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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 301

[Docket No. 04–025–2]

Gypsy Moth Generally Infested Areas

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Affirmation of interim rule as final rule.

SUMMARY: We are adopting as a final rule, without change, an interim rule that amended the gypsy moth regulations by adding one county in Ohio and seven counties in Wisconsin to the list of generally infested areas based on the detection of infestations of gypsy moth in those counties. As a result of the interim rule, the movement of regulated articles from those areas is restricted. The interim rule was necessary to prevent the artificial spread of gypsy moth to noninfested areas of the United States.

DATES: *Effective Date:* The interim rule became effective on June 7, 2004.

FOR FURTHER INFORMATION CONTACT: Dr. Weyman Fussell, Program Manager, Pest Detection and Management Programs, PPQ, APHIS, 4700 River Road Unit 134, Riverdale, MD 20737–1231; (301) 734–5705.

SUPPLEMENTARY INFORMATION:

Background

The gypsy moth, *Lymantria dispar* (Linnaeus), is a destructive pest of forest and shade trees. The gypsy moth regulations (contained in 7 CFR 301.45 through 301.45–12 and referred to below as the regulations) restrict the interstate movement of regulated articles from generally infested areas to prevent the artificial spread of the gypsy moth.

In an interim rule effective and published in the **Federal Register** on June 7, 2004 (69 FR 31722–31723, Docket No. 04–025–1), we amended the regulations by adding one county in Ohio and seven counties in Wisconsin to the list of generally infested areas in § 301.45–3.

Comments on the interim rule were required to be received on or before August 6, 2004. We did not receive any comments. Therefore, for the reasons given in the interim rule, we are adopting the interim rule as a final rule.

This action also affirms the information contained in the interim rule concerning Executive Orders 12866, 12372, and 12988 and the Paperwork Reduction Act.

Further, for this action, the Office of Management and Budget has waived its review under Executive Order 12866.

Regulatory Flexibility Act

This rule affirms an interim rule that amended the regulations by adding one county in Ohio and seven counties in Wisconsin to the list of generally infested areas. As a result of the interim rule, the interstate movement of certain articles from those areas is restricted. The interim rule was necessary to prevent the artificial spread of the gypsy moth to noninfested areas of the United States.

The following analysis addresses the economic effects of the interim rule on small entities, as required by the Regulatory Flexibility Act.

The interim rule placed restrictions on the movement of regulated articles and outdoor household articles (OHAs) from and through the one county in Ohio and the seven counties in Wisconsin that were designated as generally infested areas. These restrictions will have their primary effect on persons moving OHAs, nursery stock, Christmas trees, logs and wood chips, and mobile homes from a generally infested area into or through any area that is not generally infested.

Under the regulations, OHAs may not be moved from a generally infested area into or through a noninfested area unless they are accompanied by either a certificate issued by an inspector or an OHA document issued by the owner of the articles, attesting to the absence of all life stages of gypsy moth. Most individual homeowners moving their own articles who comply with the regulations choose to self-inspect and issue an OHA document. This takes a few minutes and involves no monetary cost unless treatment is necessary. Individuals may also have State-certified pesticide applicators, trained by the State or the U.S. Department of Agriculture (USDA), inspect and issue certificates.

Generally, regulated articles (such as logs, pulpwood, wood chips, mobile homes, nursery stock, OHAs, and Christmas trees) may only be moved from a generally infested area if they are accompanied by a certificate or limited permit issued by an inspector. However, logs, wood chips, and pulpwood may be moved without a certificate or limited permit if the person moving the articles attaches a signed accurate statement to the waybill as specified in the Gypsy Moth Program Manual, stating that he or she has inspected the articles and has found them free of all life stages of the gypsy moth. This exception minimizes the costs of moving logs, pulpwood, and wood chips. Regulated articles may also be moved from a generally infested area without a certificate if they are moved by the USDA for experimental or scientific purposes and they are accompanied by a permit issued by the Administrator of the Animal and Plant Health Inspection Service (APHIS).

Persons moving regulated articles from a generally infested area may obtain a certificate or limited permit from an inspector or a qualified certified applicator. Inspectors will issue these documents at no charge, but costs may result from delaying the movement of commercial articles while waiting for the inspection. Certificates for the movement of mobile homes from a generally infested area may also be obtained from qualified certified applicators.

When inspection of regulated articles or OHAs reveals the presence of gypsy moths, treatment is often necessary in order for the articles to be eligible for movement into or through noninfested areas. The preferred treatment, scraping egg masses and spraying caterpillars, costs an average of $10 to $30 per shipment. Fumigation is another alternative, but it is more expensive, at $100 to $150 per shipment, and may damage the shipment. Treatment is done by qualified certified applicators, most of which are small businesses. These businesses might experience a

small increase in income as a result of the interim rule.

Nurseries and Christmas tree growers that move a substantial number of shipments from the generally infested areas would be able to minimize treatment costs by treating their premises for gypsy moths under a compliance agreement with APHIS. These treatments cost businesses between $10 and $20 per acre. This alternative allows nurseries and Christmas tree growers to issue their own certificates provided they are under a compliance agreement and is less costly than treating individual shipments. The entities most likely to choose this option are nurseries that move a substantial number of shipments from generally infested areas and that treat their premises for other pests in addition to the gypsy moth. Producers that do not operate under a compliance agreement with APHIS, but treat their premises under this option, would receive certification for each shipment from an inspector.

The economic impact of the interim rule will vary depending on the size of the entities affected, the levels of infestation, and the size and number of shipments to noninfested areas. Within the one Ohio county and seven Wisconsin counties added to the list of generally infested areas, there are approximately 450 Christmas tree growers, nurseries, loggers, sawmills, and individuals involved in the movement of regulated articles that may incur costs from the interim rule. According to the size standards established by the Small Business Administration, all of these businesses are considered small entities.

In Hocking County, the newly regulated county in Ohio, there are 25 potentially affected establishments. The value of Christmas tree and greenhouse/nursery products sold by these establishments in 2002 was $541,000, which represents 0.12 percent of the total value of sales of these products in Ohio. These businesses annually ship about 400 shipments, of which approximately half, or 200 shipments, leave the regulated area. Approximately 58 percent of the shipments leaving the regulated area would require treatment, creating an approximate cost range of $11,600 to $17,400 annually. Given these estimates, the cost of additional treatments would be small relative to the total value of sales in Hocking County.

There are 425 potentially affected establishments in the seven Wisconsin counties. The value of Christmas tree and greenhouse/nursery products sold by these establishments in 2002 was $25.546 million, which represents approximately 11.57 percent of the total value of sales of these products in Wisconsin. These businesses annually ship about 2,150 shipments, of which approximately 34 percent, or 723 shipments, leave the regulated area. Only about 16 percent of the shipments from these areas would require treatment, with costs of approximately $11,568 to $17,352 annually. With these estimates, the cost of additional treatments would be very small relative to the total value of sales in the newly affected Wisconsin counties.

The regulatory requirements imposed by the interim rule are expected to cause a slight increase in costs for the affected entities. The relative negative impact that may result from the interim rule is very small when compared with the potential for harm to related industry and the U.S. economy as a whole resulting from the further spread of the pest. Since the total value of the regulated articles moved from infested to noninfested areas is a small fraction of the national total, the effect on national prices is expected to be slight. Additionally, since the rule is not prohibitive, articles that meet the requirements of the regulations would continue to enter the market. Therefore, the overall impact upon price and competitiveness is expected to be relatively insignificant.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Services has determined that this action will not have a significant impact on a substantial number of small entities.

List of Subjects in 7 CFR Part 301

Agricultural commodities, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Transportation.

PART 301—DOMESTIC QUARANTINE NOTICES

■ Accordingly, we are adopting as a final rule, without change, the interim rule that amended 7 CFR part 301 and that was published at 69 FR 31722–31723 on June 7, 2004.

Authority: 7 U.S.C. 7701–7772; 7 CFR 2.22, 2.80, and 371.3.

Section 301.75–15 also issued under Sec. 204, Title II, Pub. L. 106–113, 113 Stat. 1501A–293; sections 301.75–15 and 301.75–16 also issued under Sec. 203, Title II, Pub. L. 106–224, 114 Stat. 400 (7 U.S.C. 1421 note).

Done in Washington, DC, this 28th day of September 2004.

Elizabeth E. Gaston,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 04–22221 Filed 10–1–04; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1206

[Doc. No. FV–02–707–FR]

RIN 0581–AC05

Mango Promotion, Research, and Information Order

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rule establishes the Mango Promotion, Research, and Information Order (Order) under the Commodity Promotion, Research, and Information Act of 1996. Under the Order, first handlers and importers of 500,000 or more pounds of mangos will pay an initial assessment of ½ cent per pound on domestic and imported mangos to the National Mango Promotion Board (Board). The Board will be appointed by the Secretary of Agriculture (Secretary) to conduct a generic program of research and promotion, industry information, and consumer information needed for the maintenance, expansion, and development of domestic markets for fresh mangos.

DATES: Effective November 3, 2004. Collection and remittance of assessments and applicable reporting will begin January 3, 2005.

FOR FURTHER INFORMATION CONTACT: Jeanette A. Palmer, Research and Promotion Branch, FV, AMS, USDA, Stop 0244, 1400 Independence Avenue, SW., Room 2535–S, Washington, DC 20250–0244, telephone (202) 720–9915, fax (202) 205–2800, e-mail *Jeanette.Palmer@usda.gov.*

SUPPLEMENTARY INFORMATION: This Order is issued under the Commodity Promotion, Research, and Information Act of 1996 (Act) (7 U.S.C. 7411–7425; Public Law 104–127; 110 Stat. 1029), or any amendments thereto.

Prior Documents: Proposed rules on both the Order [67 FR 54908] and the referendum procedures [67 FR 54920] were published in the **Federal Register** on August 26, 2002, each with a 60-day comment period. A final rule on the referendum procedures [68 FR 58552]

and a second proposed rule on the Order [68 FR 58556] were published in the October 9, 2003, issue of the **Federal Register**.

Question and Answer Overview

Why Is the Final Rule Being Published?

In a recent referendum, eligible first handlers and importers of fresh mangos voted in favor of implementing the Order. This final rule, which will become effective in 30 days, completes the rulemaking process.

What Is the Purpose of the Program?

The purpose of the program is to maintain, expand, and develop domestic markets for fresh mangos.

Who Is Covered by This Order?

Domestic first handlers and importers of 500,000 or more pounds of mangos per calendar year will pay assessments under the program. Domestic mangos that are exported will not be assessed under the Order.

What Is the Assessment Rate?

The assessment rate is ½ cent per pound on domestic and imported mangos.

When Will Assessments Be Due?

Collection and remittance of assessments and applicable reporting will begin 90 days after publication in the **Federal Register**.

Will I Have To Pay the Assessment Forever?

Assessments will be due as long as the Order is in effect. However, every five years, USDA will conduct a referendum to determine whether first handlers and importers of fresh mangos want the program to continue. The program will continue if a majority of the voters in the referendum vote for approval.

Who Will Administer This Order?

The National Mango Board will administer this Order under the supervision of USDA. The Board members will be appointed by the Secretary from nominations received from the mango industry.

Who Will Sit on the Board?

The Order provides that there will be a 20-member Board consisting of eight U.S. importers, one U.S. first handler, two U.S. producers, seven foreign producers, and two non-voting U.S. wholesalers and/or retailers of mangos. The chairperson shall reside in the United States.

How Will Members of the Board Be Selected?

USDA will handle the nomination process for the initial Board. The U.S. importers, first handlers, and producers will be nominated by U.S. importers, first handlers, and producers, respectively. Foreign producers will be nominated by foreign producer associations. After the initial Board is seated, the U.S. wholesalers and/or retailers will be nominated by the Board. Two names must be submitted for each position. From the names submitted, the Secretary will appoint the members.

Executive Order 12866

This final rule has been determined to be not significant for purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget (OMB).

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have a retroactive effect. Section 524 of the Act provides that the Act shall not preempt any other Federal or state law authorizing promotion or research relating to an agricultural commodity. Under section 519 of the Act, a person subject to the Order may file a petition with USDA stating that an order, any provision of an order, or any obligation imposed in connection with an order, is not established in accordance with the law, and requesting a modification of an order or an exemption from an order. Any petition filed challenging an order, any provision of an order, or any obligation imposed in connection with an order, shall be filed within two years after the effective date of an order, provision or obligation subject to challenge in the petition. The petitioner will have the opportunity for a hearing on the petition. Thereafter, USDA will issue a ruling on the petition. The Act provides that the district court of the United States for any district in which the petitioner resides or conducts business shall have jurisdiction to review a final ruling on the petition, if the petitioner files a complaint for that purpose not later than 20 days after the date of entry of USDA's final ruling.

Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency examined the impact of the final rule on small entities and prepared a final regulatory flexibility analysis that was included in the proposed rule published in the **Federal Register** on October 9, 2003. This analysis indicates that the Agency minimized the economic impacts of the Order provisions on small entities to the fullest extent reasonably possible while adhering to the program's objectives.

Paperwork Reduction Act

The Order provisions were carefully reviewed, and every effort was made to minimize any unnecessary information collection and recordkeeping costs or requirements. In accordance with OMB regulations [5 CFR part 1320], which implement the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the information collection and recordkeeping requirements that are imposed by this Order were submitted to OMB for review and approved under OMB control numbers 0581–0209 and 0505–0001. Upon reevaluation of the response time for the ballot and nomination forms, it was determined that the response time could be reduced from 30 minutes to 15 minutes. Also, the burden for the form AD–755 was inadvertently calculated as a part of this collection. Its burden is covered under 0505–0001. These two adjustments resulted in an overall decrease of 15 burden hours between the proposed rule and the final rule.

Copies of the final regulatory flexibility analysis and the discussion of the information collection and recordkeeping requirements contained in this rulemaking can be obtained from Jeanette Palmer at the address listed above or by e-mail at *Jeanette.Palmer@usda.gov*.

Background

On June 29, 2001, the Fresh Produce Association of the Americas (Association) submitted a proposal for a national promotion, research, and information order for fresh mangos to the Department, pursuant to the Act to: (1) develop and finance an effective and coordinated program of research, promotion, industry information, and consumer information regarding mangos; (2) strengthen the position of the mango industry in U.S. markets; and (3) maintain, develop, and expand domestic markets for mangos. The Association submitted changes to their proposal on November 1, 2001 and the Department published the modified proposed rules on both the Order [67 FR 54908] and the referendum procedures [67 FR 54920] in the **Federal Register** on August 26, 2002, each with a 60-day comment period. Twenty-two comments from 21 persons or organizations were received by the deadline. Nineteen of the 22 comments were in support of the proposed program while three were opposed. These comments and related

changes to the Order were discussed in the October 9, 2003, issue of the **Federal Register** in the proposed rule on the Order [68 FR 58556] and the final rule on the referendum procedures [68 FR 58552].

First handlers and importers of mangos voted to implement the program in a referendum held November 10 through November 28, 2003. Under the Order, first handlers and importers of 500,000 or more pounds of mangos per calendar year will pay an initial assessment of ½ cent per pound on domestic and imported mangos to the National Mango Promotion Board (Board). This will generate about $2.5 million to administer the program: about 8 percent from domestic production and 92 percent from imports. (Exports of U.S. mangos are exempt from assessments.) The Board will use the funds to pay for the aforementioned program development areas as well as administration, maintenance, functioning of the Board, and expenses incurred by USDA in implementing and administrating the Order, including referendum costs.

The program will be administered by the Board under USDA supervision. The Board will be composed of 20-members; eight U.S. importers, one U.S. first handler, two U.S. producers, seven foreign producers, and two non-voting wholesalers and/or retailers. If domestic production increases, additional U.S. first handlers will be added to the Board.

The Order is summarized as follows:

Sections 1206.1 through 1206.24 of the Order define certain terms, such as mango, first handler and importer, which are used in the Order.

Sections 1206.30 through 1206.37 include provisions relating to the establishment, adjustment, and membership; nominations; appointments; term of office; vacancies; procedures; compensation; reimbursement; and powers, duties, and prohibited activities of the Board. The Board is the governing body authorized to administer the Order through the implementation of programs, plans, projects, budgets, and contracts to promote and disseminate information about mangos, subject to oversight of the Department.

Sections 1206.40 through 1206.43 cover budget review and approval; financial statements; authorize the collection of assessments; specify how assessments are used; specify who pays the assessment and how; exemptions; and authorize the imposition of a late-payment charge on past-due assessments.

The initial assessment rate shall be ½ cent per pound for domestic mangos and imported mangos. The assessment rate will be reviewed and may be modified with the approval of the Department, after the initial continuance referendum which will be conducted after the program has been in operation 5 years. The assessment rate may be changed without a referendum. Persons failing to remit total assessments due in a timely manner may also be subject to actions under federal debt collection procedures as set forth in 7 CFR 3.1 through 3.36 for all research and promotion programs administered by USDA [60 FR 12533, March 7, 1995].

Sections 1206.50 through 1206.52 address programs, plans, and projects; require the Board to periodically conduct an independent review of its overall program; and address patents, copyrights, trademarks, information, publications, and product formulations developed through the use of assessment funds.

Sections 1206.60 through 1206.62 concern reporting and recordkeeping requirements for persons subject to the Order and protect the confidentiality of information from such books, records, or reports.

Sections 1206.70 through 1206.78 describe the rights of the Secretary; address referenda; authorize the Secretary to suspend or terminate the Order when deemed appropriate; prescribe proceedings after suspension or termination; and address personal liability, separability, amendments, and the OMB control numbers.

