of small entities. As indicated in section IV ("Economic Analysis") of this preamble, the proposed rule is expected to reduce compliance costs and regulatory burden for all employers, large and small. The reduction in compliance costs is under $100 million. Accordingly, the Agency certifies that the proposed rule would not have a significant economic impact on a substantial number of small entities.

VI. Environmental Impact Assessment

OSHA has reviewed the proposed rule in accordance with the requirements of the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 *et seq.*), the regulations of the Council on Environmental Quality (40 U.S.C. 1500), and the Department of Labor's NEPA procedures (29 CFR part 11). The Agency finds that the revisions included in the final rule do not directly involve the control of hazardous materials. Therefore, the final rule would have no additional impact on the environment, including no impact on the release of materials that contaminate natural resources or the environment, beyond the impact imposed by the existing requirements these proposed revisions would amend.

VII. OMB Review Under the Paperwork Reduction Act

Under the Paperwork Reduction Act (PRA) of 1995, agencies are required to seek the Office of Management and Budget (OMB) approval for all collections of information (paperwork). As a part of the approval process, agencies are required to solicit comment from affected parties with regard to the collection of information, including the financial and time burdens estimated by the agencies for the collection of information. The paperwork burden-hour estimate and cost analysis that an Agency submits to OMB is termed an "Information Collection Request" (ICR).

In the October 31, 2002, proposed rule, OSHA requested the public to comment on the 13 ICRs that the Agency submitted to OMB. These ICRs requested OMB to approve revisions to the current collections of information. In December 2002, OMB approved the proposed burden hour and cost reduction contained in the 13 ICRs. OMB stated on the approvals: "DOL will resubmit this package as a revision if changes are made based on comments to the Standards Improvement Project Proposed Rule."

The final rule does not change any of the proposed revisions to the collections

of information contained in the 13 ICRs. Table 4 lists the 13 ICRs, their OMB control number, expiration date, and changes to the collections of information contained in the ICRs. However, based on public comment (Ex. 4–13), the Agency did increase the amount of time employers take to conduct exposure monitoring from 10 minutes to 1 hour. OSHA has submitted documentation to OMB, PRA Change Worksheet (OMB 83–C form), for Vinyl Chloride (OMB Control number 1218–0010) and Acrylonitrile (OMB Control number 1218–0126) to reflect the increased time employers take to conduct exposure monitoring, and the larger burden hour reduction from reducing the frequency of exposure-monitoring.

INFORMATION COLLECTION REQUESTS EXPIRATION DATES & FINAL REVISIONS

OMB Control Number; expiration date	ICR provision	Final changes to ICR	Burden hour changes
1218–0010 Exp. Date: 9/30/2005	Vinyl Chloride (§ 1910.1017(d)(2)(i)).	Reduced the frequency employers must conduct periodic exposure-monitoring from monthly to quarterly monitoring.	−1,048
	Vinyl Chloride (§ 1910.1017(d)(2)(ii)).	Reduced the frequency employers must conduct periodic exposure-monitoring from quarterly to semi-annual monitoring.	−262
	Vinyl Chloride (§ 1910.1017(d)(2)(iii)).	Increased the time to conduct additional exposure monitoring.	66
	Vinyl Chloride (§ 1910.1017(f) (3))	Reduced the frequency employers must update their compliance plans from every six months to annually.	−240
	Vinyl Chloride (§ 1910.1017(k)(2)(i)&(ii)).	Reduced the number of medical examinations from semi-annually to annually.	−366
	Vinyl Chloride (§ 1910.1017(k)(4)).	Reduced the number of physician's written opinions employers must provide to their employees.	−15
	Vinyl Chloride (§ 1910.1017(m)(2)).	Reduced the number of exposure records employers must develop and maintain.	−105
	Vinyl Chloride (§ 1910.1017(m)(2)).	Reduced the number of medical records employers must develop and maintain.	−14
	Vinyl Chloride (§ 1910.1017(n)(1)).	Removed burden hours for employers to notify OSHA when establishing a regulated area.	−17
	Vinyl Chloride (§ 1910.1017(n)(2)).	Removed burden hours for employers to report emergencies to OSHA area director.	−800
	Vinyl Chloride (§ 1910.1017(n)(3)).	Allows employers to post exposure monitoring results and increase time to inform employees of their exposure-monitoring results from 10 to 15 working days.	−159
Subtotal			−2,960
1218–0061 Exp. Date: 9/30/2005	Cotton Dust (§ 1910.1043 (d)(4)(i)).	Allow employers to post exposure monitoring results ..	−3,927
1218–0085 Exp. Date: 11/30/2005	13 Carcinogens (§ 1910.1003(f)(2)).	Removed burden hours for employers to report spills to local OSHA area offices.	−970
	13 Carcinogens (§ 1910.1003(f)(1)).	Removed burden hours for employers to notify OSHA when establishing a regulated area.	−194
Subtotal			−1,164
1218–0092 Exp. Date: 12/31/2005	Lead in General Industry (§ 1910.1025(d)(8)(i)).	Allow employers to post exposure-monitoring results ..	−51,401
	Lead in General Industry (§ 1910.1025(e)(3) (iv)).	Revise required compliance plan update from every six months to annually. No information on areas over the PEL in general industry, and the standard is almost 25 years old.	0
Subtotal			−51,401
1218–0101 Exp. Date: 11/30/2005	1,2-Dibromo-3-chlorpropane (DBCP) (§ 1910.1044 (d)(4)).	Removed burden hours for employers to report when DBCP is introduced into workplace to OSHA.	0
	DBCP (§ 1910.1044(f)(3)(i), (ii)) ...	Reduced the frequency employers must conduct periodic exposure monitoring.	0
	DBCP (§ 1910.1044(f) (5))	Allow employers to post exposure monitoring results and increase time to inform employees of their exposure- monitoring results from 5 working days to 15 working days.	−0
	DBCP (§ 1910.1044(g)(2)(ii))	Reduced the frequency employers must update their compliance plans from every six months to annually.	0
Subtotal			0
1218–0104 Exp. Date: 9/30/2005	Inorganic Arsenic (§ 1910.1018(d)(1)).	Removed burden hours for employers to notify OSHA when establishing a regulated area.	−3