Finally, §§ 1206.14 and 1206.42(b) have been slightly modified for clarity.

General Findings

The Department conducted a referendum among eligible first handlers and importers of mangos from November 10, 2003 through November 28, 2003, to determine whether the Order would become effective. First handlers and importers who handled or imported 500,000 pounds or more of fresh mangos, respectively, from January 1 through December 31, 2002, were eligible to vote. It is determined that a majority of the eligible first handlers and importers voting in the referendum favored implementation of the Order. After consideration of all relevant materials presented, including the proposal, comments received, and the referendum results, it is found that the Order is consistent with and effectuates the policy and purpose of the Act.

The effective date of this action will be 30 days after publication in the **Federal Register**.

List of Subjects in 7 CFR Part 1206

Administrative practice and procedure, Advertising, Consumer information, Mangos, Marketing agreements, Promotion, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, Title 7, Chapter XI of the Code of Federal Regulations is amended as follows:

PART 1206—MANGO PROMOTION, RESEARCH, AND INFORMATION

■ 1. The authority citation for part 1206 continues to read as follows:

Authority: 7 U.S.C. 7411–7425.

■ 2. Subpart A is added to part 1206 to read as follows:

Subpart A—Mango Promotion, Research, and Information Order Definitions

Sec.

Subpart A—Mango Promotion, Research, and Information Order Definitions

§ 1206.1 Act.

Act means the Commodity Promotion, Research, and Information Act of 1996 (7 U.S.C. 7411–7425; Public Law 104–127; 110 Stat. 1029), or any amendments thereto.

§ 1206.2 Board.

Board or National Mango Promotion Board means the administrative body established pursuant to § 1206.30, or such other name as recommended by the Board and approved by the Department.

§ 1206.3 Conflict of interest.

Conflict of interest means a situation in which a member or employee of the Board has a direct or indirect financial interest in a person who performs a service for, or enters into a contract with, the Board for anything of economic value.

§ 1206.4 Customs.

Customs means the Customs and Border Protection of the U.S. Department of Homeland Security.

§ 1206.5 Department.

Department means the U.S. Department of Agriculture or any officer or employee of the Department to whom authority has heretofore been delegated, or to whom authority may hereafter be delegated, to act in the Secretary's stead.

§ 1206.6 First handler.

First handler means any person, (excluding a common or contract carrier), receiving 500,000 or more pounds of mangos from producers in a calendar year and who as owner, agent, or otherwise ships or causes mangos to be shipped as specified in this Order. This definition includes those engaged in the business of buying, selling and/or offering for sale; receiving; packing; grading; marketing; or distributing mangos in commercial quantities. The term first handler includes a producer who handles or markets mangos of the producer's own production.

§ 1206.7 Fiscal period.

Fiscal period means a calendar year from January 1 through December 31, or such other period as recommended by the Board and approved by the Department.

§ 1206.8 Foreign producer.

Foreign producer means any person:

(1) Who is engaged in the production and sale of mangos outside of the United States and who owns, or shares the ownership and risk of loss of the crop for sale in the U.S. market or

(2) Who is engaged, outside of the United States, in the business of producing, or causing to be produced, mangos beyond the person's own family use and having value at first point of sale.

§ 1206.9 Importer.

Importer means any person importing 500,000 or more pounds of mangos into the United States in a calendar year as a principal or as an agent, broker, or consignee of any person who produces or handles mangos outside of the United States for sale in the United States, and who is listed as the importer of record for such mangos.

§ 1206.10 Information.

Information means information and programs that are designed to develop new markets, marketing strategies, increase market efficiency, and activities that are designed to enhance the image of mangos in the United States. These include:

(a) Consumer information, which means any action taken to provide information to, and broaden the understanding of, the general public regarding the consumption, use, nutritional attributes, and care of mangos; and

(b) Industry information, which means information and programs that will lead to the development of new markets, new marketing strategies, or increased efficiency for the mango industry, and activities to enhance the image of the mango industry.

§ 1206.11 Mangos.

Mangos means all fresh fruit of *Mangifera indica L.* of the family *Anacardiaceae.*

§ 1206.12 Market or marketing.

Marketing means the sale or other disposition of mangos in the U.S. domestic market. To market means to sell or otherwise dispose of mangos in interstate or intrastate channels of commerce.

§ 1206.13 Order.

Order means an order issued by the Department under section 514 of the Act that provides for a program of generic promotion, research, and information regarding agricultural commodities authorized under the Act.

§ 1206.14 Part.

Part means part 1206 which includes the Mango Promotion, Research, and Information Order and all rules, regulations, and supplemental orders issued pursuant to the Act and the Order.

§ 1206.15 Person.

Person means any individual, group of individuals, partnership, corporation, association, cooperative, or any other legal entity.

§ 1206.16 Producer.

Producer means any person who is engaged in the production and sale of mangos in the United States and who owns, or shares the ownership and risk of loss of, the crop or a person who is engaged in the business of producing, or causing to be produced, mangos beyond the person's own family use and having value at first point of sale.

§ 1206.17 Promotion.

Promotion means any action taken to present a favorable image of mangos to the general public and the food industry for the purpose of improving the competitive position of mangos and stimulating the sale of mangos in the United States. This includes paid advertising and public relations.

§ 1206.18 Research.

Research means any type of test, study, or analysis designed to advance the image, desirability, use, marketability, production, product development, or quality of mangos, including research relating to nutritional value, cost of production, new product development, varietal development, nutritional value and benefits, and marketing of mangos.

§ 1206.19 Retailer.

Retailer means a person engaged in the business of selling mangos only to consumers.

§ 1206.20 Secretary.

Secretary means the Secretary of Agriculture of the United States.

§ 1206.21 Suspend.

Suspend means to issue a rule under section 553 of title 5, U.S.C., to temporarily prevent the operation of an order or part thereof during a particular period of time specified in the rule.

§ 1206.22 Terminate.

Terminate means to issue a rule under section 553 of title 5, U.S.C., to cancel permanently the operation of an order or part thereof beginning on a certain date specified in the rule.

§ 1206.23 United States.

United States or U.S. means collectively the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, and the territories and possessions of the United States.

§ 1206.24 Wholesaler.

Wholesaler means any person engaged in the purchase, assembly, transportation, storage, and distribution of mangos for sale to other wholesalers, retailers, and foodservice firms.

National Mango Promotion Board

§ 1206.30 Establishment and membership.

(a) *Establishment of the National Mango Promotion Board.* There is hereby established a National Mango Promotion Board composed of eight importers, one first handler, two domestic producers, seven foreign producers, and two non-voting wholesalers and/or retailers of mangos in the United States. The chairperson shall reside in the United States and the Board office shall also be located in the United States.

(b) *Importer districts.* The importer seats shall be allocated based on the volume of mangos imported into the Customs Districts identified by their name and Code Number as defined in the Harmonized Tariff Schedule of the United States. The initial allocation will be two seats for District I, three seats for District II, two seats for District III, and one seat for District IV.

(1) *District I* includes the Customs Districts of Portland, ME (01), St. Albans, VT (02), Boston, MA (04), Providence, RI (05), Ogdensburg, NY (07), Buffalo, NY (09), New York City, NY (10), Philadelphia, PA (11), Baltimore, MD (13), Norfolk, VA (14), Charlotte, NC (15), Charleston, SC (16), Savannah, GA (17), Tampa, FL (18), San Juan, PR (49), Virgin Islands of the United States (51), Miami, FL (52) and Washington, DC (54).

(2) *District II* includes the Customs Districts of Mobile, AL (19), New Orleans, LA (20), Port Arthur, TX (21), Laredo, TX (23), Minneapolis, MN (35), Duluth, MN (36), Milwaukee, WI (37), Detroit, MI (38), Chicago, IL (39), Cleveland, OH (41), St. Louis, MO (45), Houston, TX (53), and Dallas-Fort Worth, TX (55).

(3) *District III* includes the Customs Districts of El Paso, TX (24), Nogales, AZ (26), Great Falls, MT (33), and Pembina, ND (34).

(4) *District IV* includes the Customs Districts of San Diego, CA (25), Los Angeles, CA (27), San Francisco, CA (28), Columbia-Snake, OR (29), Seattle, WA (30), Anchorage, AK (31), and Honolulu, HI (32).

(c) *Adjustment of membership.* At least once every five years, the Board will review the geographical distribution of production of mangos in the United States, the geographical distribution of the importation of mangos into the United States, the quantity of mangos produced in the United States, and the quantity of mangos imported into the United States. The review will be based on Board assessment records and statistics from the Department. If warranted, the Board will recommend to the Department that membership on the Board be altered to reflect any changes in geographical distribution of domestic mango production and importation and the quantity of domestic production and imports. To ensure equitable representation, additional first handlers may be added to the Board to reflect increases in domestic production.

§ 1206.31 Nominations and appointments.

(a) Voting for first handler, importer, and domestic producer members will be made by mail ballot.

(b) There shall be two nominees for each position on the Board.

(c) Nominations for the initial Board will be handled by the Department. Subsequent nominations will be handled by the Board's staff.

(d) Nominees to fill the first handler member position on the Board shall be solicited from all known first handlers. The nominees shall be placed on a ballot which will be sent to all first handlers for a vote. The nominee receiving the highest number of votes and the nominee receiving the second highest number of votes shall be submitted to the Department as the first handlers' first and second choice nominees.

(e) Nominees to fill the importer positions on the Board shall be solicited from all known importers of mangos. The members from each district shall select the nominees for two positions on the Board. Two nominees shall be submitted for each position. The nominees shall be placed on a ballot which will be sent to importers in the districts for a vote. For each position, the nominee receiving the highest number of votes and the nominee receiving the second highest number of votes shall be submitted to the Department as the importers' first and second choice nominees.

(f) Nominees to fill the domestic producer member positions on the Board shall be solicited from all known domestic producers. The nominees shall be placed on a ballot which will be sent to all domestic producers for a vote. The nominee receiving the highest number of votes and the nominee receiving the second highest number of votes shall be submitted to the Department as the producers' first and second choice nominees.

(g) Nominees to fill the foreign producer member positions on the Board shall be solicited from organizations of foreign mango producers. Each organization shall submit two nominees for each position, and the nominees shall be representative of the major countries exporting mangos to the United States.

(h) The Board will nominate the wholesaler and/or retailer members.

(i) From the nominations, the Secretary shall select the members of the Board.

§ 1206.32 Term of office.

The term of office for first handler, importer, domestic producer, and foreign producer members of the Board will be three years, and these members may serve a maximum of two consecutive three-year terms. The term of office for wholesaler/retailer members shall be one year, and these members may serve a maximum of three consecutive one-year terms. When the Board is first established, the first handler, two importers, one domestic producer, and two foreign producers will be assigned initial terms of four years; three importers, one domestic producer, and two foreign producers will be assigned initial terms of three years; and three importers and three foreign producers will be assigned initial terms of two years. Thereafter, each of these positions will carry a full three-year term. Members serving initial terms of two or four years will be eligible to serve a second term of three years. Each term of office will end on December 31, with new terms of office beginning on January 1.

§ 1206.33 Vacancies.

(a) In the event that any member of the Board ceases to be a member of the category of members from which the member was appointed to the Board, such position shall automatically become vacant.

(b) If a member of the Board consistently refuses to perform the duties of a Board member, or if a member of the Board engages in acts of

dishonesty or willful misconduct, the Board may recommend to the Department that the member be removed from office. If the Department finds the recommendation of the Board shows adequate cause, the Department shall remove such member from office.

(c) Should any member position become vacant, successors for the unexpired term of the member shall be appointed in the manner specified in § 1206.31, except that nomination and replacement shall not be required if the unexpired term is less than six months.

§ 1206.34 Procedure.

(a) At a Board meeting, it will be considered a quorum when at least ten voting members are present.

(b) At the start of each fiscal period, the Board will select a chairperson and vice chairperson who will conduct meetings throughout that period.

(c) All Board members will be notified at least 30 days in advance of all Board and committee meetings unless an emergency meeting is declared.

(d) Each voting member of the Board will be entitled to one vote on any matter put to the Board, and the motion will carry if supported by one vote more than 50 percent of the total votes represented by the Board members present.

(e) It will be considered a quorum at a committee meeting when at least one more than half of those assigned to the committee are present. Committees may consist of individuals other than Board members, and such individuals may vote in committee meetings. Committee members shall serve without compensation but shall be reimbursed for reasonable travel expenses, as approved by the Board.

(f) In lieu of voting at a properly convened meeting and, when in the opinion of the chairperson of the Board such action is considered necessary, the Board may take action if supported by one vote more than 50 percent of the members by mail, telephone, electronic mail, facsimile, or any other means of communication. In that event, all members must be notified and provided the opportunity to vote. Any action so taken shall have the same force and effect as though such action had been taken at a properly convened meeting of the Board. All telephone votes shall be confirmed promptly in writing. All votes shall be recorded in Board minutes.

(g) There shall be no voting by proxy.

(h) The chairperson shall be a voting member and shall reside in the U.S.

(i) The organization of the Board and the procedures for conducting meetings of the Board shall be in accordance with its bylaws, which shall be established by the Board and approved by the Department.

§ 1206.35 Compensation and reimbursement.

The members of the Board shall serve without compensation but shall be reimbursed for reasonable travel expenses, as approved by the Board, incurred by them in the performance of their duties as Board members.

§ 1206.36 Powers and duties.

The Board shall have the following powers and duties:

(a) To administer the Order in accordance with its terms and conditions and to collect assessments;

(b) To develop and recommend to the Department for approval such bylaws as may be necessary for the functioning of the Board, and such rules as may be necessary to administer the Order, including activities authorized to be carried out under the Order;

(c) To meet, organize, and select from among the members of the Board a chairperson, other officers, committees, and subcommittees, as the Board determines appropriate;

(d) To employ persons, other than the members, as the Board considers necessary to assist the Board in carrying out its duties and to determine the compensation and specify the duties of such persons;

(e) To develop programs, plans, and projects, and enter into contracts or agreements, which must be approved by the Department before becoming effective, for the development and carrying out of programs or projects of research, information, or promotion, and the payment of costs thereof with funds collected pursuant to this subpart. Each contract or agreement shall provide that: any person who enters into a contract or agreement with the Board shall develop and submit to the Board a proposed activity; keep accurate records of all of its transactions relating to the contract or agreement; account for funds received and expended in connection with the contract or agreement; make periodic reports to the Board of activities conducted under the contract or agreement; and, make such other reports available as the Board or the Department considers relevant. Furthermore, any contract or agreement shall provide that:

(1) The contractor or agreeing party shall develop and submit to the Board a program, plan, or project together with a budget or budgets that shall show the estimated cost to be incurred for such program, plan, or project;

(2) The contractor or agreeing party shall keep accurate records of all its transactions and make periodic reports to the Board of activities conducted, submit accounting for funds received and expended, and make such other reports as the Department or the Board may require;

(3) The Department may audit the records of the contracting or agreeing party periodically; and

(4) Any subcontractor who enters into a contract with a Board contractor and who receives or otherwise uses funds allocated by the Board shall be subject to the same provisions as the contractor.

(f) To prepare and submit for approval of the Department calendar year budgets in accordance with § 1206.40;

(g) To maintain such records and books and prepare and submit such reports and records from time to time to the Department as the Department may prescribe; to make appropriate accounting with respect to the receipt and disbursement of all funds entrusted to it; and to keep records that accurately reflect the actions and transactions of the Board:

(h) To cause its books to be audited by a competent auditor at the end of each calendar year and at such other times as the Department may request, and to submit a report of the audit directly to the Department;

(i) To give the Department the same notice of Board and committee meetings as is given to members in order that the Department's representative(s) may attend such meetings.

(j) To act as intermediary between the Department and any first handler or importer;

(k) To furnish to the Department any information or records that the Department may request;

(l) To receive, investigate, and report to the Department complaints of violations of the Order;

(m) To recommend to the Department such amendments to the Order as the Board considers appropriate; and

(n) To work to achieve an effective, continuous, and coordinated program of promotion, research, consumer information, evaluation, and industry information designed to strengthen the mango industry's position in the U.S. domestic market; maintain and expand existing markets and uses for mangos; and to carry out programs, plans, and projects designed to provide maximum benefits to the mango industry.

§ 1206.37 Prohibited activities.

The Board may not engage in, and shall prohibit the employees and agents of the Board from engaging in:

(a) Any action that is a conflict of interest; and

(b) Using funds collected by the Board under the Order to undertake any action

for the purpose of influencing legislation or governmental action or policy, by local, state, national, and foreign governments, other than recommending to the Department amendments to the Order.

Expenses and Assessments

§ 1206.40 Budget and expenses.

(a) At least 60 days prior to the beginning of each calendar year, and as may be necessary thereafter, the Board shall prepare and submit to the Department a budget for the calendar year covering its anticipated expenses and disbursements in administering this subpart. Each such budget shall include:

(1) A statement of objectives and strategy for each program, plan, or project;

(2) A summary of anticipated revenue, with comparative data or at least one preceding year (except for the initial budget);

(3) A summary of proposed expenditures for each program, plan, or project; and

(4) Staff and administrative expense breakdowns, with comparative data for at least one preceding year (except for the initial budget).

(b) Each budget shall provide adequate funds to defray its proposed expenditures and to provide for a reserve as set forth in this subpart.

(c) Subject to this section, any amendment or addition to an approved budget must be approved by the Department, including shifting funds from one program, plan, or project to another. Shifts of funds which do not cause an increase in the Board's approved budget and which are consistent with governing bylaws need not have prior approval by the Department.

(d) The Board is authorized to incur such expenses, including provision for a reserve, as the Department finds reasonable and likely to be incurred by the Board for its maintenance and functioning, and to enable it to exercise its powers and perform its duties in accordance with the provisions of this subpart. Such expenses shall be paid from funds received by the Board.

(e) With approval of the Department, the Board may borrow money for the payment of administrative expenses, subject to the same fiscal, budget, and audit controls as other funds of the Board. Any funds borrowed by the Board shall be expended only for startup costs and capital outlays and are limited to the first year of operation of the Board.

(f) The Board may accept voluntary contributions, but these shall only be used to pay expenses incurred in the conduct of programs, plans, and projects. Voluntary contributions shall be free from any encumbrance by the donor, and the Board shall retain complete control of their use.

(g) The Board shall reimburse the Department for all expenses incurred by the Department in the implementation, administration, and supervision of the Order, including all referendum costs in connection with the Order.

(h) The Board may not expend for administration, maintenance, and functioning of the Board in any calendar year an amount that exceeds 15 percent of the assessments and other income received by the Board for that calendar year. Reimbursements to the Department required under paragraph (g) of this section, are excluded from this limitation on spending.

(i) The Board may establish an operating monetary reserve and may carry over to subsequent fiscal periods excess funds in any reserve so established: Provided that the funds in the reserve do not exceed one fiscal period's budget. Subject to approval by the Department, such reserve funds may be used to defray any expenses authorized under this part.

§ 1206.41 Financial statements.

(a) As requested by the Department, the Board shall prepare and submit financial statements to the Department on a periodic basis. Each such financial statement shall include, but not be limited to, a balance sheet, income statement, and expense budget. The expense budget shall show expenditures during the time period covered by the report, year-to-date expenditures, and the unexpended budget.

(b) Each financial statement shall be submitted to the Department within 30 days after the end of the time period to which it applies.

(c) The Board shall submit annually to the Department an annual financial statement within 90 days after the end of the calendar year to which it applies.

§ 1206.42 Assessments.

(a) The funds to cover the Board's expenses shall be paid from assessments on first handlers and importers, donations from any person not subject to assessments under this Order, and other funds available to the Board and subject to the limitations contained therein.

(b) The assessment rate shall be ½ cent per pound on all mangos. The assessment rate will be reviewed and may be modified by the Board with the approval of the Department, after the first referendum is conducted as stated in § 1206.71(b). The Department will amend this section if the assessment rate is modified.

(c) *Domestic mangos.* First handlers of domestic mangos are required to pay assessments on all mangos handled for the U.S. market. This includes mangos of the first handler's own production.

(d) *Imported mangos.* Each importer of mangos shall pay an assessment to the Board through Customs on mangos imported for marketing in the United States.

(1) The assessment rate for imported mangos shall be the same or equivalent to the rate for mangos produced in the United States.

(2) The import assessment shall be uniformly applied to imported mangos that are identified by the numbers 0804.50.4040 and 0804.50.6040 in the Harmonized Tariff Schedule of the United States.

(3) The assessments due on imported mangos shall be paid when they enter or are withdrawn for consumption in the United States.

(e) Each person responsible for remitting assessments under paragraph (c) of this section shall remit the amounts due to the Board's office on a monthly basis no later than the fifteenth day of the month following the month in which the mangos were marketed, in such manner as prescribed by the Board.

(f) A late payment charge shall be imposed on any person failing to remit to the Board the total amount for which the person is liable by the payment due date established under this section. The amount of the late payment charge shall be prescribed by the Department.

(g) An additional charge shall be imposed on any person subject to a late payment charge in the form of interest on the outstanding portion of any amount for which the person is liable. The rate of interest shall be prescribed by the Department.

(h) Persons failing to remit total assessments due in a timely manner may also be subject to actions under federal debt collection procedures.

(i) The Board may authorize other organizations to collect assessments on its behalf with the approval of the Department.

§ 1206.43 Exemptions.

(a) Any first handler or importer of less than 500,000 pounds of mangos per calendar year may claim an exemption from the assessments required under § 1206.42. Mangos produced domestically and exported from the United States may annually claim an exemption from the assessments required under § 1206.42.

(b) A first handler or importer desiring an exemption shall apply to the Board, on a form provided by the Board, for a certificate of exemption. A first handler shall certify that the first handler will handle less than 500,000 pounds of domestic mangos for the fiscal period for which the exemption is claimed. An importer shall certify that the importer will import less than 500,000 pounds of mangos during the fiscal period for which the exemption is claimed.

(c) Upon receipt of an application, the Board shall determine whether an exemption may be granted. The Board then will issue, if deemed appropriate, a certificate of exemption to each person who is eligible to receive one. It is the responsibility of these persons to retain a copy of the certificate of exemption.

(d) Importers who receive a certificate of exemption shall be eligible for reimbursement of assessments collected by Customs. These importers shall apply to the Board for reimbursement of any assessments paid. No interest will be paid on the assessments collected by Customs. Requests for reimbursement shall be submitted to the Board within 90 days of the last day of the calendar year the mangos were actually imported.

(e) Any person who desires an exemption from assessments for a subsequent calendar year shall reapply to the Board, on a form provided by the Board, for a certificate of exemption.

(f) The Board may require persons receiving an exemption from assessments to provide to the Board reports on the disposition of exempt mangos and, in the case of importers, proof of payment of assessments.

Promotion, Research, and Information

§ 1206.50 Programs, plans, and projects.

(a) The Board shall receive and evaluate, or on its own initiative develop, and submit to the Department for approval any program, plan, or project authorized under this subpart. Such programs, plans, or projects shall provide for:

(1) The establishment, issuance, effectuation, and administration of appropriate programs for promotion, research, and information, including producer and consumer information, with respect to mangos; and

(2) The establishment and conduct of research with respect to: the use, nutritional value and benefits, sale, distribution, and marketing of mangos in the United States; the creation of new products thereof, to the end that the marketing and use of mangos in the United States may be encouraged, expanded, improved, or made more acceptable; and to advance the image, desirability, or quality of mangos in the United States.

(b) No program, plan, or project shall be implemented prior to its approval by the Department. Once a program, plan, or project is so approved, the Board shall take appropriate steps to implement it.

(c) Each program, plan, or project implemented under this subpart shall be reviewed or evaluated periodically by the Board to ensure that it contributes to an effective program of promotion, research, or information. If it is found by the Board that any such program, plan, or project does not contribute to an effective program of promotion, research, or information, then the Board shall terminate such program, plan, or project.

(d) No program, plan, or project including advertising shall be false or misleading or disparaging to another agricultural commodity. Mangos of all origins shall be treated equally.

§ 1206.51 Independent evaluation.

The Board shall, not less often than every five years, authorize and fund, from funds otherwise available to the Board, an independent evaluation of the effectiveness of the Order and other programs conducted by the Board pursuant to the Act. The Board shall submit to the Department, and make available to the public, the results of each periodic independent evaluation conducted under this paragraph.

§ 1206.52 Patents, copyrights, trademarks, information, publications, and product formulations.

Patents, copyrights, trademarks, information, publications, and product formulations developed through the use of funds received by the Board under this subpart shall be the property of the U.S. Government, as represented by the Board, and shall, along with any rents, royalties, residual payments, or other income from the rental, sales, leasing, franchising, or other uses of such patents, copyrights, trademarks, information, publications, or product formulations, inure to the benefit of the Board; shall be considered income subject to the same fiscal, budget, and audit controls as other funds of the Board; and may be licensed subject to approval by the Department Upon termination of this subpart, § 1206.73 shall apply to determine disposition of all such property.

Reports, Books, and Records

§ 1206.60 Reports.

(a) Each first handler will be required to provide to the Board periodically such information as may be required by the Board, with the approval of the Department, which may include but not be limited to the following:

(1) Number of pounds of domestic mangos handled;

(2) Number of pounds of domestic mangos on which an assessment was paid;

(3) Name and address of the producers from whom the first handler has received mangos;

(4) Date that assessment payments were made on each pound of domestic mangos handled;

(5) Number of pounds of domestic mangos exported;

(6) The first handler's tax identification number;

(b) Each importer may be required to provide to the Board periodically such information as may be required by the Board, with the approval of the Department, which may include but not be limited to the following:

(1) Number of pounds of mangos imported;

(2) Number of pounds of mangos on which an assessment was paid;

(3) Name, address, and tax identification number of the importer; and

(4) Date that assessment payments were made on each pound imported.

§ 1206.61 Books and records.

Each first handler and importer shall maintain and make available for inspection by the Department such books and records as are necessary to carry out the provisions of this part, any regulations issued under this part, including such records as are necessary to verify any reports required. Such records shall be retained for at least two years beyond the fiscal period of their applicability.

§ 1206.62 Confidential treatment.

All information obtained from books, records, or reports under the Act and this part shall be kept confidential by all persons, including all employees and former employees of the Board, all officers and employees and former officers and employees of contracting and subcontracting agencies or agreeing parties having access to such information. Such information shall not be available to Board members, first handlers, or importers. Only those persons having a specific need for such information to effectively administer the provisions of this subpart shall have access to such information. Only such information so obtained as the Secretary deems relevant shall be disclosed by them, and then only in a judicial proceeding or administrative hearing

brought at the direction, or on the request, of the Secretary, or to which the Secretary or any officer of the United States is a party, and involving this subpart. Nothing in this section shall be deemed to prohibit:

(a) The issuance of general statements based upon the reports of the number of persons subject to this subpart or statistical data collected therefrom, which statements do not identify the information furnished by any person; and

(b) The publication, by direction of the Secretary, of the name of any person who has been adjudged to have violated this part, together with a statement of the particular provisions of this part violated by such person.

Miscellaneous

§ 1206.70 Right of the Secretary.

All fiscal matters, programs, plans, or projects, rules or regulations, reports, or other substantive actions proposed and prepared by the Board shall be submitted to the Secretary for approval.

§ 1206.71 Referenda.

(a) *Initial Referendum.* The Order shall not become effective unless:

(1) The Department determines that the Order is consistent with and will effectuate the purposes of the Act; and

(2) The Order is approved by a majority of the first handlers and importers voting, who, during a representative period determined by the Department, have been engaged in the handling or importation of mangos.

(b) *Subsequent referenda.* Every five years, the Department shall hold a referendum to determine whether first handlers and importers of mangos favor the continuation of the Order. The Order shall continue if it is favored by a majority of the first handlers and importers voting who, during a representative period determined by the Department, have been engaged in the handling or importation of mangos. The Department will also conduct a referendum if 10 percent or more of all non-exempt, first handlers and importers of mangos request the Department to hold a referendum. In addition, the Department may hold a referendum at any time.

§ 1206.72 Suspension and termination.

(a) The Department shall suspend or terminate this part or subpart or a provision thereof if the Department finds that the subpart or a provision thereof obstructs or does not tend to effectuate the purposes of the Act, or if the Department determines that this subpart or a provision thereof is not favored by persons voting in a referendum conducted pursuant to the Act.

(b) The Department shall suspend or terminate this subpart at the end of the marketing year whenever the Department determines that its suspension or termination is approved or favored by a majority of the first handlers and importers voting who, during a representative period determined by the Department, have been engaged in the handling or importation of mangos.

(c) If, as a result of a referendum the Department determines that this subpart is not approved, the Department shall:

(1) Not later than 180 days after making the determination, suspend or terminate, as the case may be, collection of assessments under this subpart; and

(2) As soon as practical, suspend or terminate, as the case may be, activities under this subpart in an orderly manner.

§ 1206.73 Proceedings after termination.

(a) Upon the termination of this subpart, the Board shall recommend not more than five of its members to the Department to serve as trustees for the purpose of liquidating the affairs of the Board. Such persons, upon designation by the Department, shall become trustees of all of the funds and property then in the possession or under control of the Board, including claims for any funds unpaid or property not delivered, or any other claim existing at the time of such termination.

(b) The said trustees shall:

(1) Continue in such capacity until discharged by the Department;

(2) Carry out the obligations of the Board under any contracts or agreements entered into pursuant to the Order;

(3) From time to time, account for all receipts and disbursements and deliver all property on hand, together with all books and records of the Board and the trustees, to such person or persons as the Department may direct; and

(4) Upon request of the Department, execute such assignments or other instruments necessary and appropriate to vest in such persons title and right to all funds, property and claims vested in the Board or the trustees pursuant to the Order.

(c) Any person to whom funds, property or claims have been transferred or delivered pursuant to the Order shall be subject to the same obligations imposed upon the Board and upon the trustees.

(d) Any residual funds not required to defray the necessary expenses of liquidation shall be turned over to the Department to be disposed of, to the extent practical, to one or more mango industry organizations in the interest of continuing mango promotion, research, and information programs.

§ 1206.74 Effect of termination or amendment.

Unless otherwise expressly provided by the Department, the termination or amendment of this part or any subpart thereof, shall not:

(a) Affect or waive any right, duty, obligation or liability which shall have arisen or which may thereafter arise in connection with any provision of this part; or

(b) Release or extinguish any violation of this part; or

(c) Affect or impair any rights or remedies of the United States, or of the Department, or of any other persons with respect to any such violation.

§ 1206.75 Personal liability.

No member or employee of the Board shall be held personally responsible, either individually or jointly with others, in any way whatsoever, to any person for errors in judgment, mistakes, or other acts, either of commission or omission, as such member or employee, except for acts of dishonesty or willful misconduct.

§ 1206.76 Separability.

If any provision of this subpart is declared invalid or the applicability thereof to any person or circumstances is held invalid, the validity of the remainder of this subpart or the applicability thereof to other persons or circumstances shall not be affected thereby.

§ 1206.77 Amendments.

Amendments to this subpart may be proposed from time to time by the Board or by any interested person affected by the provisions of the Act, including the Department.

§ 1206.78 OMB control number.

The control numbers assigned to the information collection requirements of this part by the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35, are OMB control number 0505–0001 and OMB control number 0581–0209.

Dated: September 22, 2004.

A.J. Yates,

Administrator, Agricultural Marketing Service.

[FR Doc. 04–21622 Filed 10–1–04; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2004–18826; Airspace Docket No. 04–ACE–52]

Modification of Class E Airspace; Lamar, MO

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Direct final rule; request for comments.

SUMMARY: This action amends title 14 Code of Federal Regulations, part 71 (14 CFR 71) by revising Class E airspace at Lamar, MO. A review of the Class E airspace area extending upward from 700 feet above the surface at Lamar, MO revealed it does not reflect the current Lamar Municipal Airport airport reference point (ARP) and is not in compliance with established airspace criteria. This airspace area is enlarged and modified to conform to FAA Orders.

DATES: This direct final rule is effective on 0901 UTC, January 20, 2005. Comments for inclusion in the Rules Docket must be received on or before November 9, 2004.

ADDRESSES: Send comments on this proposal to the Docket Management System, U.S. Department of Transportation, Room Plaza 401, 400 Seventh Street, SW., Washington, DC 20590–0001. You must identify the docket number FAA–2004–18826/ Airspace Docket No. 04–ACE–52, at the beginning of your comments. You may also submit comments on the Internet at *http://dms.dot.gov*. You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9 a.m. and 6 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone 1–800–647–5527) is on the plaza level of the Department of Transportation NASSIF Building at the above address.

FOR FURTHER INFORMATION CONTACT: Brenda Mumper, Air Traffic Division, Airspace Branch, ACE–520A, DOT Regional Headquarters Building, Federal Aviation Administration, 901 Locust Kansas City, MO 64106; telephone: (816) 329–2524.

SUPPLEMENTARY INFORMATION: This amendment to 14 CFR part 71 modifies the Class E airspace area extending upward from 700 feet above the surface at Lamar, MO. An examination of controlled airspace for Lamar, MO revealed that the Lamar Municipal Airport ARP used in the legal description for this Class E airspace area is incorrect and that the airspace area does not comply with airspace requirements for diverse departures as set forth in FAA Order 7400.2E, Procedures for Handling Airspace Matters. The examination also identified that the dimensions of the extension to the Class E airspace area are not in compliance with FAA Order 8260.19C, Flight Procedures and Airspace. This action expands the Lamar, MO Class E airspace area extending upward from 700 feet above the surface from a 6-mile radius to a 6.3-mile radius of Lamar Municipal Airport, corrects the ARP in the legal description, decreases the length and width of the extension from 7.4 to 7 miles and from 2.6 to 2.5 miles respectively and brings the legal description of the airspace area into compliance with FAA Orders 7400.2E and 8260.19C. This area will be depicted on appropriate aeronautical charts. Class E airspace areas extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9M, Airspace Designations and Reporting Points, dated August 30, 2004, and effective September 16, 2004, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

The Direct Final Rule Procedure

The FAA anticipates that this regulation will not result in adverse or negative comment and, therefore, is issuing it as a direct final rule. Previous actions of this nature have not been controversial and have not resulted in adverse comments or objections. Unless a written adverse or negative, comment, or a written notice of intent to submit an adverse or negative comment is received within the comment period, the regulation will become effective on the date specified above. After the close of the comment period, the FAA will publish a document in the **Federal Register** indicating that no adverse or negative comments were received and confirming the date on which the final rule will become effective. If the FAA does receive, within the comment period, an adverse or negative comment, or written notice of intent to submit such a comment, a document withdrawing the direct final rule will be published in the **Federal Register**, and a notice of proposed rulemaking may be published with a new comment period.