INFORMATION COLLECTION REQUESTS EXPIRATION DATES & FINAL REVISIONS—Continued

OMB Control Number; expiration date	ICR provision	Final changes to ICR	Burden hour changes
	Inorganic Arsenic (§ monitoring results 1910.1018(e)(5)(i)).	Allow employers to post exposure-monitoring results ..	−541
	Inorganic Arsenic (§ 1910.1018(g)(2)(iv)).	Reduced the frequency employers must update their compliance plans from every six months to annually.	−72
	Inorganic Arsenic (§ 1910.1018(n)(2)(ii)(A)).	Revise the x-ray rating procedure; no significant change.	0
	Inorganic Arsenic (§ 1910.1018(n)(3)(ii)).	Reduced the number of medical examinations from semi-annually to annually.	−1,661
	Inorganic Arsenic (§ 1910.1018(n)(5)).	Reduced the frequency employers must provide information to the physician.	−80
	Inorganic Arsenic (§ 1910.1018(n)(6)).	Reduced the frequency employers must provide the physician's written opinion to their employers.	−80
	Inorganic Arsenic (§ 1910.1018(q)(6)).	Reduced the number of medical records employers must develop and maintain.	−79
Subtotal			−2,516
1218–0126 Exp. Date: 9/30/2005	Acrylonitrile (§ 1910.1045(d)(1)) ...	Removed burden hours for employers to notify OSHA when establishing a regulated area.	−23
	Acrylonitrile (§ 1910.1045(d)(2)) ...	Removed burden hours for employers to report emergencies to OSHA area director.	−92
	Acrylonitrile (§ conduct 1910.1045(e)(3)(ii).	Reduced the frequency employers must periodic exposure monitoring from monthly to quarterly and from quarterly to semi-annually.	−1,819
	Acrylonitrile (§ 1910.1045(e)(4)) ...	Increased the time to conduct additional monitoring	+11
	Acrylonitrile (§ 1910.1045(e)(5)) ...	Allow employers to post exposure-monitoring results ..	−476
	Acrylonitrile (§ 1910.1045(g)(2)(ii)).	Reduced the frequency employers must update their compliance plans from every six months to annually.	−11
	Acrylonitrile (§ 1910.1045) (q)(2))	Reduced the number of exposure monitoring records employers must develop and maintain.	−291
Subtotal			−2,701
1218–0128 Exp. Date: 9/30/2005	Coke Ovens 1910.1029(e)(3)(i)) ..	Allows employers to post exposure-monitoring results	−1,486
	Coke Ovens (§ 1910.1029(f)(6)(iv)).	Reduced the frequency employers must update their compliance plans from every six months to annually.	−42
	Coke Ovens (§ 1910.1029(j)((2)(ii)).	Revise the x-ray rating procedure; no significant change.	0
	Coke Ovens (§ 1910.1029(j)(3)(iii)).	Reduced the number of medical examinations from semi-annually to annually.	−2,898
Subtotal			−4,426
1218–0134 Exp. Date: 12/31/2005	Asbestos (§ 1926.1101(f)(5)(i))	Modified time to inform employees of their exposure-monitoring results from "as soon as possible" to no later than 5 days after receipt.	0
	Asbestos (§ 1926.1101(g)(6)(l)	Remove burden hours for employers to submit alternative control methods to OSHA.	−1
Subtotal			−1
1218–0185 Exp. Date: 12/31/2005	Cadmium in General Industry (§ 1910.1027(d)(5)).	Allows employers to post exposure-monitoring results	−2,903
	Cadmium in General Industry (§ 1910.1027(l)(10)(l)).	Removed the requirement that the physician's written opinion be signed.	0
Subtotal			−2,903
1218–0186 Exp. Date: 12/31/2005	Cadmium Construction (§ 1926.1127(d)(5)(i)).	Allow employers to post exposure-monitoring results ..	−1,440
	Cadmium Construction (§ 1926.1127(l)(10)(i)).	Remove the physician's written opinion	0
Subtotal			−1,440
1218–0189 Exp. Date: 12/31/2005	Lead in Const. (§ 1926.62 9(d)(8)).	Allow employers to post exposure-monitoring results ..	−28,493
	Lead in Const. (§ 1926.62(e)(2)(v)).	Reduce the frequency of updating written compliance programs.	−108,172

INFORMATION COLLECTION REQUESTS EXPIRATION DATES & FINAL REVISIONS—Continued

OMB Control Number; expiration date	ICR provision	Final changes to ICR	Burden hour changes
Subtotal			−136,665
1218–0195 Exp. Date: 12/31/2005	Asbestos (§ 1915.1001(f)(5))	Modified time to inform employees of their exposure-monitoring results from "as soon as possible" to no later than 5 days after receipt.	0
	Asbestos (§ 1915.1001(g)(6)(iii))	Remove burden hours for employers to submit alternative control methods to OSHA.	−1
Subtotal			−1
Total Burden Hour Reduction			−210,105

VIII. Unfunded Mandates

OSHA has reviewed the final rule in accordance with the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1501 *et seq.*, and Executive Order 12875. As discussed above, OSHA has determined that the final rule is likely to reduce the regulatory burdens imposed on public and private employers by the existing requirements these final revisions would amend. The final rule would not expand existing regulatory requirements or increase the number of employers who are covered by the existing rules. Consequently, compliance with the final rule would require no additional expenditures by either public or private employers. In sum, the final rule does not mandate that state, local, and tribal governments adopt new, unfunded regulatory obligations.

IX. Federalism

The Agency has reviewed the final rule in accordance with the Executive Order on Federalism (Executive Order 13132, 64 FR 43255, August 10, 1999), which requires that Federal agencies, to the extent possible, refrain from limiting state policy options, consult with states before taking actions that restrict state policy options, and take such actions only when clear constitutional authority exists and the problem is of national scope. The Executive Order provides for preemption of state law only when Congress expresses an intent that a Federal agency do so. The Federal agency must limit any such preemption to the extent possible.

With respect to states that do not have occupational safety and health plans approved by OSHA under Section 18 of the Occupational Safety and Health Act of 1970 (the "Act") (29 U.S.C. 667), the Agency finds that the final rule conforms to the preemption provisions of the Act. These provisions authorize OSHA to preempt state promulgation and enforcement of requirements dealing with occupational safety and health issues covered by Agency standards, unless the state has a state occupational safety and health plan approved by the Agency. (See *Gade* v. *National Solid Wastes Management Association*, 112 S.Ct. 2374 (1992).) The provisions of 29 U.S.C. 667 prohibit states without such programs from issuing citations for violations of requirements covered by Agency standards. The final rule would not expand this limitation.

Regarding states that have OSHA-approved occupational safety and health plans ("State-plan states"), the Agency finds that the final rule complies with Executive Order 13132 because it addresses a problem (*i.e.*, health hazards) that is national in scope. Adoption of these final revisions, section 18(c)(2) of the Act (29 U.S.C. 667(c)(2)) would not preempt any alternative revisions made by State-plan states if these revisions are at least as effective as the final revisions.

X. State-Plan States

The 24 states and two territories with their own federally-approved occupational safety and health plans must develop revisions that are at least as effective as the final revisions adopted by the Agency within six months after publication of the final rule. These states and territories are: Alaska, Arizona, California, Connecticut (State and local government employees only), Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Jersey (State and local government employees only), New Mexico, New York (State and local government employees only), North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Virgin Islands, Washington, and Wyoming.

XI. Authority

John L. Henshaw, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, directed the preparation of this document.

Signed in Washington, DC, on the 20th day of December 2004.

John L. Henshaw,

Assistant Secretary of Labor.

List of Subjects

29 CFR Part 1910

Hazardous substances, Occupational safety and health, Reporting and recordkeeping requirements.

29 CFR Part 1915

Hazardous substances, Occupational safety and health, Reporting and recordkeeping requirements, Shipyard employment, Vessels.

29 CFR Part 1926

Construction industry, Hazardous substances, Occupational safety and health, Reporting and recordkeeping requirements.

■ In accordance with sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, and 657)), section 41 of the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 941), section 107 of the Contract Work and Safety Standards Act (40 U.S.C. 333), section 4 of the Administrative Procedures Act (5 U.S.C. 553) and Secretary of Labor's Order No. 3–2000 (65 FR 50017), the Agency is amending 29 CFR parts 1910, 1915, and 1926 as follows:

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

Subpart J—General Environmental Controls

■ 1. The authority citation for subpart J is revised to read as follows:

Authority: Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970, 29 U.S.C. 653, 655, and 657; Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76

(41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), or 3–2000 (65 FR 50017), as applicable.

Sections 1910.141, 1910.142, 1910.145, 1910.146, and 1910.147 also issued under 29 CFR part 1911.

§ 1910.142 [Amended]

■ 2. In § 1910.142, remove the words "telegram or telephone" at the end of paragraph (l)(2) and add in their place, "telegram, telephone, electronic mail or any method that is equally fast."

Subpart K—Medical and First Aid

■ 3. The authority citation for subpart K is revised to read as follows:

Authority: Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970, 29 U.S.C. 653, 655, and 657; Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), or 3–2000 (65 FR 50017), as applicable, and 29 CFR part 1911.

■ 4. In the first paragraph of Appendix A to § 1910.151, remove the words "American National Standard (ANSI) Z308.1–1978, "Minimum Requirements for Industrial Unit-Type First-aid Kits" and add, in their place, "American National Standard (ANSI) Z308.1–1998 "Minimum Requirements for Workplace First-aid Kits."

Subpart R—Special Industries

■ 5. The authority citation for subpart R is revised to read as follows:

Authority: Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970, 29 U.S.C. 653, 655, and 657; Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), or 3–2000 (65 FR 50017), as applicable, and 29 CFR part 1911.