Comments Invited

Interested parties are invited to participate in this rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. FAA–2004–18826/Airspace Docket No. 04–ACE–52." The postcard will be date/time stamped and returned to the commenter.

Agency Findings

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.

The FAA has determined that this regulation is noncontroversial and unlikely to result in adverse or negative comments. For the reasons discussed in the preamble, I certify that this regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under Department of Transportation (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.

List of Subjects in 14 CFR Part 71

Airspace, Incorporated by reference, Navigation (air)

Adoption of the Amendment

■ Accordingly, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9M, dated August 30, 2004, and effective September 16, 2004, is amended as follows:

* * * * *

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ACE MO E5 Lamar, MO

Lamar Municipal Airport, MO
(Lat. 37°29′22″ N., long. 94°18′41″ W.)
Spring River NDB
(Lat. 37°29′13″ N., long. 94°18′37″ W.)

That airspace extending upward from 700 feet above the surface within a 6.3-mile radius of Lamar Municipal Airport and within 2.5 miles each side of the 221° bearing from the Spring River NDB extending from the 6.3-mile radius of the airport to 7 miles southwest of the NDB.

* * * * *

Dated: Issued in Kansas City, MO on September 21, 2004.

Elizabeth S. Wallis,

Acting Manager, Air Traffic Division, Central Region.

[FR Doc. 04–22278 Filed 10–1–04; 8:45 am]

BILLING CODE 4910–13–M

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 211

[Release No. SAB 106]

Staff Accounting Bulletin No. 106

AGENCY: Securities and Exchange Commission.

ACTION: Publication of staff accounting bulletin.

SUMMARY: The interpretations in this staff accounting bulletin express the staff's views regarding the application of FASB Statement No. 143, *Accounting for Asset Retirement Obligations*, by oil and gas producing companies following the full cost accounting method.

DATES: Effective September 28, 2004.

FOR FURTHER INFORMATION CONTACT: Cathy J. Cole or John W. Albert, Office of the Chief Accountant (202) 942–4400 or Leslie A. Overton, Division of Corporation Finance (202) 942–2960, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–1103.

SUPPLEMENTARY INFORMATION: The statements in staff accounting bulletins are not rules or interpretations of the Commission, nor are they published as bearing the Commission's official approval. They represent interpretations and practices followed by the Division of Corporation Finance and the Office of the Chief Accountant in administering the disclosure requirements of the Federal securities laws.

Dated: September 28, 2004.

Margaret H. McFarland,

Deputy Secretary.

PART 211—[AMENDED]

■ Accordingly, part 211 of title 17 of the Code of Federal Regulations is amended by adding Staff Accounting Bulletin No. 106 to the table found in subpart B.

Note: The text of SAB 106 will not appear in the Code of Federal Regulations.

Staff Accounting Bulletin No. 106

The staff hereby adds Section 4 to Topic 12–D of the staff accounting bulletin series. Topic 12–D.4 provides guidance regarding the interaction of Statement of Financial Accounting Standards No. 143, *Accounting for Asset Retirement Obligations*, with the full cost accounting rules in Article 4–10 of Regulation S–X.

Topic 12: Oil and Gas Producing Activities

* * * * *

D. Application of Full Cost Method of Accounting

* * * * *

4. Interaction of Statement 143 [1] and the Full Cost Rules

a. Impact of Statement 143 on the Full Cost Ceiling Test

Facts: A company following the full cost method of accounting under Rule 4–10(c) of Regulation S–X must periodically calculate a limitation on capitalized costs, *i.e.*, the full cost ceiling. Prior to adopting Statement 143, in calculating the full cost ceiling a company reduced the expected future revenues from proved oil and gas reserves by the estimated future expenditures to be incurred in developing and producing such reserves discounted using a factor specified in the rule. While expected future cash flows related to the asset retirement obligation (ARO) were included in the calculation of the ceiling test, no associated asset was recorded. Under Statement 143, a company must recognize a liability for an asset retirement obligation at fair value in the period in which the obligation is incurred, if a reasonable estimate of fair value can be made. The company also must initially capitalize the associated asset retirement costs by increasing long-lived oil and gas assets by the same amount as the liability. Any asset retirement costs capitalized pursuant to Statement 143 are subject to the full cost ceiling limitation under Rule 4–10(c)(4) of Regulation S–X. If after adoption of Statement 143, a company were to continue calculating the full cost ceiling by reducing expected future net revenues by the cash flows required to settle the ARO, then the effect would be to "double-count" such costs in the ceiling test. The assets that must be recovered would be increased while the future net revenues available to recover the assets continue to be reduced by the amount of the ARO settlement cash flows.

Question 1: After adopting Statement 143, how should a company compute the full cost ceiling to avoid double-counting the expected future cash outflows associated with asset retirement costs?

Interpretive Response: After adoption of Statement 143, the future cash outflows associated with settling AROs that have been accrued on the balance sheet should be excluded from the computation of the present value of estimated future net revenues for purposes of the full cost ceiling calculation.[2] [3]

Question 2: What disclosures should the company provide on the interaction of Statement 143 and the full cost rules?

Interpretive Response: In order to inform financial statement users on the interaction of Statement 143 and the full cost rules, a company following such rules is expected to provide appropriate disclosures in the financial statement footnotes and Management's Discussion and Analysis explaining in detail how

[1] Statement of Financial Accounting Standards No. 143 (Statement 143), *Accounting for Asset Retirement Obligations*, is effective for financial statements issued for fiscal years beginning after June 15, 2002.

[2] If an obligation for expected asset retirement costs has not been accrued under Statement 143 for certain asset retirement costs required to be included in the full cost ceiling calculation under Rule 4–10(c)(4), such costs should continue to be included in the full cost ceiling calculation.

[3] This approach is consistent with the guidance in paragraph 12 of Statement 143 on testing for impairment under Statement of Financial Accounting Standards No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets.* Under that guidance, the asset tested should include capitalized asset retirement costs. The estimated cash flows related to the associated ARO that has been recognized in the financial statements are to be excluded from both the undiscounted cash flows used to test for recoverability and the discounted cash flows used to measure the asset's fair value.

the adoption of Statement 143 impacts its accounting for oil and gas operations. This disclosure is expected to address each area of accounting that is impacted or expected to be impacted and should specifically address each way that the company's application of full cost accounting has changed as a result of adoption of Statement 143. These disclosures and discussions should include, but are not limited to, how the company's calculation of the ceiling test and depreciation, depletion, and amortization are affected by the adoption of Statement 143.

b. Impact of Statement 143 on the Calculation of Depreciation, Depletion, and Amortization

Facts: Regarding the base for depreciation, depletion, and amortization (DD&A) of proved reserves, Rule 4–10(c)(3)(i) of Regulations S–X states that "[c]osts to be amortized shall include (A) all capitalized costs, less accumulated amortization, other than the cost of properties described in paragraph (ii) below;[4] (B) the estimated future expenditures (based on current costs) to be incurred in developing proved reserves; and (C) estimated dismantlement and abandonment costs, net of estimated salvage values." Statement 143 requires that upon initial recognition of an ARO, the associated asset retirement costs be included in the capitalized costs of the company. Therefore, subsequent to the adoption of Statement 143, the estimated dismantlement and abandonment costs described in (C) above may be included in the capitalized costs described in (A) above, at least to the extent that an ARO has been incurred as a result of acquisition, exploration and development activities to date. Future development activities on proved reserves may result in additional asset retirement obligations when such activities are performed and the associated asset retirement costs will be capitalized at that time.

Question: Following the adoption of Statement 143, should the costs to be amortized under Rule 4–10(c)(3) of Regulation S–X include an amount for estimated dismantlement and abandonment costs, net of estimated salvage values, that are expected to result from future development activities?

Interpretive Response: Yes. To the extent that estimated dismantlement and abandonment costs, net of estimated salvage values, have not been included as capitalized costs in the base for computing DD&A because they have not yet been capitalized as asset retirement costs under Statement 143, compliance with Rule 4–10(c)(3) of Regulation S–X continues to require that they be included in the base for computing DD&A. Companies should estimate the amount of dismantlement and abandonment costs that will be incurred as a result of future development activities on proved reserves and include those amounts in the costs to be amortized.

c. Transition

Question: When will registrants be expected to comply with the accounting and disclosures described in this bulletin?

Interpretive Response: All registrants are expected to apply the accounting and disclosures described in this bulletin prospectively as of the beginning of the first fiscal quarter beginning after the publication of this bulletin in the **Federal Register**. If a registrant files financial statements with the Commission before applying the guidance in this bulletin, disclosures similar to those described in Staff Accounting Bulletin Topic 11–M should be provided.

[FR Doc. 04–22186 Filed 10–1–04; 8:45 am]
BILLING CODE 8010–01–P

[4] The reference to "cost of properties described in paragraph (ii) below" relates to the costs of investments in unproved properties and major development projects, as defined.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Ivermectin Paste

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Merial Ltd. The supplemental NADA provides revised labeling for ivermectin oral paste used in horses.

DATES: This rule is effective October 4, 2004.

FOR FURTHER INFORMATION CONTACT: Martine Hartogensis, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–7815, e-mail: *martine.hartogensis@fda.gov.*

SUPPLEMENTARY INFORMATION: Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096–4640, filed a supplement to NADA 134–314 for EQVALAN (ivermectin 1.87 percent) Paste for Horses. The supplemental application provides for revisions to the labeled indications. Specifically, under the sub-heading "Small Strongyles," the labeling has been revised to separate the listing of adult species from the fourth-stage larvae. The supplemental NADA is approved as of August 9, 2004, and 21 CFR 520.1192 is amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(d)(1) 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.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 520

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. Section 520.1192 is amended by revising paragraph (e)(1) to read as follows:

§ 520.1192 Ivermectin paste.

* * * * *

(e) *Conditions of use*—(1) *Horses*—(i) *Amount.* 200 micrograms per kilogram (91 micrograms per pound) of body weight.

(ii) *Indications for use.* For treatment and control of:

(A) Large Strongyles (adults): *Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*, *Triodontophorus* spp. including *T. brevicauda* and *T. serratus*, and *Craterostomum acuticaudatum*; Small Strongyles (adults, including those resistant to some benzimidazole class compounds): *Coronocyclus* spp. including *C. coronatus*, *C. labiatus*, and *C. labratus*, *Cyathostomum* spp. including *C. catinatum* and *C. pateratum*, *Cylicocyclus* spp. including *C. insigne*, *C. leptostomum*, *C. nassatus*, and *C. brevicapsulatus*, *Cylicodontophorus* spp., *Cylicostephanus* spp., including *C. calicatus*, *C. goldi*, *C. longibursatus*, and *C. minutus*, and *Petrovinema poculatum*; Small Strongyles (fourth-stage larvae); Pinworms (adults and fourth stage larvae): *Oxyuris equi*; Ascarids (adults and third- and fourth-stage larvae): *Parascaris equorum*; Hairworms (adults): *Trichostrongylus axei*; Large mouth Stomach Worms (adults), *Habronema muscae*; Bots (oral and gastric stages): *Gasterophilus* spp. including *G. intestinalis* and *G. nasalis*; Lungworms (adults and fourth-stage larvae): *Dictyocaulus arnfieldi*; Intestinal Threadworms (adults): *Strongyloides westeri*;Summer Sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

(B) Large Strongyles (adult) (*Strongylus equinus*), (adult and arterial larval stages) (*Strongylus vulgaris*), (adult and migrating tissue stages) (*Strongylus edentatus*), (adult) (*Triodontophorus* spp.); Small Strongyles, including those resistant to some benzimidazole class compounds (adult and fourth-stage larvae) (*Cyathostomum* spp., *Cylicocyclus* spp., *Cylicodontophorus* spp., *Cylicostephanus* spp.); Pinworms (adult and fourth-stage larvae) (*Oxyuris equi*); Ascarids (third- and fourth-stage larvae and adults) (*Parascaris equorum*); hairworms (adult) (*Trichostrongylus axei*); Large mouth Stomach Worms (adult) (*Habronema muscae*); Stomach Bots (oral and gastric stages) (*Gastrophilus* spp.); Lungworms (adults and fourth-stage larvae) (*Dictyocaulus arnfieldi*); Intestinal Threadworms (adults) (*Strongyloides westeri*); Summer Sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; and Dermatitis caused by neck threadworm microfilariae (*Onchocerca* sp.).

(iii) *Limitations.* For oral use only. Do not use in horses intended for human consumption.

* * * * *

Dated: September 14, 2004.

Daniel G. McChesney,

Director, Office of Surveillance and Compliance, Center for Veterinary Medicine.

[FR Doc. 04–22182 Filed 10–1–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. 2003N–0561]

Orthopedic Devices; Effective Date of Requirement for Premarket Approval for Hip Joint Metal/Polymer or Ceramic/Polymer Semiconstrained Resurfacing Cemented Prosthesis

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis. The agency also is summarizing its proposed findings regarding the degree of risk of illness or injury designed to be eliminated or reduced by requiring the devices to meet the statute's approval requirements and the benefits to the public from the use of the devices. This action implements certain statutory requirements.

DATES: This rule is effective October 4, 2004. Under this final rule, a PMA or a notice of completion of a PDP is required to be filed on or before January 3, 2005, for any hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis.

FOR FURTHER INFORMATION CONTACT: Pei Sung, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2036.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295) and the Safe Medical Devices Act of 1990 (Public Law 101–629), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Section 515(b)(1) of the act (21 U.S.C. 360e(b)(1)) established the requirement that a preamendments device that FDA has classified into class III is subject to premarket approval. A preamendments class III device may be commercially distributed without an approved PMA or a notice of completion of a PDP until 90 days after FDA issues a final rule requiring premarket approval for the device, or 30 months after final classification of the device under section 513 of the act, whichever is later. Also, a preamendments device subject to the rulemaking procedure under section 515(b) of the act is not required to have an approved investigational device exemption (IDE) (see part 812 (21 CFR part 812)) contemporaneous with its interstate distribution until the date identified by FDA in the final rule requiring the submission of a PMA for the device. At that time, an IDE is required only if a PMA has not been submitted or a PDP completed.

When a rule to require premarket approval for a preamendments device is finalized, section 501(f)(2)(B) of the act (21 U.S.C. 351(f)(2)(B)) requires that a PMA or notice of completion of a PDP for any such device be filed within 90 days of the date of issuance of the final rule or 30 months after the final classification of the device under section 513 of the act, whichever is later. If a PMA or notice of completion of a PDP is not filed by the latter of the two dates, commercial distribution of the device must cease.

The device may, however, be distributed for investigational use if the manufacturer, importer, or other sponsor of the device complies with the IDE regulations. If a PMA or notice of completion of a PDP is not filed by the latter of the two dates, and no IDE is in effect, the device is deemed to be adulterated within the meaning of

section 510(f)(1)(A) of the act (21 U.S.C. 360(f)(1)(A)), and subject to seizure and condemnation under section 304 of the act (21 U.S.C. 334), if its distribution continues. Shipment of devices in interstate commerce will be subject to injunction under section 302 of the act (21 U.S.C. 332), and the individuals responsible for such shipment will be subject to prosecution under section 303 of the act (21 U.S.C. 333). In the past, FDA has requested that manufacturers take action to prevent the further use of devices for which no PMA has been filed and may determine that such a request is appropriate for the class III device that is the subject of this regulation.

The act does not permit an extension of the 90-day period after issuance of a final rule within which an application or notice is required to be filed. The House Report on the 1976 amendments states that "* * * the thirty month 'grace period' afforded after classification of a device into class III * * * is sufficient time for manufacturers and importers to develop the data and conduct the investigations necessary to support an application of premarket approval" (H. Rept. 94–853, 94th Cong., 2d sess. 42 (1976)).

In the **Federal Register** of September 4, 1987 (47 FR 33686), FDA issued a final rule classifying the hip joint metal/polymer semiconstrained resurfacing cemented prosthesis into class III. Subsequently, FDA determined that the ceramic/polymer semiconstrained resurfacing cemented prosthesis was substantially equivalent to the metal/polymer semiconstrained resurfacing cemented prosthesis.

In the **Federal Register** of March 5, 2004 (69 FR 10390), FDA issued a proposed rule to require the filing of a PMA or a notice of completion of a PDP for the hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis (the proposed rule). In accordance with section 515(b)(2)(A) of the act, FDA included in the preamble to the proposed rule the agency's proposed findings regarding the degree of risk of illness or injury intended to be eliminated or reduced by requiring the device to meet the statute's approval requirements as well as the benefits to the public from the use of the device.

The March 5, 2004, proposed rule also provided an opportunity for interested persons to submit comments on the proposed rule and the agency's proposed findings. In accordance with section 515(b)(2)(A) of the act, FDA also provided an opportunity for interested persons to request a change in the classification of the device based on new information relevant to its classification. Interested persons requesting a change in the classification of the devices were to submit a petition by March 22, 2004. The comment period closed June 3, 2004.

FDA received no petitions requesting a change in the classification of the hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis. FDA received no comments on the proposed rule.

II. Device Subject to This Proposal

A hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis is a two-part device intended to be implanted to replace the articulating surfaces of the hip while preserving the femoral head and neck. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across the joint. This generic type of device includes prostheses that consist of a femoral cap component made of a metal alloy, such as cobalt-chromium-molybdenum, or a ceramic material, that is placed over a surgically prepared femoral head, and an acetabular resurfacing polymer component. Both components are intended for use with bone cement.