■ 6. In § 1910.268, revise paragraph (b)(3) to read as follows:

§ 1910.268 Telecommunications.

* * * * *

(b) * * *

(3) Employers must provide employees with readily accessible, adequate, and appropriate first aid supplies. A non-mandatory example of appropriate supplies is listed in Appendix A to 29 CFR 1910.151.

* * * * *

Subpart Z—Toxic and Hazardous Substances

■ 7. The authority citation for subpart Z is revised to read as follows:

Authority: Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970, 29 U.S.C. 653, 655, and 657; 5 U.S.C. 553; Secretary of Labor's Orders No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), and 3–2000 (65 FR 50017), as applicable, and 29 CFR part 1911.

All of subpart Z issued under section 6(b) of the Occupational Safety and Health Act of 1970, except those substances that have exposure limits in Tables Z–1, Z–2, and Z–3 of 29 CFR1910.1000. The Agency issued 29 CFR 1910.1000 under section (6)(a) of the Act (29 U.S.C. 655(a)).

Section 1910.1000, Tables Z–1, Z–2, and Z–3 also issued under 5 U.S.C. 553, but not under 29 CFR part 1911, except for the inorganic arsenic, benzene, and cotton dust listings.

Section 1910.1001 also issued under section 107 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 333) and 5 U.S.C. 553.

Section 1910.1002 also issued under 5 U.S.C. 553, but not under 29 U.S.C. 655 or 29 CFR part 1911.

Sections 1910.1018, 1910.1029, and1910.1200 also issued under 29 U.S.C. 653.

■ 8. In § 1910.1001, revise paragraph (d)(7)(i) to read as set forth below, and remove the word "signed" from the first sentence of the introductory text of paragraph (l)(7)(i).

§ 1910.1001 Asbestos.

* * * * *

(d) * * *

(7) *Employee notification of monitoring results.* (i) The employer must, within 15 working days after the receipt of the results of any monitoring performed under this sections, notify each affected employee of these results either individually in writing or by posting the results in an appropriate location that is accessible to affected employees.

* * * * *

§ 1910.1003 [Amended]

■ 9–10. Section 1910.1003 is amended by removing and reserving paragraph (f).

■ 11. Section 1910.1017 is amended by:

■ a. Revising paragraphs (d)(2)(i), (d)(2)(ii), the last sentence of paragraph (f)(3) and paragraphs (k)(2), (k)(6) and (n)(3);

■ b. Removing paragraphs (n)(1) and (n)(2) and redesignating paragraph (n)(3) as new paragraph (n) and revising it.

The revisions read as follows:

§ 1910.1017 Vinyl chloride.

* * * * *

(d) * * *

(2) * * * (i) Must be repeated at least quarterly for any employee exposed, without regard to the use of respirators, in excess of the permissible exposure limit.

(ii) Must be repeated not less than every 6 months for any employee exposed without regard to the use of respirators, at or above the action level.

* * * * *

(f) * * *

(3) * * *Such plans must be updated at least annually.

* * * * *

(k) * * *

(2) Examinations must be provided in accordance with this paragraph at least annually.

* * * * *

(6) Laboratory analyses for all biological specimens included in medical examination shall be performed by accredited laboratories.

* * * * *

(n) *Employee notification of monitoring results.* The employer must, within 15 working days after the receipt of the results of any monitoring performed under this section, notify each affected employee of these results and the steps being taken to reduce exposures within the permissible exposure limit either individually in writing or by posting the results in an appropriate location that is accessible to affected employees.

* * * * *

■ 12. Section 1910.1018 is amended by:

■ a. Removing and reserving paragraph (d);

■ b. Revising paragraphs (e)(5)(i), (g)(2)(iv), (n)(2)(ii)(A), (n)(3)(i);

■ c. Removing paragraph (n)(3)(ii) and redesignating paragraph (n)(3)(iii) as new (n)(3)(ii); and

■ d. Removing in Appendix C Section I, second paragraph, item (2), the words "and an International Labor Office UICC/Cincinnati (ILO U/C) rating."

The revisions read as follows:

§ 1910.1018 Inorganic arsenic.

* * * * *

(e) * * *

(5) * * * (i) The employer must, within 15 working days after the receipt of the results of any monitoring performed under this section, notify each affected employee of these results either individually in writing or by posting the results in an appropriate location that is accessible to affected employees.

* * * * *

(g) * * *

(2) * * *

(iv) The plans required by this paragraph must be revised and updated at least annually to reflect the current status of the program.

* * * * *

(n) * * *

(2) * * *

(ii) * * *

(A) A standard posterior-anterior chest x-ray;

* * * * *

(3) * * *(i) Examinations must be provided in accordance with this paragraph at least annually.

* * * * *

■ 13. In § 1910.1025, revise paragraphs (d)(8)(i) and (e)(3)(iv) to read as follows:

§ 1910.1025 Lead.

* * * * *

(d) * * *

(8) * * *

(i) The employer must, within 15 working days after the receipt of the results of any monitoring performed under this section, notify each affected employee of these results either individually in writing or by posting the results in an appropriate location that is accessible to affected employees.

* * * * *

(e) * * *

(3) * * *

(iv) Written programs must be revised and updated at least annually to reflect the current status of the program.

* * * * *

■ 14. In § 1910.1027 revise paragraph (d)(5)(i) to read as set forth below and remove the word "signed" from the first sentence of the introductory text of paragraph (l)(10)(i).

§ 1910.1027 Cadmium.

* * * * *

(d) * * *

(5) * * * (i)The employer must, within 15 working days after the receipt of the results of any monitoring performed under this section, notify each affected employee of these results either individually in writing or by posting the results in an appropriate location that is accessible to employees.

* * * * *

■ 15–16. In § 1910.1028 revise paragraph (e)(7)(i) to read as follows:

§ 1910.1028 Benzene.

* * * * *

(e) * * *

(7) * * * (i) The employer must, within 15 working days after the receipt of the results of any monitoring performed under this section, notify each affected employee of these results either individually in writing or by posting the results in an appropriate location that is accessible to employees.

* * * * *

■ 17. Section § 1910.1029 is amended by:

■ a. Revising paragraphs (e)(3)(i), (f)(6)(iv), (j)(2)(ii), (j)(3)(ii) and (j)(3)(iii);

■ b. Removing paragraph (j)(3)(iv);

■ c. Redesignating paragraph (j)(3)(v) as (j)(3)(iv); and

■ d. Removing the words "14″ by 17″" and the words "and a ILO/UC rating to assure some standard of x-ray reading" from the third sentence of Appendix B.II.A.

The revision read as follows:

§ 1910.1029 Coke oven emissions.

* * * * *

(e) * * *

(3) * * * (i) The employer must, within 15 working days after the receipt of the results of any monitoring performed under this section, notify each affected employee of these results either individually in writing or by posting the results in an appropriate location that is accessible to employees.

* * * * *

(f) * * *

(6) * * *

(iv) Written plans for such programs shall be submitted, upon request, to the Secretary and the Director, and shall be available at the worksite for examination and copying by the Secretary, the Director, and the authorized employee representative. The plans required under paragraph (f)(6) of this section shall be revised and updated at least annually to reflect the current status of the program.

* * * * *

(j)* * *

(2)* * *

(ii) A standard posterior-anterior chest x-ray;

* * * * *

(3) * * *

(ii) The employer must provide the examinations specified in paragraphs (j)(2)(i) through (j)(2)(vii) of this section at least annually for employees 45 years of age or older or with five (5) or more years employment in the regulated area.

(iii) Whenever an employee who is 45 years of age or older or with five (5) or more years employment in a regulated area transfers or is transferred from employment in a regulated area, the employer must continue to provide the examinations specified in paragraphs (j)(2)(i) through (j)(2)(vii) of this section at least annually as long as that employee is employed by the same employer or a successor employer.

* * * * *

■ 18–19. In § 1910.1043, revise paragraph (d)(4)(i) to read as follows:

§ 1910.1043 Cotton dust.

* * * * *

(d) * * *

(4) * * * (i) The employer must, within 15 working days after the receipt of the results of any monitoring performed under this section, notify each affected employee of these results either individually in writing or by posting the results in an appropriate location that is accessible to employees.

* * * * *

■ 20–21. In § 1910.1044 remove and reserve paragraph (d), and revise paragraphs (f)(3)(i), (f)(3)(ii), (f)(5)(i) and the last sentence of paragraph (g)(2)(ii) to read as follows:

§ 1910.1044 1,2-Dibromo-3-chloropropane.

* * * * *

(f) * * *

(3) * * * (i) If the monitoring required by this section reveals employee exposures to be at or below the permissible exposure limit, the employer must repeat these measurements at least every 6 months.

(ii) If the monitoring required by this section reveals employee exposures to be in excess of the permissible exposure limit, the employer must repeat these measurements for each such employee at least quarterly. The employer must continue quarterly monitoring until at least two consecutive measurements, taken at least seven (7) days apart, are at or below the permissible exposure limit. Thereafter the employer must monitor at least every 6 months.

* * * * *

(5) * * * (i) The employer must, within 15 working days after the receipt of the results of any monitoring performed under this section, notify each employee of these results either individually in writing or by posting the results in an appropriate location that is accessible to employees.

* * * * *

(g) * * *

(2) * * *

(ii) * * * These plans must be revised at least annually to reflect the current status of the program.

* * * * *

■ 22–23. In § 1910.1045 remove and reserve paragraph (d), and revise paragraphs (e)(3)(ii), (e)(3)(iii), (e)(5)(i) and (g)(2)(v) to read as follows:

§ 1910.1045 Acrylonitrile.

* * * * *

(e) * * *

(3) * * *

(ii) If the monitoring required by this section reveals employee exposure to be at or above the action level but at or below the permissible exposure limits, the employer must repeat such monitoring for each such employee at least every 6 months. The employer must continue these measurements every 6 months until at least two consecutive measurements taken at least seven (7) days a part, are below the action level, and thereafter the employer

may discontinue monitoring for that employee.

(iii) If the monitoring required by this section reveals employee exposure to be in excess of the permissible exposure limits, the employer must repeat these determinations for each such employee at least quarterly. The employer must continue these quarterly measurements until at least two consecutive measurements, taken at least seven (7) days apart, are at or below the permissible exposure limits, and thereafter the employer must monitor at least every 6 months.

* * * * *

(5) * * * (i) The employer must, within 15 working days after the receipt of the results of any monitoring performed under this section, notify each affected employee of these results either individually in writing or by posting the results in an appropriate location that is accessible to employees.

* * * * *

(g) * * *

(2) * * *

(v) The plans required by this paragraph must be revised and updated at least annually to reflect the current status of the program.

* * * * *

■ 24. In § 1910.1047, revise (d)(7)(i) to read as follows:

§ 1910.1047 Ethylene oxide.

* * * * *

(d) * * *

(7) * * * (i) The employer must, within 15 working days after the receipt of the results of any monitoring performed under this section, notify each affected employee of these results either individually in writing or by posting the results in an appropriate location that is accessible to employees.

* * * * *

■ 25. In § 1910.1048, revise (d)(6) to read as follows:

§ 1910.1048 Formaldehyde.

* * * * *

(d) * * *

(6) *Employee notification of monitoring results.* The employer must, within 15 working days after the receipt of the results of any monitoring performed under this section, notify each affected employee of these results either individually in writing or by posting the results in an appropriate location that is accessible to employees. If employee exposure is above the PEL, affected employees shall be provided with a description of the corrective actions being taken by the employer to decrease exposure.

* * * * *

■ 26. In § 1910.1051, revise paragraph (d)(7)(i) to read as follows:

§ 1910.1051 1,3-Butadiene.

* * * * *

(d) * * *

(7) * * * (i) The employer must, within 15 working days after the receipt of the results of any monitoring performed under this section, notify each affected employee of these results either individually in writing or by posting the results in an appropriate location that is accessible to employees.

* * * * *

PART 1915—OCCUPATIONAL SAFETY AND HEALTH STANDARDS FOR SHIPYARD EMPLOYMENT

■ 27. The authority citation for Part 1915 is revised to read as follows:

Authority: Section 41, Longshore and Harbor Workers' Compensation Act (33 U.S.C. 941); sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 ("the Act"), 29 U.S.C. 653, 655, and 657; Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), and 3–2000 (65 FR 50017), as applicable.

Sections 1915.120 and 1915.152 also issued under 29 CFR part 1911.

Section 1915.1001 also issued under 5 U.S.C. 553.

Subpart Z—Toxic and Hazardous Substances

■ 28. In § 1915.1001, revise paragraph (f)(5) to read as set forth below and remove paragraph (g)(6)(iii).

§ 1915.1001 Asbestos.

* * * * *

(f) * * *

(5) *Employee notification of monitoring results.* The employer must, as soon as possible but no later than 5 days after the receipt of the results of any monitoring performed under this section, notify each affected employee of these results either individually in writing or by posting the results in an appropriate location that is accessible to employees.

* * * * *

PART 1926—SAFETY AND HEALTH REGULATIONS FOR CONSTRUCTION

Subpart D—Occupational Health and Environmental Controls

■ 30. The authority citation for subpart D is revised to read as follows:

Authority: Section 107, Contract Work Hours and Safety Standards Act (40 U.S.C. 333); sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 ("the Act"), 29 U.S.C. 653, 655, and 657; 5 U.S.C. 553; Secretary of Labor's Orders No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), and 3–2000 (65 FR 50017), as applicable; and 29 CFR part 1911.

■ 31. In § 1926.60, revise paragraph (f)(7)(i) to read as follows:

§ 1926.60 Methylenedianilene.

* * * * *

(f) * * *

(7) * * *(i) The employer must, as soon as possible but no later than 5 working days after the receipt of the results of any monitoring performed under this section, notify each affected employee of these results either individually in writing or by posting the results in an appropriate location that is accessible to employees.

* * * * *

■ 32. In § 1926.62, revise paragraphs (d)(8)(i) and (e)(2)(v) to read as follows:

§ 1926.62 Lead.

* * * * *

(d) * * *

(8) * * * (i) The employer must, as soon as possible but no later than 5 working days after the receipt of the results of any monitoring performed under this section, notify each affected employee of these results either individually in writing or by posting the results in an appropriate location that is accessible to employees.

* * * * *

(e) * * *

(2) * * *

(v) Written programs must be revised and updated at least annually to reflect the current status of the program.

* * * * *

Subpart Z—Toxic and Hazardous Substances

■ 33. The authority citation for subpart Z is revised to read as follows:

Authority: Section 107, Contract Work Hours and Safety Standards Act (40 U.S.C. 333); sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 ("the Act"), 29 U.S.C. 653, 655, and 657; Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), and 3–2000 (65 FR 50017), as applicable; and 29 CFR part 1911.

Sections 1926.1101 and 1926.1127 also issued under 5 U.S.C. 553.

Section 1926.1102 also issued under 5 U.S.C. 553, but not under 29 U.S.C. 655 or 29 CFR part 1911.

■ 34. In § 1926.1101, revise paragraph (f)(5) to read as set forth below and remove paragraph (g)(6)(iii).

§ 1926.1101 Asbestos.

* * * * *

(f) * * *

(5) *Employee notification of monitoring results.* The employer must, as soon as possible but no later than 5 working days after the receipt of the results of any monitoring performed under this section, notify each affected employee of these results either individually in writing or by posting the results in an appropriate location that is accessible to employees.

* * * * *

■ 35–36. In § 1926.1127 revise paragraph (d)(5)(i) to read as set forth below and remove the word "signed" from the first sentence of the introductory text of paragraph (l)(10)(i).

§ 1926.1127 Cadmium.