III. Findings With Respect to Risks and Benefits

Under section 515(b)(3) of the act, FDA is adopting the findings as published in the proposed rule of March 5, 2004. As required by section 515(b) of the act, FDA published its findings regarding the following topics: (1) The degree of risk of illness or injury designed to be eliminated or reduced by requiring that these devices have an approved PMA or a declared completed PDP and (2) the benefits to the public from the use of the device.

These findings are based on the reports and recommendations of the Orthopaedic Device Classification Panel, an FDA advisory committee, for the classification of the device, along with FDA's comprehensive review of the literature.

IV. The Final Rule

Under section 515(b)(3) of the act, FDA adopts the findings as published in the preamble to the proposed rule and issues this final rule to require premarket approval for the hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis. This final rule revises part 888 (21 CFR part 888).

Under the final rule, a PMA or a notice of completion of a PDP is required to be filed on or before 90 days after the date of publication of this rule in the **Federal Register** (see **DATES**), for any hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis that was in commercial distribution before May 28, 1976, or that has been found by FDA to be substantially equivalent to such a device on or before 90 days after the date of publication of this rule in the **Federal Register**. If a PMA or notice of completion of a PDP is filed for any such device within this time limit, the applicant will be permitted to continue marketing its hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis during FDA's review of its submission. Any other hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis that was not in commercial distribution before May 28, 1976, is required to have an approved PMA or a declared completed PDP in effect before it may be marketed.

If a PMA or a notice of completion of a PDP for a hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis is not filed on or before 90 days after the date of publication of this rule in the **Federal Register**, that device is deemed adulterated under section 501(f)(1)(A) of the act (21 U.S.C. 351(f)(1)(A)), and commercial distribution of the device must cease immediately. The device may, however, be distributed for investigational use, if the requirements of the IDE regulations (part 812) are met. Because the hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis is intended to be used as an implant, FDA considers it to be a significant risk device as defined in the IDE regulation in § 812.3(m)(1).

The exemptions in § 812.2(c)(1) and (c)(2) from the requirements of the IDE regulations for preamendments class III devices cease to apply to any hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis that is either: (1) Not legally on the market on or before 90 days after the date of publication of this rule in the **Federal Register** or (2) legally on the market but for which a PMA or notice of completion of a PDP is not filed within 90 days after the date of publication of this final rule in the **Federal Register**, or for which PMA approval has been denied or withdrawn. FDA cautions that manufacturers who are not immediately planning to submit a PMA or notice of completion of a PDP should submit IDE applications to FDA by 60 days after the date of publication of this final rule in the **Federal Register**,

to minimize the possibility of interrupting shipment of the device. At this time, FDA is not aware of any firm that is marketing this device.

V. PMA Requirements

A PMA for these devices must include the information required by section 515(c)(1) of the act. Such a PMA should also include a detailed discussion of the risks identified previously, as well as a discussion of the effectiveness of the device for which premarket approval is sought. In addition, a PMA must include all data and information on the following topics: (1) Any risks known, or that should be reasonably known, to the applicant that have not been identified in this document; (2) the effectiveness of the device that is the subject of the application; and (3) full reports of all preclinical and clinical information from investigations on the safety and effectiveness of the device for which premarket approval is sought.

VI. PDP Requirements

A PDP for any of these devices may be submitted in lieu of a PMA, and must follow the procedures outlined in section 515(f) of the act. A PDP should provide the following information: (1) A description of the device, (2) preclinical trial information (if any), (3) clinical trial information (if any), (4) a description of the manufacturing and processing of the devices, (5) labeling of the device, and (6) all other relevant information about the device. In addition, the PDP must include progress reports and records of the trials conducted under the protocol on the safety and effectiveness of the device for which the completed PDP is sought.

Information about the PDP process is also available from the Center for Devices and Radiological Health on the Internet at *http://www.fda.gov/cdrh/devadvice/pma/app_methods.html#product_dev.*

VII. Environmental Impact

The agency has determined under 21 CFR 25.30(h) 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. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). 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 agency believes that this final rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the device has fallen out of use and FDA is not aware of any firm marketing the device, the agency has concluded that there is little or no interest in marketing this device in the future. The agency, therefore, certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $110 million. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

IX. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA). The burden hours required for § 888.3410(c), included in the collection entitled "Premarket Approval of Medical Devices—21 CFR Part 814," are reported and approved under OMB control number 0910–0231. Therefore, clearance by OMB under the PRA is not required.

List of Subjects in 21 CFR Part 888

Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 888 is amended as follows:

PART 888—ORTHOPEDIC DEVICES

■ 1. The authority citation for 21 CFR part 888 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 888.3410 is revised to read as follows:

§ 888.3410 Hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis.

(a) *Identification.* A hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis is a two-part device intended to be implanted to replace the articulating surfaces of the hip while preserving the femoral head and neck. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across the joint. This generic type of device includes prostheses that consist of a femoral cap component made of a metal alloy, such as cobalt-chromium-molybdenum, or a ceramic material, that is placed over a surgically prepared femoral head, and an acetabular resurfacing polymer component. Both components are intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before January 3, 2005, for any hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before January 3, 2005, been found to be substantially equivalent to a hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis that was in commercial distribution before May 28, 1976. Any other hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis must have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

Dated: September 23, 2004.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 04–22210 Filed 10–1–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD01–04–121]

Drawbridge Operation Regulations: Annisquam River and Blynman Canal, MA

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, First Coast Guard District, has issued a temporary deviation from the drawbridge operation regulations for the SR 127 Bridge, mile 0.0, across the Annisquam River, Blynman Canal, at Gloucester, Massachusetts. This deviation allows the bridge to remain in the closed position from 6 a.m. on November 6, 2004 through 6 p.m. on November 7, 2004. In the event of inclement weather the alternate bridge closure would be from 6 a.m. on November 13, 2004 through 6 p.m. on November 14, 2004. This temporary deviation is necessary to facilitate structural repairs at the bridge.

DATES: This deviation is effective from November 6, 2004 through November 14, 2004.

FOR FURTHER INFORMATION CONTACT: John McDonald, Project Officer, First Coast Guard District, at (617) 223–8364.

SUPPLEMENTARY INFORMATION: The SR 127 Bridge, at mile 0.0, across the Annisquam River, Blynman Canal, has a vertical clearance of 7 feet at mean high water, and 16 feet at mean low water in the closed position. The existing regulations are listed at 33 CFR 117.586.

The bridge owner, Massachusetts Highway Department, requested a temporary deviation from the drawbridge operating regulations to facilitate necessary structural repairs, the replacement of the swing cables, at the bridge.

This deviation to the operating regulations allows the SR 127 Bridge to remain in the closed position from 6 a.m. on November 6, 2004 through 6 p.m. on November 7, 2004. In the event the repair work scheduled above can not be performed due to inclement weather an alternate bridge closure will be implemented from 6 a.m. on November 13, 2004 through 6 p.m. on November 14, 2004.

This deviation from the operating regulations is authorized under 33 CFR 117.35 and will be performed with all due speed in order to return the bridge to normal operation as soon as possible.

Dated: September 17, 2004.

David P. Pekoske,

Rear Admiral, U.S. Coast Guard, Commander, First Coast Guard District.

[FR Doc. 04–22275 Filed 10–1–04; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD01–04–122]

Drawbridge Operation Regulations: Merrimack River, MA

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, First Coast Guard District, has issued a temporary deviation from the drawbridge operation regulations for the Newburyport US1 Bridge, mile 3.4, across the Merrimack River, Massachusetts. This deviation allows the bridge to remain in the closed position from 6 a.m. on October 18, 2004 through 6 p.m. on October 22, 2004. This temporary deviation is necessary to facilitate structural repairs at the bridge.

DATES: This deviation is effective from October 18, 2004 through October 22, 2004.

FOR FURTHER INFORMATION CONTACT: John McDonald, Project Officer, First Coast Guard District, at (617) 223–8364.

SUPPLEMENTARY INFORMATION: The Newburyport US1 Bridge, at mile 3.4, across the Merrimack River, has a vertical clearance of 35 feet at mean high water and 44 feet at mean low water in the closed position. The existing regulations are listed at 33 CFR 117.605(a).

The bridge owner, Massachusetts Highway Department, requested a temporary deviation from the drawbridge operating regulations to facilitate necessary structural repairs, the replacement of the locking pin motor and the brake unit, at the bridge.

This deviation to the operating regulations allows the bridge to remain in the closed position from 6 a.m. on October 18, 2004 through 6 p.m. on October 22, 2004.

This deviation from the operating regulations is authorized under 33 CFR 117.35 and will be performed with all due speed in order to return the bridge to normal operation as soon as possible.

Dated: September 17, 2004.

David P. Pekoske,

Rear Admiral, U.S. Coast Guard, Commander, First Coast Guard District.

[FR Doc. 04–22274 Filed 10–1–04; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD01–04–116]

Drawbridge Operation Regulations: Connecticut River, CT

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, First Coast Guard District, has issued a temporary deviation from the drawbridge operation regulations for the Amtrak Old Saybrook-Old Lyme Bridge, mile 3.4, across the Connecticut River, Connecticut. This deviation from the regulations allows the bridge to remain closed from 9 p.m. on October 5, 2004 through 9 a.m. on October 6, 2004, and from 9 p.m. on October 6, 2004 through 9 a.m. on October 7, 2004. This deviation is necessary in order to facilitate necessary inspection and repairs at the bridge.

DATES: This deviation is effective from October 5, 2004 through October 7, 2004.

FOR FURTHER INFORMATION CONTACT: Judy Leung-Yee, Project Officer, First Coast Guard District, at (212) 668–7195.

SUPPLEMENTARY INFORMATION: The Old Saybrook-Old Lyme, at mile 3.4, across the Connecticut River has a vertical clearance in the closed position of 19 feet at mean high water and 22 feet at mean low water. The existing drawbridge operating regulations are listed at 33 CFR 117.205(b).

The owner of the bridge, Amtrak, requested a temporary deviation from the drawbridge operating regulations to facilitate inspection and maintenance repairs at the bridge.

This deviation to the operating regulations allows the Old Saybrook-Old Lyme Bridge to remain closed from 9 p.m. on October 5, 2004 through 9 a.m. on October 6, 2004, and from 9 p.m. on October 6, 2004 through 9 a.m. on October 7, 2004.

In accordance with 33 CFR 117.35(c), this work will be performed with all due speed in order to return the bridge to normal operation as soon as possible.

This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: September 17, 2004.

David P. Pekoske,

Rear Admiral, U.S. Coast Guard, Commander, First Coast Guard District.

[FR Doc. 04–22273 Filed 10–1–04; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD01–04–123]

Drawbridge Operation Regulations: Connecticut River, CT

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, First Coast Guard District, has issued a temporary deviation from the drawbridge operation regulations for the Route 82 Bridge, mile 16.8, across the Connecticut River at East Haddam, Connecticut. This deviation from the regulations allows the bridge to operate on a fixed opening schedule from October 16, 2004 through November 30, 2004. Under this temporary deviation the bridge must open on signal at 5:30 a.m., 1:30 p.m., and 8 p.m., daily. The bridge must open on signal at all times for commercial vessels after at least a two-hour advance notice is given. This deviation is necessary in order to facilitate necessary repairs at the bridge.

DATES: This deviation is effective from October 16, 2004 through November 30, 2004.

FOR FURTHER INFORMATION CONTACT: Judy Leung-Yee, Project Officer, First Coast Guard District, at (212) 668–7195.

SUPPLEMENTARY INFORMATION: The Route 82 Bridge, at mile 16.8, across the Connecticut River has a vertical clearance in the closed position of 22 feet at mean high water and 25 feet at mean low water. The existing drawbridge operating regulations are listed at 33 CFR 117.205(c).

The owner of the bridge, Connecticut Department of Transportation, requested a temporary deviation from the drawbridge operating regulations to facilitate maintenance repairs at the bridge.

This deviation to the operating regulations allows the Route 82 Bridge to operate on a fixed opening schedule from October 16, 2004 through November 30, 2004. Under this temporary deviation the bridge must open on signal at 5:30 a.m., 1:30 p.m., and 8 p.m., daily. At all other times, the bridge must open on signal for commercial vessels, provided that at least a two hour advance notice is given.

In accordance with 33 CFR 117.35(c), this work will be performed with all due speed in order to return the bridge to normal operation as soon as possible. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: September 17, 2004.

David P. Pekoske,

Rear Admiral, U.S. Coast Guard, Commander, First Coast Guard District.

[FR Doc. 04–22272 Filed 10–1–04; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[COTP San Francisco Bay 04–022]

RIN 1625–AA87

Security Zone; Suisun Bay, Concord, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary security zone in the navigable waters of the United States adjacent to Pier Three at the Military Ocean Terminal Concord (MOTCO), California (formerly United States Naval Weapons Center Concord, California). In light of recent terrorist actions against the United States, this security zone is necessary to ensure the safe loading of military equipment and to ensure the safety of the public from potential subversive acts. The security zone will prohibit all persons and vessels from entering, transiting through or anchoring within a portion of Suisun Bay within 500 yards of Pier Three at the MOTCO facility unless authorized by the Captain of the Port (COTP) or his designated representative.

DATES: This rule is effective from 11:59 p.m. on October 2, 2004, to 11:59 p.m. on October 12, 2004. If the need for this security zone ends before the scheduled termination time, the Captain of the Port will cease enforcement of the security zone and will announce that fact via Broadcast Notice to Mariners.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket [COTP San Francisco Bay 04–022] and are available for inspection or copying at Coast Guard Marine Safety Office San Francisco Bay, Coast Guard Island, Alameda, California, 94501, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lieutenant Doug L. Ebbers, U.S. Coast Guard Marine Safety Office San Francisco Bay, at (510) 437–2770.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM because the duration of the NPRM rulemaking process would extend beyond the actual period of the scheduled operations and defeat the protections afforded by the temporary rule to the cargo vessels, their crews, the public and national security.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register** as the schedule and other logistical details were not known until a date fewer than 30 days prior to the start date of the military operation. Delaying this rule's effective date would be contrary to the public interest since the safety and security of the people, ports, waterways, and properties of the Port Chicago and Suisun Bay areas would be jeopardized without the protection afforded by this security zone.

Background and Purpose

Since the September 11, 2001 terrorist attacks on the World Trade Center in New York; the Pentagon in Arlington, Virginia; and Flight 93; the Federal Bureau of Investigation (FBI) has issued several warnings concerning the potential for additional terrorist attacks within the United States. In addition, the ongoing hostilities in Afghanistan and the conflict in Iraq have made it prudent for U.S. ports to be on a higher state of alert because Al-Qaeda and other organizations have declared an ongoing intention to conduct armed attacks on U.S. interests worldwide.

The threat of maritime attacks is real as evidenced by the attack on USS COLE and the subsequent attack in October 2002 against a tank vessel off the coast of Yemen. These threats manifest a continuing threat to U.S. assets as described in the President's finding in Executive Order 13273 of August 21, 2002 (67 FR 56215, September 3, 2002) that the security of

the U.S. is endangered by the September 11, 2001, attacks and that such aggression continues to endanger the international relations of the United States. See also Continuation of the National Emergency with Respect to Certain Terrorist Attacks (67 FR 58317, September 13, 2002), and Continuation of the National Emergency with Respect to Persons Who Commit, Threaten To Commit, Or Support Terrorism (67 FR 59447, September 20, 2002). The U.S. Maritime Administration (MARAD) in Advisory 02–07 advised U.S. shipping interests to maintain a heightened status of alert against possible terrorist attacks. MARAD more recently issued Advisory 03–05 informing operators of maritime interests of increased threat possibilities to vessels and facilities and a higher risk of terrorist attack to the transportation community in the United States. Ongoing foreign hostilities have made it prudent for U.S. ports and waterways to be on a higher state of alert because the Al-Qaeda organization and other similar organizations have declared an ongoing intention to conduct armed attacks on U.S. interests worldwide.

In its effort to thwart terrorist activity, the Coast Guard has increased safety and security measures on U.S. ports and waterways. As part of the Diplomatic Security and Antiterrorism Act of 1986 (Pub. L. 99–399), Congress amended section 7 of the Ports and Waterways Safety Act (PWSA), 33 U.S.C. 1226, to allow the Coast Guard to take actions, including the establishment of security and safety zones, to prevent or respond to acts of terrorism against individuals, vessels, or public or commercial structures. The Coast Guard also has authority to establish security zones pursuant to the Act of June 15, 1917, as amended by the Magnuson Act of August 9, 1950, (50 U.S.C. 191 *et seq.*) and implementing regulations promulgated by the President in subparts 6.01 and 6.04 of part 6 of Title 33 of the Code of Federal Regulations.

In this particular rulemaking, to address the aforementioned security concerns, United States Army officials have requested that the Captain of the Port, San Francisco Bay, California, establish a temporary security zone in the navigable waters of the United States within 500 yards of Pier Three at the Military Ocean Terminal Concord (MOTCO), California, to safeguard vessels, cargo and crew engaged in military operations. This temporary security zone is necessary to safeguard the MOTCO terminal and the surrounding property from sabotage or other subversive acts, accidents or criminal acts. This zone is also necessary to protect military operations from compromise and interference and to specifically protect the people, ports, waterways, and properties of the Port Chicago and Suisun Bay areas.

Discussion of Rule

In this temporary rule, the Coast Guard is establishing a fixed security zone encompassing the navigable waters, extending from the surface to the sea floor, within 500 yards of any portion of Pier Three at Military Ocean Terminal Concord (MOTCO), California. There are three existing piers at the MOTCO facility. Originally there were four piers, numbered One through Four from west to east, but Pier One was destroyed in an explosion in 1944. Therefore, Pier Three is the middle of the 3 remaining piers. The area encompassed by this security zone includes a portion of the Port Chicago Reach section of the deepwater channel. Persons and vessels are prohibited from entering, transiting through or anchoring within this security zone unless authorized by the Captain of the Port (COTP) or his designated representative.