* * * * *

(d) * * *

(5) * * * (i) The employer must, as soon as possible but no later than 5 working days after the receipt of the results of any monitoring performed under this section, notify each affected employee of these results either individually in writing or by posting the results in an appropriate location that is accessible to employees.

* * * * *

[FR Doc. 04–28221 Filed 12–30–04; 8:45 am]

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Federal Register

Wednesday,
January 5, 2005

Part VI

The President

Executive Order 13368—Adjustments of Certain Rates of Pay

Federal Register
Vol. 70, No. 3
Wednesday, January 5, 2005

Presidential Documents

Title 3—

The President

Executive Order 13368 of December 30, 2004

Adjustments of Certain Rates of Pay

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the laws cited herein, it is hereby ordered as follows:

Section 1. *Statutory Pay Systems.* The rates of basic pay or salaries of the statutory pay systems (as defined in 5 U.S.C. 5302(1)), as adjusted under 5 U.S.C. 5303(a), are set forth on the schedules attached hereto and made a part hereof: (a) The General Schedule (5 U.S.C. 5332(a)) at Schedule 1; (b) The Foreign Service Schedule (22 U.S.C. 3963) at Schedule 2; and (c) The schedules for the Veterans Health Administration of the Department of Veterans Affairs (38 U.S.C. 7306, 7404; section 301(a) of Public Law 102–40) at Schedule 3.

Sec. 2. *Senior Executive Service.* The ranges of rates of basic pay for senior executives in the Senior Executive Service, as established pursuant to 5 U.S.C. 5382, are set forth on Schedule 4 attached hereto and made a part hereof.

Sec. 3. *Certain Executive, Legislative and Judicial Salaries.* The rates of basic pay or salaries for the following offices and positions are set forth on the schedules attached hereto and made a part hereof:

(a) The Executive Schedule (5 U.S.C. 5312–5318) at Schedule 5;

(b) The Vice President (3 U.S.C. 104) and the Congress (2 U.S.C. 31) at Schedule 6; and

(c) Justices and judges (28 U.S.C. 5, 44(d), 135, 252, and 461(a), section 140 of Public Law 97–92, and section 306 of Division B of Public Law 108–447) at Schedule 7.

Sec. 4. *Uniformed Services.* Pursuant to section 601(a)–(b) of Public Law 108–375, the rates of monthly basic pay (37 U.S.C. 203(a)) for members of the uniformed services, as adjusted under 37 U.S.C. 1009, and the rate of monthly cadet or midshipman pay (37 U.S.C. 203(c)) are set forth on Schedule 8 attached hereto and made a part hereof.

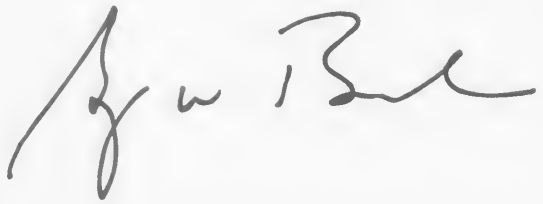
Sec. 5. *Locality-Based Comparability Payments.* (a) Pursuant to section 5304 of title 5, United States Code, and section 640 of Division H of Public Law 108–447, locality-based comparability payments shall be paid in accordance with Schedule 9 attached hereto and made a part hereof.

(b) The Director of the Office of Personnel Management shall take such actions as may be necessary to implement these payments and to publish appropriate notice of such payments in the **Federal Register**.

Sec. 6. *Administrative Law Judges.* The rates of basic pay for administrative law judges, as adjusted under 5 U.S.C. 5372(b)(4), are set forth on Schedule 10 attached hereto and made a part hereof.

Sec. 7. *Effective Dates.* Schedule 8 is effective on January 1, 2005. The other schedules contained herein are effective on the first day of the first applicable pay period beginning on or after January 1, 2005.

Sec. 8. *Prior Order Superseded.* Executive Order 13332 of March 3, 2004, is superseded.



THE WHITE HOUSE,
December 30, 2004.

Billing code 3195–01–P

SCHEDULE 1--GENERAL SCHEDULE

(Effective on the first day of the first applicable pay period beginning on or after January 1, 2005)

	1	2	3	4	5	6	7	8	9	10
GS-1	$16,016	$16,550	$17,083	$17,613	$18,146	$18,459	$18,984	$19,515	$19,537	$20,036
GS-2	18,007	18,435	19,031	19,537	19,755	20,336	20,917	21,498	22,079	22,660
GS-3	19,647	20,302	20,957	21,612	22,267	22,922	23,577	24,232	24,887	25,542
GS-4	22,056	22,791	23,526	24,261	24,996	25,731	26,466	27,201	27,936	28,671
GS-5	24,677	25,500	26,323	27,146	27,969	28,792	29,615	30,438	31,261	32,084
GS-6	27,507	28,424	29,341	30,258	31,175	32,092	33,009	33,926	34,843	35,760
GS-7	30,567	31,586	32,605	33,624	34,643	35,662	36,681	37,700	38,719	39,738
GS-8	33,852	34,980	36,108	37,236	38,364	39,492	40,620	41,748	42,876	44,004
GS-9	37,390	38,636	39,882	41,128	42,374	43,620	44,866	46,112	47,358	48,604
GS-10	41,175	42,548	43,921	45,294	46,667	48,040	49,413	50,786	52,159	53,532
GS-11	45,239	46,747	48,255	49,763	51,271	52,779	54,287	55,795	57,303	58,811
GS-12	54,221	56,028	57,835	59,642	61,449	63,256	65,063	66,870	68,677	70,484
GS-13	64,478	66,627	68,776	70,925	73,074	75,223	77,372	79,521	81,670	83,819
GS-14	76,193	78,733	81,273	83,813	86,353	88,893	91,433	93,973	96,513	99,053
GS-15	89,625	92,613	95,601	98,589	101,577	104,565	107,553	110,541	113,529	116,517

SCHEDULE 2--FOREIGN SERVICE SCHEDULE

(Effective on the first day of the first applicable pay period beginning on or after January 1, 2005)

Step	Class 1	Class 2	Class 3	Class 4	Class 5	Class 6	Class 7	Class 8	Class 9
1	$89,625	$72,622	$58,845	$47,682	$38,636	$34,540	$30,878	$27,604	$24,677
2	92,314	74,801	60,610	49,112	39,795	35,576	31,804	28,432	25,417
3	95,083	77,045	62,429	50,586	40,989	36,643	32,758	29,285	26,180
4	97,936	79,356	64,302	52,103	42,219	37,743	33,741	30,164	26,965
5	100,874	81,737	66,231	53,667	43,485	38,875	34,753	31,069	27,774
6	103,900	84,189	68,217	55,277	44,790	40,041	35,796	32,001	28,607
7	107,017	86,714	70,264	56,935	46,133	41,243	36,870	32,961	29,466
8	110,227	89,316	72,372	58,643	47,517	42,480	37,976	33,949	30,350
9	113,534	91,995	74,543	60,402	48,943	43,754	39,115	34,968	31,260
10	116,517	94,755	76,779	62,214	50,411	45,067	40,289	36,017	32,198
11	116,517	97,598	79,083	64,081	51,924	46,419	41,497	37,097	33,164
12	116,517	100,526	81,455	66,003	53,481	47,811	42,742	38,210	34,159
13	116,517	103,542	83,899	67,983	55,086	49,246	44,025	39,357	35,184
14	116,517	106,648	86,416	70,023	56,738	50,723	45,345	40,537	36,239

SCHEDULE 3--VETERANS HEALTH ADMINISTRATION SCHEDULES DEPARTMENT OF VETERANS AFFAIRS

(Effective on the first day of the first applicable pay period beginning on or after January 1, 2005)

Schedule for the Office of the Under Secretary for Health (38 U.S.C. 7306)*

Deputy Under Secretary for Health	$152,207 **
Associate Deputy Under Secretary for Health	145,786 ***
Assistant Under Secretaries for Health	141,488 ***

	Minimum	Maximum	
Medical Directors	$120,718	$136,818	***
Service Directors	105,113	130,543	
Director, National Center for Preventive Health	89,625	130,543	

Physician and Dentist Schedule

Director Grade	$105,113	$130,543
Executive Grade	97,061	123,701
Chief Grade	89,625	116,517
Senior Grade	76,193	99,053
Intermediate Grade	64,478	83,819
Full Grade	54,221	70,484
Associate Grade	45,239	58,811

Clinical Podiatrist, Chiropractor, and Optometrist Schedule

Chief Grade	$89,625	$116,517
Senior Grade	76,193	99,053
Intermediate Grade	64,478	83,819
Full Grade	54,221	70,484
Associate Grade	45,239	58,811

Physician Assistant and Expanded-Function Dental Auxiliary Schedule ****

Director Grade	$89,625	$116,517
Assistant Director Grade	76,193	99,053
Chief Grade	64,478	83,819
Senior Grade	54,221	70,484
Intermediate Grade	45,239	58,811
Full Grade	37,390	48,604
Associate Grade	32,175	41,832
Junior Grade	27,507	35,760

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* This schedule does not apply to the Assistant Under Secretary for Nursing Programs or the Director of Nursing Services. Pay for these positions is set by the Under Secretary for Health under 38 U.S.C. 7451.

** Pursuant to section 3 of Public Law 108-445 and section 7404(d)(1) of title 38, United States Code, the rate of basic pay payable to this employee is limited to the rate for level IV of the Executive Schedule, which is $140,300.

*** Pursuant to section 3 of Public Law 108-445 and section 7404(d)(2) of title 38, United States Code, the rate of basic pay payable to these employees is limited to the rate for level V of the Executive Schedule, which is $131,400.

**** Pursuant to section 301(a) of Public Law 102-40, these positions are paid according to the Nurse Schedule in 38 U.S.C. 4107(b) as in effect on August 14, 1990, with subsequent adjustments.

SCHEDULE 4--SENIOR EXECUTIVE SERVICE

(Effective on the first day of the first applicable pay period beginning on or after January 1, 2005)

	Minimum	Maximum
Agencies with a Certified SES Performance Appraisal System	$107,550	$162,100
Agencies without a Certified SES Performance Appraisal System	$107,550	$149,200

SCHEDULE 5--EXECUTIVE SCHEDULE

(Effective on the first day of the first applicable pay period beginning on or after January 1, 2005)

Level I	$180,100
Level II	162,100
Level III	149,200
Level IV	140,300
Level V	131,400

SCHEDULE 6--VICE PRESIDENT AND MEMBERS OF CONGRESS

(Effective on the first day of the first applicable pay period beginning on or after January 1, 2005)

Vice President	$208,100
Senators	162,100
Members of the House of Representatives	162,100
Delegates to the House of Representatives	162,100
Resident Commissioner from Puerto Rico	162,100
President pro tempore of the Senate	180,100
Majority leader and minority leader of the Senate	180,100
Majority leader and minority leader of the House of Representatives	180,100
Speaker of the House of Representatives	208,100

SCHEDULE 7--JUDICIAL SALARIES

(Effective on the first day of the first applicable pay period beginning on or after January 1, 2005

Chief Justice of the United States	$208,100
Associate Justices of the Supreme Court	199,200
Circuit Judges	171,800
District Judges	162,100
Judges of the United States Court of International Trade	162,100

SCHEDULE 8-PAY OF THE UNIFORMED SERVICES
(Effective on January 1, 2005)

Part I-MONTHLY BASIC PAY

YEARS OF SERVICE (COMPUTED UNDER 37 U.S.C. 205)

Pay Grade	2 or less	Over 2	Over 3	Over 4	Over 6	Over 8	Over 10	Over 12	Over 14	Over 16	Over 18	Over 20	Over 22	Over 24	Over 26
COMMISSIONED OFFICERS															
O-10**	-	-	-	-	-	-	-	-	-	-	-	$12,963.00*	$13,026.60*	$13,297.50*	$13,769.40*
O-9	-	-	-	-	-	-	-	-	-	-	-	11,337.90	11,501.10	11,737.20	12,149.10
O-8	$8,022.30	$8,285.10	$8,459.40	$8,508.30	$8,725.50	$9,089.40	$9,173.70	$9,519.00	$9,618.00	$9,915.30	$10,345.50	10,742.40	11,007.60	11,007.60	11,007.60
O-7	6,666.00	6,975.60	7,119.00	7,233.00	7,439.10	7,642.50	7,878.30	8,113.50	8,349.00	9,089.40	9,714.60	9,714.60	9,714.60	9,714.60	9,763.80
O-6	4,940.70	5,427.90	5,784.00	5,784.00	5,805.90	6,054.90	6,087.90	6,087.90	6,433.80	7,045.50	7,404.60	7,763.40	7,967.70	8,174.10	8,575.50
O-5	4,118.70	4,639.80	4,961.10	5,021.40	5,221.50	5,341.80	5,605.50	5,799.00	6,048.60	6,431.10	6,613.20	6,793.20	6,997.50	6,997.50	6,997.50
O-4	3,553.80	4,113.90	4,388.40	4,449.60	4,704.30	4,977.60	5,317.50	5,582.70	5,766.60	5,872.20	5,933.70	5,933.70	5,933.70	5,933.70	5,933.70
O-3***	3,124.50	3,542.10	3,823.20	4,168.20	4,367.70	4,586.70	4,728.60	4,962.00	5,083.20	5,083.20	5,083.20	5,083.20	5,083.20	5,083.20	5,083.20
O-2***	2,699.40	3,074.70	3,541.20	3,660.90	3,736.20	3,736.20	3,736.20	3,736.20	3,736.20	3,736.20	3,736.20	3,736.20	3,736.20	3,736.20	3,736.20
O-1***	2,343.60	2,439.00	2,948.10	2,948.10	2,948.10	2,948.10	2,948.10	2,948.10	2,948.10	2,948.10	2,948.10	2,948.10	2,948.10	2,948.10	2,948.10
COMMISSIONED OFFICERS WITH OVER 4 YEARS ACTIVE DUTY SERVICE AS AN ENLISTED MEMBER AND/OR WARRANT OFFICER**															
O-3E	-	-	-	$4,168.20	$4,367.70	$4,586.70	$4,728.60	$4,962.00	$5,158.50	$5,271.00	$5,424.60	$5,424.60	$5,424.60	$5,424.60	$5,424.60
O-2E	-	-	-	3,660.90	3,736.20	3,855.30	4,055.70	4,211.10	4,326.60	4,326.60	4,326.60	4,326.60	4,326.60	4,326.60	4,326.60
O-1E	-	-	-	2,948.10	3,148.80	3,264.90	3,383.70	3,500.70	3,660.90	3,660.90	3,660.90	3,660.90	3,660.90	3,660.90	3,660.90

* Basic pay for these officers is limited to the rate of basic pay for level III of the Executive Schedule, which is $12,433.20 per month.

** For officers serving as Chairman or Vice Chairman of the Joint Chiefs of Staff, Chief of Staff of the Army, Chief of Naval Operations, Chief of Staff of the Air Force, Commandant of the Marine Corps, Commandant of the Coast Guard, or commander of a unified or specified combatant command (as defined in section 161(c) of title 10, United States Code), basic pay for this grade is calculated to be $15,146.40 per month, regardless of cumulative years of service computed under section 205 of title 37, United States Code. Nevertheless, actual basic pay for these officers is limited to the rate of basic pay for level III of the Executive Schedule, which is $12,433.20 per month.

*** Does not apply to commissioned officers who have been credited with over 4 years of active duty service as an enlisted member or warrant officer.

**** Reservists with at least 1,460 points as an enlisted member and/or warrant officer which are creditable toward reserve retirement also quality for these rates.