The Captain of the Port will enforce this zone and may enlist the aid and cooperation of any Federal, State, county, municipal, and private agency to assist in the enforcement of the regulation. Section 165.33 of Title 33, Code of Federal Regulations, prohibits any unauthorized person or vessel from entering or remaining in a security zone. Vessels or persons violating this section may be subject to the penalties set forth in 33 U.S.C. 1232 and 50 U.S.C. 192. Pursuant to 33 U.S.C. 1232, any violation of the security zone described herein, is punishable by civil penalties (not to exceed $32,500 per violation, where each day of a continuing violation is a separate violation), criminal penalties (imprisonment from 5 to 10 years and a maximum fine of $250,000), and in rem liability against the offending vessel. Any person who violates this section using a dangerous weapon, or who engages in conduct that causes bodily injury or fear of imminent bodily injury to any officer authorized to enforce this regulation, will also face imprisonment from 10 to 25 years. Vessels or persons violating this section are also subject to the penalties set forth in 50 U.S.C. 192: Seizure and forfeiture of the vessel to the United States, a maximum criminal fine of $10,000, imprisonment up to 10 years, and a civil penalty of not more than $25,000 for each day of a continuing violation.

Regulatory Evaluation

This 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 section 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 (DHS).

Although this regulation restricts access to a portion of navigable waters, the effect of this regulation will not be significant because mariners will be advised about the security zone via public notice to mariners, and the zone will encompass only a small portion of the waterway for a short duration. In addition, vessels and persons may be allowed to enter this zone on a case-by-case basis with permission of the Captain of the Port or his designated representative.

The size of the zone is the minimum necessary to provide adequate protection for MOTCO, vessels engaged in operations at MOTCO, their crews, other vessels operating in the vicinity, and the public. The entities most likely to be affected are commercial vessels transiting to or from Suisun Bay via the Port Chicago Reach section of the channel.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this 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 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This rule will affect the following entities, some of which may be small entities: The owners and operators of vessels intending to anchor or transit to or from Suisun Bay via the Port Chicago Reach section of the channel. Although the security zone will occupy a section of the navigable channel (Port Chicago Reach) adjacent to the Marine Ocean Terminal Concord (MOTCO), vessels may receive authorization to transit through the zone by the Captain of the Port or his designated representative on a case-by-case basis. Additionally, vessels engaged in recreational activities, sightseeing and commercial fishing will have ample space outside of the security zone to engage in those

activities. Small entities and the maritime public will be advised of this security zone via public notice to mariners.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), we offer to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process. If the rule will affect your small business, organization, or government jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** for assistance in understanding this rule.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). 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 rule calls 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 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 rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This 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 rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does 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 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 rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Commandant Instruction M16475.lD, 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 rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation because we are establishing a security zone.

A final "Environmental Analysis Check List" and a final "Categorical Exclusion Determination" will be available in the docket where located under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T11–041 to read as follows:

§ 165.T11–041 Security Zone; Navigable Waters of the United States Surrounding Pier Three at Military Ocean Terminal Concord (MOTCO), Concord, California.

(a) *Location.* The security zone will encompass the navigable waters, extending from the surface to the sea floor, within 500 yards of any portion of

Pier Three at Military Ocean Terminal Concord (MOTCO), California.

(b) *Regulations.* (1) In accordance with the general regulations in § 165.33 of this part, entering, transiting through or anchoring in this zone is prohibited unless authorized by the Coast Guard Captain of the Port, San Francisco Bay, or his designated representative.

(2) Persons desiring to transit the area of this security zone may contact the Patrol Commander on scene on VHF–FM channel 13 or 16 or the Captain of the Port at telephone number 415–399–3547 to seek permission to transit the area. If permission is granted, all persons and vessels must comply with the instructions of the Captain of the Port or his designated representative.

(c) *Effective period.* This section becomes effective at 11:59 p.m. on October 2, 2004, and terminates at 11:59 p.m. on October 12, 2004. If the need for this security zone ends before the scheduled termination time, the Captain of the Port will cease enforcement of the security zone and will announce that fact via Broadcast Notice to Mariners.

Dated: September 27, 2004.

Gordon A. Loebl,

Commander, U.S. Coast Guard, Acting Captain of the Port, San Francisco Bay, California.

[FR Doc. 04–22271 Filed 10–1–04; 8:45 am]

BILLING CODE 4910–15–P

POSTAL SERVICE

39 CFR Part 111

General Information on Postal Service

AGENCY: Postal Service.

ACTION: Final Rule.

SUMMARY: This rule amends the Postal Service regulations to reflect current information regarding the publication and availability of the Domestic Mail Manual (DMM).

DATES: *Effective Date:* This final rule is effective on October 4, 2004.

FOR FURTHER INFORMATION CONTACT: Sherry L. Freda, (202) 268–7259.

SUPPLEMENTARY INFORMATION: This rule amends 39 CFR part 111 to conform to the yearly publication schedule of the Domestic Mail Manual, and to reflect the publication and availability of the DMM to all users on the Internet at *http://pe.usps.gov*. The table of contents of the DMM previously set forth in § 111.5 is removed as superfluous.

List of Subjects in 39 CFR Part 111

Administrative practice and procedure.

■ In view of the considerations discussed above, the Postal Service hereby amends 39 CFR part 111 as follows:

■ 1. The authority citation for part 111 continues to read as follows:

Authority: 5 U.S.C. 552(a); 39 U.S.C. 101, 401, 403, 414, 416, 3001–3011, 3201–3219, 3403–3406, 3621, 3626, 5001.

§ 111.1 [Amended]

■ 2. Amend § 111.1 by removing the words "published twice each year in January and July, unless otherwise determined by the Postal Service" and adding the words "published and maintained by the Postal Service" in their place.

§ 111.2 [Amended]

■ 3. Amend § 111.2—

■ A. In paragraph (a) by adding at the end the following sentence: "The Domestic Mail Manual is available for examination on the Internet at *http://pe.usps.gov.*"; and

■ B. In paragraph (c) by removing the words "A 1-year subscription to the Domestic Mail Manual for two consecutive issues" and adding the words "Subscriptions to the Domestic Mail Manual" in their place.

§ 111.5 [Removed and reserved]

■ 4. Remove and reserve § 111.5.

Stanley F. Mires,

Chief Counsel, Legislative.

[FR Doc. 04–22231 Filed 10–1–04; 8:45 am]

BILLING CODE 7710–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[FRL–7823–8]

Nebraska: Final Authorization of State Hazardous Waste Management Program Revision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Immediate final rule.

SUMMARY: Nebraska has applied to the EPA for final authorization of the changes to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). The EPA has determined that these changes satisfy all requirements needed to qualify for final authorization, and is authorizing the State's changes through this immediate final action. The EPA is publishing this rule to authorize the changes without a prior proposal because we believe this action is not controversial and do not expect comments that oppose it. Unless we receive written comments which oppose this authorization during the comment period, the decision to authorize Nebraska's changes to its hazardous waste program will take effect. If we receive comments that oppose this action, we will publish a document in the **Federal Register** withdrawing this rule before it takes effect, and a separate document in the proposed rules section of this **Federal Register** will serve as a proposal to authorize the changes.

DATES: This final authorization will become effective on December 3, 2004 unless the EPA receives adverse written comment by November 3, 2004. If the EPA receives such comment, it will publish a timely withdrawal of this immediate final rule in the **Federal Register** and inform the public that this authorization will not take effect.

ADDRESSES: Submit your comments by one of the following methods:

1. Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.

2. E-mail: *haugen.lisa@epa.gov.*

3. Mail: Lisa Haugen, Environmental Protection Agency, ARTD/RESP, 901 North 5th Street, Kansas City, Kansas 66101.

4. Hand Delivery or Courier. Deliver your comments to Lisa Haugen, Environmental Protection Agency, ARTD/RESP, 901 North 5th Street, Kansas City, Kansas 66101.

Instructions: Do not submit information that you consider to be CBI or otherwise protected through *regulations.gov,* or e-mail. The Federal *regulations.gov* Web site is an "anonymous access" system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to the EPA without going through *regulations.gov,* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Publicly available materials are available in hard copy at the Environmental Protection Agency, ARTD/RESP, 901 North 5th Street, Kansas City, Kansas 66101. The Regional Office's official hours of business are Monday through Friday, 8 a.m. to 4:30 p.m., excluding Federal holidays. Interested persons wanting to examine these documents should make an appointment with the office at least 24 hours in advance.

FOR FURTHER INFORMATION CONTACT: Lisa V. Haugen, U.S. EPA Region 7, ARTD/RESP, 901 North 5th Street, Kansas City, Kansas 66101, (913) 551–7877, or by e-mail at *haugen.lisa@epa.gov*.

SUPPLEMENTARY INFORMATION:

A. Why Are Revisions to State Programs Necessary?

States which have received final authorization from the EPA under RCRA section 3006(b), 42 U.S.C. 6926(b), must maintain a hazardous waste program that is equivalent to, consistent with, and no less stringent than the Federal program. As the Federal program changes, States must change their programs and ask the EPA to authorize the changes. Changes to State programs may be necessary when Federal or State statutory or regulatory authority is modified or when certain other changes occur. Most commonly, States must change their programs because of changes to the EPA's regulations in 40 Code of Federal Regulations (CFR) parts 124, 260 through 266, 268, 270, 273, and 279.

B. What Decisions Have We Made in This Rule?

We conclude that Nebraska's application to revise its authorized program meets all of the statutory and regulatory requirements established by RCRA. Therefore, we grant Nebraska final authorization to operate its hazardous waste program with the changes described in the authorization application. Nebraska has responsibility for permitting treatment, storage, and disposal facilities within its borders (except in Indian Country) and for carrying out the aspects of the RCRA program described in its revised program application, subject to the limitations of the Hazardous and Solid Waste Amendments of 1984 (HSWA). New Federal requirements and prohibitions imposed by Federal regulations that the EPA promulgates under the authority of HSWA take effect in authorized States before they are authorized for the requirements. Thus, the EPA will implement those requirements and prohibitions in Nebraska, including issuing permits, until the State is granted authorization to do so.

C. What Is the Effect of Today's Authorization Decision?

The effect of this decision is that a facility in Nebraska subject to RCRA will now have to comply with the authorized State requirements instead of the equivalent Federal requirements in order to comply with RCRA. Nebraska has enforcement responsibilities under its State hazardous waste program for violations of such program, but the EPA retains its authority under RCRA sections 3007, 3008, 3013, and 7003, which include, among others, authority to:

- Do inspections, and require monitoring, tests, analyses, or reports;
- Enforce RCRA requirements and suspend or revoke permits.

This action does not impose additional requirements on the regulated community because the regulations for which Nebraska is being authorized by today's action are already effective under State law, and are not changed by today's action.

D. Why Wasn't There a Proposed Rule Before Today's Rule?

The EPA did not publish a proposal before today's rule because we view this as a routine program change and do not expect comments that oppose this approval. We are providing an opportunity for public comment now. In addition to this rule, in the proposed rules section of today's **Federal Register** we are publishing a separate document that proposes to authorize the State program changes.

E. What Happens if the EPA Receives Comments That Oppose This Action?

If the EPA receives comments that oppose this authorization, we will withdraw this rule by publishing a document in the **Federal Register** before the rule becomes effective. The EPA will base any further decision on the authorization of the State program changes on the proposal mentioned in the previous paragraph. We will then address all public comments in a later final rule. You may not have another opportunity to comment. If you want to comment on this authorization, you must do so at this time. If we receive comments that oppose only the authorization of a particular change to the State hazardous waste program, we will withdraw only that part of this rule, but the authorization of the program changes that the comments do not oppose will become effective on the date specified above. The **Federal Register** withdrawal document will specify which part of the authorization will become effective, and which part is being withdrawn.

F. For What Has Nebraska Previously Been Authorized?

Nebraska initially received final authorization on January 24, 1985, effective February 7, 1985 (50 FR 3345), to implement the RCRA hazardous waste management program. We granted authorization for changes to its program on October 4, 1985, effective December 3, 1988 (53 FR 38950); June 25, 1996, effective August 26, 1996 (61 FR 32699); June 4, 2002, effective April 22, 2002 (67 FR 38418); and April 10, 2003, effective June 9, 2003 (68 FR 17553).

G. What Changes Are We Authorizing With Today's Action?

On May 11, 2004, Nebraska submitted a final complete program revision application, seeking authorization of its changes in accordance with 40 CFR 271.21. We now make an immediate final decision, subject to the EPA's receipt of written comments that oppose this action, that Nebraska's hazardous waste program revision satisfies all of the requirements necessary to qualify for final authorization. Therefore, we grant Nebraska final authorization for the following program changes:

Description of federal requirement (include checklist #, if relevant)	**Federal Register** date and page (and/or RCRA statutory authority)	Analogous state authority
Listing of EBDC—Checklist 33	51 FR 37725–37729, October 24, 1986	Title 128 3–014; Appendix II (effective July 15, 2003).
Revised Manual SW–846—Checklist 35	52 FR 8072–8073, March 16, 1987	Title 128 1–003 (effective July 15, 2003).
Identification and Listing of Hazardous Waste; Technical Correction—Checklist 47.	53 FR 27162–27163, July 19, 1988	Title 128 8–005; 8–006.02 (effective July 15, 2003).

Description of federal requirement (include checklist #, if relevant)	**Federal Register** date and page (and/or RCRA statutory authority)	Analogous state authority
Farmer Exemptions; Technical Corrections—Checklist 48.	53 FR 27164–27165, July 19, 1988)	Title 128 9–001.02; 10–001.06–.07; 12–001.03B; 21–001.02D; 22–001.01E; effective July 15, 2003).
Identification and Listing of Hazardous Waste; Treatability Studies Sample Exemption—Checklist 49.	53 FR 27290–29302, July 19, 1988	Title 128 1–120; 2–012.01–.03; 2–013.01–.02 (effective July 15, 2003).
Land Disposal Restrictions for First Third Scheduled Wastes—Checklist 50.	53 FR 311–38–31222, August 17, 1988	Title 128 7–007.01B; 20–001.03C; 20–001.04; 20–004; 20–005.01–.03; 20–007; 20–008.01; 20–008.03; 20–012.04 21–002; 21–005; 22–002; 22–005 (effective July 15, 2003).
Hazardous Waste Management System; Standards for Hazardous Waste Storage and Treatment Tank Systems—Checklist 52.	53 FR 34079–34087 September 2, 1988	Title 128 1–039; 1–132; 9–009.02C; 21–007; 21–010; 22–007; 22–010 (effective July 15, 2003).
Identification and Listing of Hazardous Waste; and Designation, Reportable Quantities, and Notification—Checklist 53 (Amended).	53 FR 35412–35421 September 13, 1988	Title 128 2–009.05; 3–014; Appendix II (effective July 15, 2003).
Statistical Methods for Evaluating Ground-Water Monitoring Data from Hazardous Waste Facilities—Checklist 55.	53 FR 39720–39731 October 11, 1988	Title 128 21–006 (effective July 15, 2003).
Identification and Listing of Hazardous Waste Removal of Iron Dextran from the List Hazardous Wastes—Checklist 56.	53 FR 43878–4381 October 31, 1988	Title 128 3–016; Appendix I (effective July 15, 2003).
Identification and Listing of Hazardous Waste; Removal of Strontium Sulfide from the List of Hazardous Wastes—Checklist 57.	53 FR 43881–43884 October 31, 1988	Title 128 3–015–05; Appendix I (effective July 15, 2003).
Standards for Generators of Hazardous Waste—Checklist 58.	53 FR 45089–45093 November 8, 1988	Title 128 10–002.01 (effective July 15, 2003).
Hazardous Waste Miscellaneous Units; Standards Applicable to Owners and Operators—Checklist 59.	54 FR 615–617, January 9, 1989	Title 128 13–012.02 (effective July 15, 2003).
Amendment to Requirements for Hazardous Waste Incinerator Permits—Checklist 60.	54 FR 4286–4288, January 30, 1989	Title 128 12–001.04C.
Land Disposal Restrictions Amendments to First Third Scheduled Wastes: Checklist 62.	54 FR 18836–18838, May 2, 1989	Title 128 20–008, Table 9 (effective July 15, 2003).
Land Disposal Restrictions Amendments to Second Third Scheduled Wastes—Checklist 63.	54 FR 26594–26652, June 23, 1989	Title 128 20–009, Table 9 (effective July 15, 2003).
Delay of Closure Period for Hazardous Waste Management Facilities—Checklist 64.	54 FR 33376–33398, August 14, 1989	Title 128 21–002; 21–007–008; 22–002; 22–007–008; Appendix V (effective July 15, 2003).
Mining Waste Exclusion—Checklist 65	54 FR 36592–3664, September 1, 1989	Title 128 2–004.02A; 2–004.02C; 2–009.05 (effective July 15, 2003).
Land Disposal Restrictions; Correction to the First Third Scheduled Wastes—Checklist 66.	54 FR 36967, September 6, 1989, as amended on June 13, 1990, at 55 FR 23935.	Title 128 7–007.01B; 20–001.03; 20–001.05; 20–005.01C; 20–005.02; 20–007; 20–012.04 (effective July 15, 2003).
Testing and Monitoring Activities—Checklist 67	54 FR 40260–40269, September 29, 1989	Title 128 1–003 (effective July 15, 2003).
Reportable Quantity Adjustment Methyl Bromide Production Wastes—Checklist 68.	54 FR 41402–41408, October 6, 1989	Title 128 3–014; Appendix II (effective July 15, 2003).
Reportable Quantity Adjustment—Checklist 69	54 FR 50968–50979, December 11, 1989	Title 128 3–013; Appendices I–II (effective July 15, 2003).
Mining Waste Exclusion II—Checklist 71	55 FR 2322–2354, January 23, 1990	Title 128 1–031; 2–009.05; 9–007.06; 10–002.13 (effective July 15, 2003).
Modification of F019 Listing—Checklist 72	55 FR 5340–5342, February 14, 1990	Title 128 3–013 (effective July 15, 2003).
Testing and Monitoring Activities; Technical Corrections—Checklist 73.	55 FR 8948–8950, March 9, 1990	Title 128 1–003 (effective July 15, 2003).
Listing of 1, 1-Dimethylhydrazine Production Wastes—Checklist 75.	55 FR 18496–18506, May 2, 1990	Title 128 1–003; 3–014; Appendix II (effective July 15, 2003).
Criteria for Listing Toxic Wastes; Technical Amendment—Checklist 76.	55 FR 18726, May 4,1990	Title 128 3–002.03 (effective July 15, 2003).
HSWA Codification Rule, Double Liners, Correction—Checklist 77.	55 FR 19262–19264, May 9, 1990	Title 128 21–011; 21–014 (effective July 15, 2003).
Land Disposal Restrictions for Third Third Scheduled Wastes—Checklist 78.	55 FR 22520–22720, June 1, 1990	Title 128 3–006, 3–007.02; 3–008.02; 3–009.02; 3–010–02; 3–013; 3–015.03; 4–002.03; 10–004.01H; 15–012/Appendix V; 20–001.03C; 20–002; 20–002.01–07; 20–003.01–02; 20–005.01E2; 20–005.01G–H; 20–005.01J; 20–005.02–03; 20–006.01–04; 20–007; 20–009.01; 20–009.01/Table 10; 20–009.02–03; 20–015–17; 20–019; 21–002; 21–011–014; 22–001.03; 22–002; 22–011–14 Appendix II (effective July 15, 2003).