SCHEDULE 8-PAY OF THE UNIFORMED SERVICES (PAGE 2)

YEARS OF SERVICE (COMPUTED UNDER 37 U.S.C. 205)

Pay Grade	2 or less	Over 2	Over 3	Over 4	Over 6	Over 8	Over 10	Over 12	Over 14	Over 16	Over 18	Over 20	Over 22	Over 24	Over 26
WARRANT OFFICERS															
W-5	-	-	-	-	-	-	-	-	-	-	-	$5,548.20	$5,738.40	$5,929.20	$6,121.20
W-4	$3,228.60	$3,473.40	$3,573.30	$3,671.40	$3,840.30	$4,007.10	$4,176.30	$4,341.00	$4,511.70	$4,779.00	$4,950.00	5,117.40	5,290.80	5,461.80	5,636.40
W-3	2,948.40	3,071.70	3,197.40	3,238.80	3,371.10	3,522.30	3,721.80	3,918.90	4,128.30	4,285.50	4,442.10	4,509.30	4,578.90	4,730.10	4,881.30
W-2	2,593.50	2,741.70	2,871.30	2,965.50	3,046.20	3,268.20	3,438.00	3,564.00	3,687.00	3,771.30	3,842.40	3,977.40	4,111.50	4,247.40	4,247.40
W-1	2,290.20	2,477.70	2,603.10	2,684.40	2,900.40	3,030.90	3,146.40	3,275.40	3,360.90	3,438.30	3,564.30	3,659.70	3,659.70	3,659.70	3,659.70
ENLISTED MEMBERS															
E-9 *	-	-	-	-	-	-	$3,901.20	$3,989.70	$4,101.00	$4,232.40	$4,364.10	$4,575.90	$4,755.00	$4,943.70	$5,231.70
E-8	-	-	-	-	-	$3,193.50	3,334.80	3,422.10	3,527.10	3,640.50	3,845.40	3,949.20	4,125.90	4,224.00	4,465.20
E-7	$2,220.00	$2,423.10	$2,515.80	$2,638.80	$2,734.50	2,899.50	2,992.20	3,084.60	3,249.60	3,332.40	3,410.70	3,458.70	3,620.40	3,725.10	3,990.00
E-6	1,920.30	2,112.60	2,205.90	2,296.50	2,391.00	2,604.30	2,687.10	2,779.20	2,859.90	2,888.70	2,908.20	2,908.20	2,908.20	2,908.20	2,908.20
E-5	1,759.50	1,877.10	1,967.70	2,060.70	2,205.30	2,329.80	2,421.60	2,450.70	2,450.70	2,450.70	2,450.70	2,450.70	2,450.70	2,450.70	2,450.70
E-4	1,612.80	1,695.60	1,787.10	1,877.70	1,957.80	1,957.80	1,957.80	1,957.80	1,957.80	1,957.80	1,957.80	1,957.80	1,957.80	1,957.80	1,957.80
E-3	1,456.20	1,547.70	1,641.00	1,641.00	1,641.00	1,641.00	1,641.00	1,641.00	1,641.00	1,641.00	1,641.00	1,641.00	1,641.00	1,641.00	1,641.00
E-2	1,384.50	1,384.50	1,384.50	1,384.50	1,384.50	1,384.50	1,384.50	1,384.50	1,384.50	1,384.50	1,384.50	1,384.50	1,384.50	1,384.50	1,384.50
E-1 **	1,235.10	1,235.10	1,235.10	1,235.10	1,235.10	1,235.10	1,235.10	1,235.10	1,235.10	1,235.10	1,235.10	1,235.10	1,235.10	1,235.10	1,235.10
E-1 ***	1,142.70	-	-	-	-	-	-	-	-	-	-	-	-	-	-

* For noncommissioned officers serving as Sergeant Major of the Army, Master Chief Petty Officer of the Navy or Coast Guard, Chief Master Sergeant of the Air Force, or Sergeant Major of the Marine Corps, basic pay for this grade is $6,304.20 per month, regardless of cumulative years of service under section 205 of title 37, United States Code.

** Applies to personnel who have served 4 months or more on active duty.

*** Applies to personnel who have served less than 4 months on active duty.

SCHEDULE 8-PAY OF THE UNIFORMED SERVICES (PAGE 3)

Part II-RATE OF MONTHLY CADET OR MIDSHIPMAN PAY

The rate of monthly cadet or midshipman pay authorized by section 203(c) of title 37, United States Code, is $820.20.

Note: As a result of the enactment of sections 602-694 of Public Law 105-85, the National Defense Authorization Act for Fiscal Year 1998, the Secretary of Defense now has the authority to adjust the rates of basic allowances for subsistence and housing. Therefore, these allowances are no longer adjusted by the President in conjunction with the adjustment of basic pay for members of the uniformed services. Accordingly, the tables of allowances included in previous orders are not included here.

SCHEDULE 9--LOCALITY-BASED COMPARABILITY PAYMENTS

(Effective on the first day of the first applicable pay period beginning on or after January 1, 2005)

Locality Pay Area[1]	Rate
Atlanta-Sandy Springs-Gainesville, GA-AL.	13.87%
Boston-Worcester-Manchester, MA-NH-ME-RI.	18.49%
Chicago-Naperville-Michigan City, IL-IN-WI.	19.70%
Cincinnati-Middletown-Wilmington, OH-KY-IN	16.04%
Cleveland-Akron-Elyria, OH	14.24%
Columbus-Marion-Chillicothe, OH	13.98%
Dallas-Fort Worth, TX	15.07%
Dayton-Springfield-Greenville, OH	12.86%
Denver-Aurora-Boulder, CO	18.06%
Detroit-Warren-Flint, MI	19.67%
Hartford-West Hartford-Willimantic, CT-MA	19.52%
Houston-Baytown-Huntsville, TX	24.77%
Huntsville-Decatur, AL.	12.42%
Indianapolis-Anderson-Columbus, IN.	12.01%
Kansas City-Overland Park-Kansas City, MO-KS.	12.36%
Los Angeles-Long Beach-Riverside, CA.	21.65%
Miami-Fort Lauderdale-Miami Beach, FL	16.77%
Milwaukee-Racine-Waukesha, WI	13.62%
Minneapolis-St. Paul-St. Cloud, MN-WI	15.99%
New York-Newark-Bridgeport, NY-NJ-CT-PA	20.99%
Orlando-The Villages, FL.	11.75%
Philadelphia-Camden-Vineland, PA-NJ-DE-MD	16.67%
Pittsburgh-New Castle, PA	12.86%
Portland-Vancouver-Beaverton, OR-WA	15.93%
Richmond, VA.	13.15%
Sacramento--Arden-Arcade--Truckee, CA-NV	16.51%
St. Louis-St. Charles-Farmington, MO-IL	12.09%
San Diego-Carlsbad-San Marcos, CA	17.68%
San Jose-San Francisco-Oakland, CA	26.39%
Seattle-Tacoma-Olympia, WA.	16.53%
Washington-Baltimore-Northern Virginia, DC-MD-PA-VA-WV.	15.98%
Rest of U.S.	11.72%

SCHEDULE 10-ADMINISTRATIVE LAW JUDGES

(Effective on the first day of the first applicable pay period beginning on or after January 1, 2005)

AL-3/A	$93,500
AL-3/B	100,600
AL-3/C	107,800
AL-3/D	115,000
AL-3/E	122,200
AL-3/F	129,300
AL-2	136,600
AL-1	140,300

[1]Locality Pay Areas are defined in 5 CFR 531.603.