Description of federal requirement (include checklist #, if relevant)	**Federal Register** date and page (and/or RCRA statutory authority)	Analogous state authority
Organic Air Emission Standards for Process Vents and Equipment Leaks—Checklist 79.	55 FR 25454–25519, June 21, 1990	Title 128 1–003; 7–005; 7–005.01; 7–006.03; 13–012.02; 13–012.04; 21–002; 21–005; 21–019–020; 22–002; 22–005; 22–019–20 (effective July 15, 2003).
Toxicity Characteristic: Hydrocarbon Recovery Operations—Checklist 80.	55 FR 40834–40837, October 5, 1990	This requirement has expired.
Petroleum Refinery Primary and Secondary Oil/Water/Solids Separation Sludge Listings (F03 and F038)—Checklist 81.	55 FR 46354–46397 November 2, 1990, as amended on December 17, 1990 at 55 FR 51707.	Title 128 3–013.01–02; Appendix II (effective July 15, 2003).
Wood Preserving Listings—Checklist 82	55 FR 50450–50490, December 6, 1990	Title 128 1–003; 1–038; 2–008.09; 3–013.01; 3–017; 10–004.01G–H; 13–12.04; 21–010; 21–017; 22–010; 22–018 Appendix I; Appendix II (effective July 15, 2003).
Land Disposal Restrictions for Third Third Scheduled Wastes; Technical Amendments—Checklist 83.	56 FR 3864–3928, January 31, 1991	Title 128 2–007.01A; 3–006; 3–013.01; 4–002.03; 9–007.03D; 9–007.03F-G; 20–002.04; 20–002.07; 20–005.01; 20–005.01C2; 20–005.01F–J; 20–005.02; 20–006.01; 20–006.04A2; 20–008.01; 20–009, Table 9; 20–009, Table 10; 20–016–019; Appendix V (effective July 15, 2003).
Toxicity Characteristic; Chlorofluorocarbon Refrigerants—Checklist 84.	56 FR 5910–5915, February 13, 1991	Title 128 2–009.11 (effective July 15, 2003).
Burning of Hazardous Waste in Boilers and Industrial Furnaces—Checklist 85.	56 FR 7134–7240, February 21, 1991	Title 128 1–003; 1–004; 1–014; 1–061.01–.02; 1–064; 1–064.12–.13; 1–065; 1–094; 1–104; 2–003.04B–C; 2–008.10; 2–009.03; 2–009.05–.06; 7–002.07–.10; 7–008.01A–.01C; 7–008.02A–.02C; 7–008.03; 12–001.04F; 12–003.04D–.04E; 13–012.04; 15–012.02Q; 21–007; 21–015; 22–007; 22–015; Appendix V (effective July 15, 2003).
Removal of Strontium Sulfide from the List of Hazardous Wastes; Technical Amendment—Checklist 86.	56 FR 7567–7568, February 25, 1991	Title 128 3–015.05; Appendix I (effective July 15, 2003).
Organic Air Emission Standards for Process Vents and Equipment Leaks; Technical Amendment—Checklist 87.	56 FR 19290, April 26, 1991	Title 128 13–012.04; 21–019–020; 22–002; 22–005; 22–019–020 (effective July 15, 2003).
Administrative Stay for K069 Listing—Checklist 88.	56 FR 19951, May 1, 1991	Title 128 3–014 (effective July 15, 2003).
Revision to the Petroleum Refining Primary and Secondary Oil/Water/Solids Separation Sludge Listings (F037 and F038)—Checklist 89.	56 FR 21955–21960, May 13, 1991	Title 128 3–013.01 (effective July 15, 2003).
Mining Waste Exclusion III—Checklist 90	56 FR 27300–27330, June 13, 1991	Title 128 2–009.05 (effective July 15, 2003).
Wood Preserving Listings; Technical Corrections—Checklist 92.	56 FR 30192–30198, July 1, 1991	Title 128 2–008.09; 3–017; 10–004.01A–.01C; 10–004.01F–.01H; 13–012.04; 21–017; 22–018 (effective July 15, 2003).
Burning of Hazardous Waste in Boilers and Industrial Furnaces; Corrections and Technical Amendments—Checklist 94.	56 FR 32688–32852, July 17, 1991	Title 128 2–006.03B; 7–003; 7–003.02; 7–008.01B2–.01B3;7–008.03; 7–009.01C–.01D; 12–001.04E–.04F; 13–012.04; 15–012.02K1(d); 15–012.02Q1; 15–012.02Q1(a); 15–012.02Q1(d); 22–016; Appendix V (effective July 15, 2003).
Land Disposal Restrictions for Electric Arc Furnace Dust (K061)—Checklist 95.	56 FR 41164–41178, August 19, 1991	Title 128 2–006.03C–.03C1; 2–008.11 (effective July 15, 2003).
Burning of Hazardous Waste in Boilers and Industrial Furnaces; Technical Amendments II—Checklist 96.	56 FR 42504–42517, August 27, 1991	Title 128 2–003.04B; 2–003.04B1–.04B3; 7–008.01A; 7–008.01C; 7–008.03; 22–007 (effective July 15, 2003).
Amendments to Interim Status Standards for Downgradiant Ground-Water Monitoring Well Locations—Checklist 99.	56 FR 66365–66369, December 23, 1991	Title 128 22–006 (effective July 15, 2003).
Liners and Leak Detection Systems for Hazardous Waste Land Disposal Units—Checklist 100.	57 FR 3462–3497, January 29, 1992	Title 128 1–098; 1–110; 12–002.01; 12–002.01A–.01C; 13–.012.04; 21–002; 21–005; 21–011–012; 21–014; 22–002; 22–005; 22–011–012; 22–014; Appendix V (effective July 15, 2003).
Second Correction to the Third Third Land Disposal Restrictions—Checklist 102.	57 FR 8086–8089, March 6, 1992, March 6, 1992.	Title 128 20–003.02; 21–002; 22–002 (effective July 15, 2003).
Used Oil Filter Exclusion—Checklist 104	57 FR 21524–21534, May 20, 1992	Title 128 2–009.12; 2–009.12A–009.12A–.12D (effective July 15, 2003).
Recycled Coke By-Product Exclusion—Checklist 105.	57 FR 27880–27888, June 22, 1992	Title 128 2–008.10; 7–008.01A (effective July 15, 2003).
Used Oil Filter Exclusion; Technical Corrections—Checklist 107.	57 FR 29220, July 1, 1992	Title 128 2–009.12 (effective July 15, 2003).

Description of federal requirement (include checklist #, if relevant)	Federal Register date and page (and/or RCRA statutory authority)	Analogous state authority
Toxicity Characteristics Revisions: Technical Corrections—Checklist 108.	57 FR 30657–30658, July 10, 1992	Title 128 2–009.07; 2–009.09D; 22–014 (effective July 15, 2003).
Coke By-Products Listings—Checklist 110	57 FR 37284–37306, August 18, 1992	Title 128 2–008.10; 3–014; Appendix II (effective July 15, 2003).
Burning of Hazardous Waste in Boilers and Industrial Furnaces; Technical Amendment III—Checklist 111.	57 FR 38558–38566, August 25, 1992	Title 128 1–065; 1–094; 2–003.05B4; 6–001.01; 7–008.01A; 7–008.01C; 7–008.02C; 7–008.03; 21–001.02B; 22–001.01C (effective July 15, 2003).
Consolidated Liability Requirements—Checklist 113.	57 FR 42832–42844, September 16, 1992	Title 128 21–008; 22–008 (effective July 15, 2003).
Burning of Hazardous Waste in Boilers and Industrial Furnaces; Technical Amendment IV—Checklist 114.	57 FR 44999–45001, September 30, 1992	Title 128 7–008.03 (effective July 15, 2003).
Clorinated Toleunes Production Waste Listings—Checklist 115.	57 FR 47376–47386, October 15, 1992	Title 128 3–014; Appendix II (effective July 15, 2003).
Toxicity Characteristic Amendment—Checklist 117B.	57 FR 23062–23063, June 1, 1992	Title 128 2–004.02A (effective July 15, 2003).
Liquids in Landfills II—Checklist 118	57 FR 54452–54461, November 18, 1992	Title 128 21–002; 21–014; 22–002; 22–014 (effective July 15, 2003).
Toxicity Characteristic Revision; TCLP Correction—Checklist 119.	57 FR 55114–55117, November 24, 1992	All sections have been removed from the Federal regulations.
Wood Preserving; Revisions to Listings and Technical Requirements—Checklist 120.	57 FR 61492–61505, December 24, 1992	Title 128 3–013.01; 21–017; 22–018 (effective July 15, 2003).
Boilers and Industrial Furnaces; Changes for Consistency with New Air Regulations—Checklist 125.	58 FR 38816–38884, July 20, 1993	Title 128 1–003; 7–008.03 (effective July 15, 2003).
Testing and Monitoring Activities—Checklist 126.	58 FR 46040–46051, August 31, 1993	Title 128 1–003; 3–008.01A–.01B; 3–010.01; 6–003.03A1; 12–001.04C; 12–001.04F; 13–012.04; 20–005.01A; 20–008.01; 20–019; 21–010; 21–014; 22–010; 22–014 (effective July 15, 2003).
Boilers and Industrial Furnaces; Administrative Stay and Interim Standards for Bevill Residues—Checklist 127.	58 FR 59598–59603, November 9, 1993	Title 128 7–008.03 (effective July 15, 2003).
Wastes From the Use of Chlorophenolic Formulations in Wood Surface Protection—Checklist 128.	59 FR 458–469, January 4, 1994	Title 128 1–003; Appendix I (effective July 15, 2003).
Revision of Conditional Exemption for Small Scale Treatability Studies—Checklist 129.	59 FR 8362–8366, February 18, 1994	Title 128 2–012; 2–012.03; 2–013.02 (effective July 15, 2003).
Recordkeeping Instructions; Technical Amendment—Checklist 131.	59 FR 13891–13893, March 24, 1994	Title 128 21–023; 22–023 (effective July 15, 2003).
Wood Surface Protection; Correction—Checklist 132.	59 FR 28484, June 2, 1994	Title 128 1–003 (effective July 15, 2003).
Letter of Credit Revision—Checklist 133	59 FR 29958–29960, June 10, 1994	Title 128 21–008 (effective July 15, 2003).
Correction of Beryllium Powder (P015) Listing—Checklist 134.	59 FR 31551–31552, June 20, 1994	Title 128 3–015.05; Appendix I (effective July 15, 2003).
Recovered Oil Exclusion—Checklist 135	59 FR 38536–38545, July 28, 1994	Title 128 2–006.03B; 2–008.12; 7–002; 7–008.01B3 (effective July 15, 2003).
Testing and Monitoring Activities Amendment I—Checklist 139.	60 FR 3089–3095, January 13, 1995	Title 128 1–003 (effective July 15, 2003).
Carbamate Production Identification and Listing of Hazardous Waste—Checklist 140.	60 FR 7824–7859, February 9, 1995	Title 128 2–004.02D5–.02D7; 2–006.03D; 3–014; 3–015.05; 3–016; Appendices I–II (effective July 15, 2003).
Testing and Monitoring Activities Amendment II—Checklist 141.	60 FR 17001–17004, April 4, 1995	Title 128 1–003 (effective July 15, 2003).
Removal of Legally Obsolete Rules—Checklist 144.	60 FR 33912–33915, June 29, 1995	Title 128 3–013.01; 7+008.03; 13–005–007 (effective July 15, 2003).
Liquids in Landifills III—Checklist 145	60 FR 35703–35706, July 11, 1995	Title 128 21–014; 22–014 (effective July 15, 2003).
Amendments to the Definition of Solid Waste; Amendment II—Checklist 150.	61 FR 13103–13106, March 26, 1996	Title 128 2–008.12 (effective July 15, 2003).
Conditionally Exempt Small Quantity Generator Disposal Options under Subtitle D—Checklist 153.	61 FR 34252–34278, July 1, 1996	Title 128 8–006.03; 8–006.03A–.03F (effective July 15, 2003).
Conformance With the Carbamate Vacatur—Checklist 159.	62 FR 1992–1997, May 29, 1997	Title 128 3–014/Table 5; 3–016/Table 7; Appendices I–II; 20–007; 20–008/Table 9 (effective July 15, 2003).

H. Where Are the Revised State Rules Different From the Federal Rules?

In this authorization of the Fourth Program Revision for the State of Nebraska there are no provisions that are more stringent or broader in scope. Broader in scope requirements are not part of the authorized program and the EPA cannot enforce them.

I. Who Handles Permits After the Authorization Takes Effect?

Nebraska will issue permits for all the provisions for which it is authorized and will administer the permits it issues. The EPA will continue to administer any RCRA hazardous waste permits or portions of permits which we issued prior to the effective date of this authorization. We will not issue any more new permits or new portions of permits for the provisions listed in the Table above after the effective date of this authorization. The EPA will continue to implement and issue permits for HSWA requirements for which Nebraska is not yet authorized.

J. What Is Codification and Is the EPA Codifying Nebraska's Hazardous Waste Program as Authorized in This Rule?

Codification is the process of placing the State's statutes and regulations that comprise the State's authorized hazardous waste program into the CFR. We do this by referencing the authorized State rules in 40 CFR part 272. We reserve the amendment of 40 CFR part 272, subpart CC for this authorization of Nebraska's program changes until a later date.

K. Statutory and Executive Order Reviews

The Office of Management and Budget (OMB) has exempted this action from the requirements of Executive Order 12866 (58 FR 51735, October 4, 1993), and therefore this action is not subject to review by OMB. This action authorizes State requirements for the purpose of RCRA 3006 and imposes no additional requirements beyond those imposed by State law. Accordingly, I certify that this action will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this action authorizes preexisting requirements under State law and does not impose any additional enforceable duty beyond that required by State law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). For the same reason, this action also does not significantly or uniquely affect the communities of Tribal governments, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action 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 (64 FR 43255, August 10, 1999), because it merely authorizes State requirements as part of the State RCRA hazardous waste program without altering the relationship or the distribution of power and responsibilities established by RCRA. This action also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant and it does not make decisions based on environmental health or safety risks. 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)) because it is not a significant regulatory action under Executive Order 12866.

Under RCRA 3006(b), the EPA grants a State's application for authorization as long as the State meets the criteria required by RCRA. It would thus be inconsistent with applicable law for the EPA, when it reviews a State authorization application, to require the use of any particular voluntary consensus standard in place of another standard that otherwise satisfies the requirements of RCRA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this rule, the EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. The EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the "Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings" issued under the Executive Order. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

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 document 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 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).

List of Subjects in 40 CFR Part 271

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous waste, Hazardous waste transportation, Indian lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements.

Authority: This action is issued under the authority of sections 2002(a), 3006, and 7004(b) of the Solid Waste Disposal Act as amended 42 U.S.C. 6912(a), 6926, 6974(b).

Dated: September 2, 2004.

William Rice,

Acting Regional Administrator, Region 7.

[FR Doc. 04–22252 Filed 10–1–04; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

42 CFR Part 71

Foreign Quarantine

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Amendment of February 4, 2004, order to embargo bird and bird products imported from Malaysia.