[FR Doc. 05–306
Filed 1–4–05; 9:01 am]
Billing Code 6325–01–C

Federal Register

Wednesday,
January 5, 2005

Part VII

The President

Proclamation 7859—Honoring the Memory of the Victims of the Indian Ocean Earthquake and Tsunamis

Federal Register
Vol. 70, No. 3
Wednesday, January 5, 2005

Presidential Documents

Title 3—

The President

Proclamation 7859 of January 1, 2005

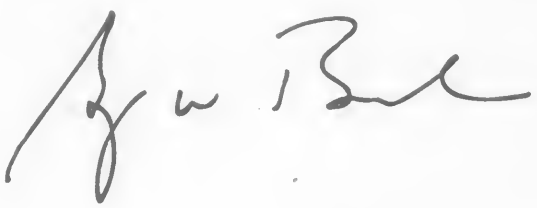
Honoring the Memory of the Victims of the Indian Ocean Earthquake and Tsunamis

By the President of the United States of America

A Proclamation

As a mark of respect for the victims of the Indian Ocean Earthquake and the resulting Tsunamis, I hereby order, by the authority vested in me by the Constitution and laws of the United States of America, that the flag of the United States shall be flown at half-staff at the White House and on all public buildings and grounds, at all military posts and naval stations, and on all naval vessels of the Federal Government in the District of Columbia and throughout the United States and its Territories and possessions from Monday, January 3, 2005, until sunset, Friday, January 7, 2005. I also direct that the flag shall be flown at half-staff for the same period at all United States embassies, legations, consular offices, and other facilities abroad, including all military facilities and naval vessels and stations.

IN WITNESS WHEREOF, I have hereunto set my hand this first day of January, in the year of our Lord two thousand five, and of the Independence of the United States of America the two hundred and twenty-ninth.



[FR Doc. 05–328
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H.J. Res. 102/P.L. 108–479

Recognizing the 60th anniversary of the Battle of Peleliu and the end of Imperial Japanese control of Palau during World War II and urging the Secretary of the Interior to work to protect the historic sites of the Peleliu Battlefield National Historic Landmark and to establish commemorative programs honoring the Americans who fought there. (Dec. 21, 2004; 118 Stat. 3905)

H.R. 2457/P.L. 108–480

To authorize funds for an educational center for the Castillo de San Marcos National Monument, and for other purposes. (Dec. 23, 2004; 118 Stat. 3907)

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To authorize the exchange of certain land in Everglades National Park. (Dec. 23, 2004; 118 Stat. 3919)

H.R. 3818/P.L. 108–484

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H.R. 4027/P.L. 108–485

To authorize the Secretary of Commerce to make available to the University of Miami property under the administrative jurisdiction of the National Oceanic and Atmospheric Administration on Virginia Key, Florida, for use by the University for a Marine Life Science Center. (Dec. 23, 2004; 118 Stat. 3932)

H.R. 4116/P.L. 108–486

American Bald Eagle Recovery and National Emblem Commemorative Coin Act (Dec. 23, 2004; 118 Stat. 3934)

H.R. 4548/P.L. 108–487

To authorize appropriations for fiscal year 2005 for intelligence and intelligence-related activities of the United States Government, the Community Management Account, and the Central Intelligence Agency Retirement and Disability System, and for other purposes. (Dec. 23, 2004; 118 Stat. 3939)

H.R. 4569/P.L. 108–488

To provide for the development of a national plan for the control and management of Sudden Oak Death, a tree disease caused by the fungus-like pathogen Phytophthora ramorum, and for other purposes. (Dec. 23, 2004; 118 Stat. 3964)

H.R. 4657/P.L. 108–489

District of Columbia Retirement Protection Improvement Act of 2004 (Dec. 23, 2004; 118 Stat. 3966)

H.R. 5204/P.L. 108–490

To amend section 340E of the Public Health Service Act (relating to children's hospitals) to modify provisions regarding the determination of the amount of payments for indirect expenses associated with operating approved graduate medical residency training programs. (Dec. 23, 2004; 118 Stat. 3972)

H.R. 5363/P.L. 108–491

To authorize salary adjustments for Justices and judges of the United States for fiscal year 2005. (Dec. 23, 2004; 118 Stat. 3973)

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H.R. 5394/P.L. 108–493

To amend the Internal Revenue Code of 1986 to modify the taxation of arrow components. (Dec. 23, 2004; 118 Stat. 3984)

H.R. 5419/P.L. 108–494

To amend the National Telecommunications and Information Administration Organization Act to facilitate the reallocation of spectrum from governmental to commercial users; to improve, enhance, and promote the Nation's homeland security, public safety, and citizen activated emergency response capabilities through the use of enhanced 911 services, to further upgrade Public Safety Answering Point capabilities and related functions in receiving E-911 calls, and to support in the construction and operation of a ubiquitous and reliable citizen activated system; and to provide that funds received as universal service contributions under section 254 of the Communications Act of 1934 and the universal service support programs established pursuant thereto are not subject to certain provisions of title 31, United States Code, commonly known as the Antideficiency Act, for a period of time. (Dec. 23, 2004; 118 Stat. 3986)

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S. 2856/P.L. 108–498

To limit the transfer of certain Commodity Credit Corporation funds between conservation programs for technical assistance for the programs. (Dec. 23, 2004; 118 Stat. 4020)

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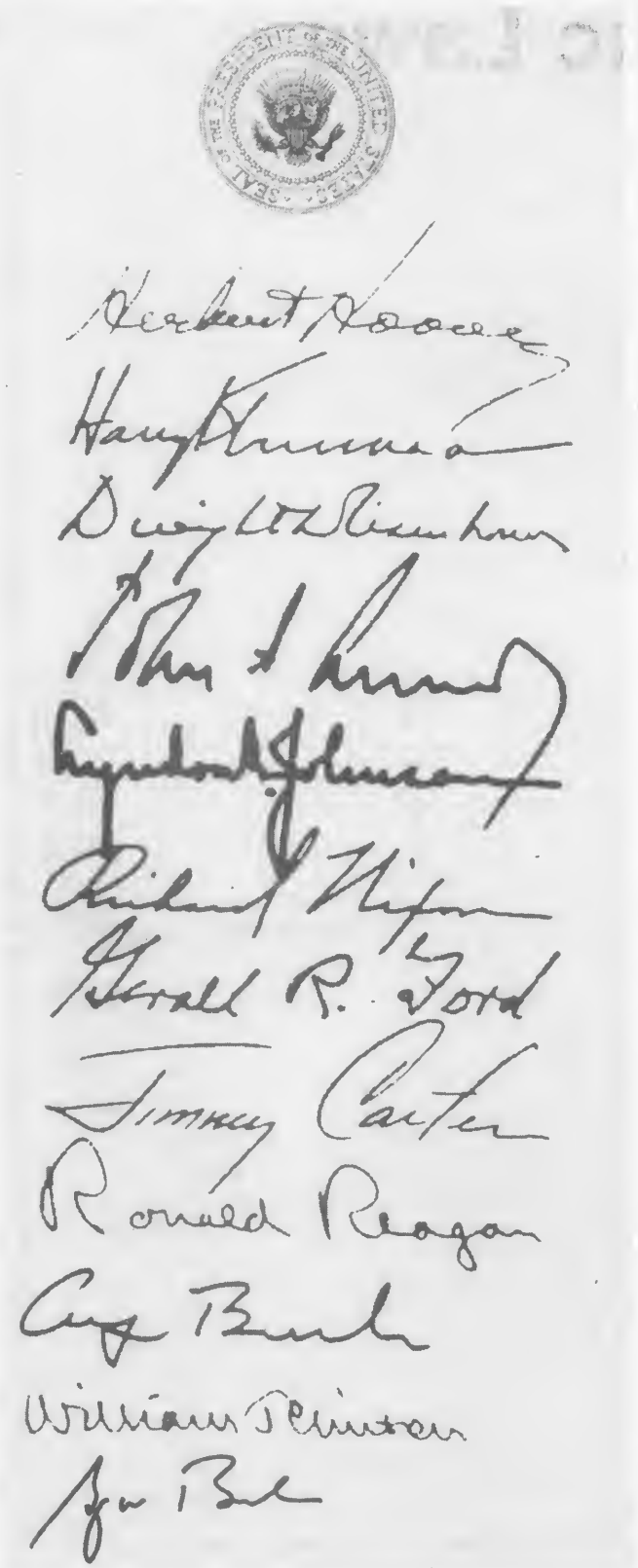

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