SUMMARY: On February 4, 2004, the Centers for Disease Control and Prevention (CDC) issued an order immediately banning the import of all birds (Class: *Aves*) from specified Southeast Asian countries, subject to limited exemptions for pet birds and certain bird-derived products. CDC took this step because birds from these countries potentially can infect humans with avian influenza (Influenza A (H5N1)). The February 4 order complemented a similar action taken by the U.S. Department of Agriculture (USDA), Animal and Plant Health

Inspection Service (APHIS). On March 10, 2004, CDC lifted the embargo of birds and bird products from Hong Kong Special Administrative Region because of the documented public health and animal health measures taken by Hong Kong officials to prevent spread of the outbreak within Hong Kong and the absence of avian influenza cases in Hong Kong's domestic and wild bird populations. APHIS took a similar action. CDC and APHIS are now imposing an embargo on birds and bird products from Malaysia because of the documented cases of Influenza A (H5N1) in poultry in Malaysia. All other portions of the February 4, 2004, order and March 10, 2004, amendment remain in effect until further notice.

DATES: This action is effective on September 28, 2004 and will remain in effect until further notice.

FOR FURTHER INFORMATION CONTACT: Paul Arguin, National Center for Infectious Diseases, Centers for Disease Control and Prevention, Mailstop C–14, 1600 Clifton Road, Atlanta, GA 30330, telephone, 404–498–1600.

SUPPLEMENTARY INFORMATION:

Background

On August 19, 2004, the Office of International Epizootics (OIE), an international organization that reports the occurrence of animal diseases detected worldwide, listed Malaysia among the countries in which an outbreak of avian influenza was occurring. According to the OIE emergency report, there was a laboratory-confirmed report of H5N1 influenza virus on one farm in Malaysia at Kelantan State, Tumpat district, Pasir Pekan village. The initial flock of village chickens consisted of 60 birds of mixed ages, reared free range. Within a 1-km radius of the affected flock there are another 103 village chickens, 62 birds of mixed species and 8 ducks (173 birds total). On September 9, 2004, OIE reported a second laboratory-confirmed occurrence of H5N1 influenza in a flock of birds located in an area 5 kilometers from the previously infected flock. The susceptible avian population within the village included 1,608 chickens, 68 bantam chickens, 4 turkeys, 93 ducks, 9 geese, 60 quail, and 193 other species (2,035 birds total).

The government of Malaysia has instituted a number of control measures, including depopulation of poultry and birds within a one-kilometer radius of the infective flock; quarantine and clinical surveillance within a 10-kilometer radius of the inflected flock; and restrictions on the movement of birds and their products to other states within Malaysia.

Introduction of influenza A (H5N1)-infected birds into the United States could lead to outbreaks of disease in the human population, a significant public health threat. Banning the importation of all avian species from affected countries, including Malaysia, is an effective means of limiting this threat. CDC is therefore taking this action to reduce the chance of introduction or spread of influenza A (H5N1).

Immediate Action

Therefore, pursuant to 42 CFR 71.32(b), the February 4, 2004, order is amended to add Malaysia to the list of countries subject to that order's embargo of birds and products derived from birds (including hatching eggs). All other portions of the February 4, 2004 order (69 FR 7165, Feb. 13, 2004) and the March 10, 2004 amendment (69 FR 12975, Mar. 19, 2004) shall remain in effect until further notice.

Julie Louise Gerberding,

Director, Centers for Disease Control and Prevention.

[FR Doc. 04–22258 Filed 10–1–04; 8:45 am]

BILLING CODE 4160–17–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 0, 1, and 54

[CC Docket No. 02–6; FCC 04–190]

Schools and Libraries Universal Service Support Mechanism

AGENCY: Federal Communications Commission.

ACTION: Final rule, correction.

SUMMARY: This document corrects an error in the dates and final rules sections of a **Federal Register** document regarding the Commission adopting measures to protect against waste, fraud, and abuse in the administration of the schools and libraries universal service support mechanism. In addition, the Commission resolved a number of issues that have arisen from audit activities conducted as part of ongoing oversight over the administration of the universal service fund, and the Commission addressed programmatic concerns raised by our Office of Inspector General. The summary was published in the **Federal Register** on September 13, 2004.

DATES: Effective October 4, 2004.

FOR FURTHER INFORMATION CONTACT: Jennifer Schneider, Attorney, Telecommunications Access Policy Division, Wireline Competition Bureau, (202) 418–7400.

SUPPLEMENTARY INFORMATION: This summary contains a correction to the dates and final rules sections of a **Federal Register** summary, 69 FR 55097 (September 13, 2004). The full text of the Commission's Fifth Report and Order and Order in CC Docket No. 02–6, FCC 04–190 released on August 13, 2004 is available for public inspection during regular business hours in the FCC Reference Center, Room CY–A257, 445 Twelfth Street, SW., Washington, DC 20554.

■ In rule FR Doc. 04–20363 published September 13, 2004 (69 FR 55097) make the following corrections.

■ 1. On page 55097, in the second column, in the dates section, remove "54.504(f)" and add in its place "54.504(h)."

PART 54—[CORRECTED]

■ 2. On page 55109, in the third column, in paragraph 8, third line, remove "(f)" and add in its place "(h)."

§ 54.504 [Corrected]

■ 3. On page 55110, in the third column, in the twentieth line, remove "(f)" and add in its place "(h)."

■ 4. On page 55110, in the third column, in paragraph 9, remove "E" and add in its place "F."

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 04–22228 Filed 10–1–04; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 101

[ET Docket No. 98–206; RM–9147; RM–9245; DA 04–3007]

Amendment of the Commission's Rules Governing Multichannel Video Distribution and Data Service in the 12.2–12.7 GHz Band

AGENCY: Federal Communications Commission.

ACTION: Correcting amendment.

SUMMARY: On April 11, 2002, the Commission adopted rules to establish technical, service and licensing rules governing Multichannel Video Distribution and Data Service (MVDDS) in the 12 GHz band. Because an error was made in the final rules, this document contains correcting amendments to the final rules that were published in the **Federal Register**.

DATES: Effective on October 4, 2004.

FOR FURTHER INFORMATION CONTACT: Jennifer Mock, Broadband Division, Wireless Telecommunications Bureau at (202) 418–2487.

SUPPLEMENTARY INFORMATION: The Federal Communications Commission published in the **Federal Register** final rules, 67 FR 43031, June 26, 2002, in the above captioned proceeding (Memorandum Opinion and Order and Second Report and Order). The instant document corrects an error in a note to section 101.1412.

Procedural Matters

Any impact as defined by the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13, the Congressional Review Act (CRA), and the Regulatory Flexibility Act of 1980, as amended (RFA) was addressed at the time of adoption and release of the *Memorandum Opinion and Order and Second Report and Order*, FCC 02–116, adopted on April 11, 2002, and released on May 23, 2003, 67 FR 43031, June 26, 2002. Therefore, the PRA, CRA and RFA requirements have already been fulfilled for these rules.

List of Subjects in 47 CFR Part 101

Communications common carriers, Communications equipment, Radio.

Federal Communications Commission.

Peter J. Daronco,

Assistant Chief, Broadband Division Wireless Telecommunications Bureau.

■ Accordingly, 47 CFR part 101 is corrected by making the following correcting amendments:

PART 101—FIXED MICROWAVE SERVICES

■ 1. The authority citation for part 101 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

■ 2. Section 101.1412 is amended by removing the Note immediately following paragraph (f)(6) and by adding a Note immediately following paragraph (g)(6) to read as follows:

§ 101.1412 MVDDS eligibility restrictions for cable operators.

* * * * *

(g) * * *

(6) * * *

Note to § 101.1412: Waivers of § 101.1412(f) may be granted upon an affirmative showing:

(a) That the interest holder has less than a fifty percent voting interest in the licensee and there is an unaffiliated single holder of a fifty percent or greater voting interest;

(b) That the interest holder is not likely to affect the local market in an anticompetitive manner;

(c) That the interest holder is not involved in the operations of the licensee and does not have the ability to influence the licensee on a regular basis; and

(d) That grant of a waiver is in the public interest because the benefits to the public of common ownership outweigh any potential anticompetitive harm to the market.

[FR Doc. 04–22226 Filed 10–1–04; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket NHTSA–03–15351]

RIN 2127–AI34

Federal Motor Vehicle Safety Standards; Child Restraint Systems; Correction

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Correcting amendments.

SUMMARY: This document corrects a final rule (Docket NHTSA–03–15351) that was published Tuesday, June 24, 2003 (68 FR 37620). The rule updated test procedures in Federal Motor Vehicle Safety Standard (FMVSS) No. 213, "Child Restraint Systems," and expanded the standard to restraints for children weighing up to 65 pounds.

DATES: Effective October 4, 2004.

FOR FURTHER INFORMATION CONTACT: Deirdre Fujita, Office of the Chief Counsel, NHTSA, telephone 202–366–2992; fax 202–366–3820, 400 Seventh St., SW., Washington, DC 20590.

SUPPLEMENTARY INFORMATION: The final rule that is the subject of this correction amended Federal Motor Vehicle Safety Standard No. 213, *Child Restraint Systems* (49 CFR 571.213) to update the procedures used to test child restraint systems.

Need for Correction

As published, the final rule contains two minor errors that the agency wants to correct to ensure the clarity of the standard. First, there are two paragraphs designed (ii) in S6.1.1(a)(1). The first such paragraph should be changed to (i). Second, paragraph (e) of S7.1.1 should be removed. S7.1.1 sets forth requirements that apply to child restraints manufactured before August 1, 2005. Paragraph (e) relates to child restraints manufactured on or after August 1, 2005 and thus does not belong in S7.1.1.

List of Subjects in 49 CFR Part 571

Imports, Incorporation by reference, Motor vehicle safety, Reporting and recordkeeping requirements, Tires.

■ In consideration of the foregoing, NHTSA amends 49 CFR Chapter V as set forth below.

PART 571—FEDERAL MOTOR VEHICLE SAFETY STANDARDS

■ 1. The authority citation for Part 571 continues to read as follows:

Authority: 49 U.S.C. 322, 30111, 30115, 30117 and 30166; delegation of authority at 49 CFR 1.50.

■ 2. Correct § 571.213 as follows:

■ a. S6.1.1(a)(1) is revised to read as set forth below.

■ b. In S7.1.1, paragraph (e) is removed.

§ 571.213 Standard No. 213; Child restraint systems.

* * * * *

S6.1.1 Test conditions.

(a) *Test devices.*

(1) Add-on child restraints.

(i) The test device for add-on restraint systems manufactured before August 1, 2005 is a standard seat assembly consisting of a simulated vehicle bench seat, with three seating positions, which is described in Drawing Package SAS–100–1000 with Addendum A: Seat Base Weldment (consisting of drawings and a bill of materials), dated October 23, 1998 (incorporated by reference in § 571.5). The assembly is mounted on a dynamic test platform so that the center SORL of the seat is parallel to the direction of the test platform travel and so that movement between the base of the assembly and the platform is prevented.

(ii) The test device for add-on restraint systems manufactured on or after August 1, 2005 is a standard seat assembly consisting of a simulated vehicle bench seat, with three seating positions, which is depicted in Drawing Package, "NHTSA Standard Seat Assembly; FMVSS No. 213, No. NHTSA–213–2003," (consisting of drawings and a bill of materials) dated June 3, 2003 (incorporated by reference; see § 571.5). The assembly is mounted on a dynamic test platform so that the center SORL of the seat is parallel to the direction of the test platform travel and so that movement between the base of the assembly and the platform is prevented.

* * * * *

Issued on September 28, 2004.

Stephen R. Kratzke,

Associate Administrator for Rulemaking.

[FR Doc. 04–22279 Filed 10–1–04; 8:45 am]

BILLING CODE 4910–59–P

Proposed Rules

Federal Register
Vol. 69, No. 191
Monday, October 4, 2004

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–2004–19138; Directorate Identifier 2004–NM–102–AD]

RIN 2120–AA64

Airworthiness Directives; Gulfstream Aerospace LP Model Gulfstream 100 Airplanes; and Model Astra SPX and 1125 Westwind Astra 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 Gulfstream Aerospace LP Model Gulfstream 100 airplanes; and Model Astra SPX and 1125 Westwind Astra series airplanes. This proposed AD would require adjusting the ground contact switches of the main landing gear. This proposed AD is prompted by two occurrences of uncommanded deployments of the ground airbrakes during descent. We are proposing this AD to prevent a false "Ground" position signal, which could result in deployment of the ground airbrakes and reduced controllability of the airplane.

DATES: We must receive comments on this proposed AD by November 3, 2004.

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 Gulfstream Aerospace Corporation, P.O. Box 2206, Mail Station D–25, Savannah, Georgia 31402.

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: 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.

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–2004–19138; Directorate Identifier 2004–NM–102–AD" at the beginning 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 our docket website, 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 the 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

The Civil Aviation Administration of Israel (CAAI), which is the airworthiness authority for Israel, notified us that an unsafe condition may exist on certain Gulfstream Aerospace LP Model Gulfstream 100 airplanes; and Model Astra SPX and 1125 Westwind Astra series airplanes. The CAAI advises that increasing the adjustment margin of the ground contact switches of the main landing gear (MLG) could prevent a false "Ground" position signal. This condition, if not corrected, could result in deployment of the ground airbrakes and reduced controllability of the airplane.

Relevant Service Information

Gulfstream Aerospace LP has issued Alert Service Bulletin 1125–32A–233, Revision 1, dated August 1, 2003. The service bulletin describes procedures for adjusting the ground contact switches of the MLG. Accomplishing the actions specified in the service information is intended to adequately address the unsafe condition. The CAAI mandated the service information and issued Israeli airworthiness directive 32–03–08–05, dated September 4, 2003, to ensure the continued airworthiness of these airplanes in Israel.

FAA's Determination and Requirements of the Proposed AD

These airplane models are manufactured in Israel and are type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the CAAI has kept the FAA informed of the situation described above. We have examined the CAAI's findings, evaluated all pertinent information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Therefore, we are proposing this AD, which would require adjusting the ground contact switches of the MLG. The proposed AD would require you to use the service information described previously to perform these actions, except as discussed under "Difference Between the Proposed AD and Service Bulletin."

Difference Between the Proposed AD and the Service Bulletin

Operators should note that, although the Accomplishment Instructions of the referenced service bulletin describe procedures for submitting a service reply card, this proposed AD would not require that action. We do not need this information from operators.

Costs of Compliance

This proposed AD would affect about 106 airplanes of U.S. registry. The proposed actions would take about 3 work hours per airplane, at an average labor rate of $65 per work hour. Based on these figures, the estimated cost of the proposed AD for U.S. operators is $20,670, or $195 per airplane.

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):

Gulfstream Aerospace LP (Formerly Israel Aircraft Industries, Ltd.): Docket No. FAA–2004–19138; Directorate Identifier 2004–NM–102–AD.

Comments Due Date

(a) The Federal Aviation Administration must receive comments on this AD action by November 3, 2004.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Gulfstream Aerospace LP Model Gulfstream 100 airplanes; and Model Astra SPX and 1125 Westwind Astra series airplanes; serial numbers 004 through 127 inclusive; certificated in any category.

Unsafe Condition

(d) This AD was prompted by two occurrences of uncommanded deployments of the ground airbrakes during descent. We are issuing this AD to prevent a false "Ground" position signal, which could result in deployment of the ground airbrakes and 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.

Corrective Action

(f) Within 250 flight hours after the effective date of this AD, adjust the ground contact switches of the left and right main landing gear, in accordance with the Accomplishment Instructions of Gulfstream Alert Service Bulletin 1125–32A–233, Revision 1, dated August 1, 2003. Although the service bulletin referenced in this AD specifies to submit certain information to the manufacturer, this AD does not include that requirement.

Alternative Methods of Compliance (AMOCs)

(g) 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.

Related Information

(h) Israeli airworthiness directive 32–03–08–05, dated September 4, 2003, also addresses the subject of this AD.

Issued in Renton, Washington, on September 15, 2004.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–22193 Filed 10–1–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–19157; Directorate Identifier 2004–NE–30–AD]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce Deutschland (RRD) (Formerly Rolls-Royce plc) Tay 650–15 Series Turbofan Engines

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 RRD Tay 650–15 series turbofan engines. This proposed AD would require inspection of the high pressure compressor (HPC) shaft and high pressure turbine (HPT) shaft for spline flank wear. This proposed AD results from a number of occurrences of excessive HPC shaft and HPT shaft

spline flank wear discovered during on-wing and in-shop inspections. We are proposing this AD to prevent spline disengagement resulting in an overspeed event, which could lead to an uncontained engine failure and possible damage to the airplane.

DATES: We must receive any comments on this proposed AD by December 3, 2004.

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 20590–001.
- 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 Rolls-Royce Deutschland Ltd & Co KG, Eschenweg 11, D–15827 Dahlewitz, Germany; telephone 49 (0) 33–7086–1768; fax 49 (0) 33–7086–3356.

You may examine the comments on this proposed AD in the AD docket on the Internet at *http://dms.dot.gov*.

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:

Docket Management System (DMS)

We have implemented new procedures for maintaining AD dockets electronically. As of May 17, 2004, we post new AD actions on the DMS and assign a DMS docket number. We track each action and assign a corresponding Directorate identifier. The DMS docket No. is in the form "Docket No. FAA–200X–XXXXX." Each DMS 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 proposal. Send your comments to an address listed under **ADDRESSES.** Include "Docket No. FAA–2004–19157; Directorate Identifier 2004–NE–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 received 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 the DMS 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 the 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 AD Docket

You may examine the docket that contains the proposal, any comments received, and any final disposition in person at the DMS Docket Offices between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone (800) 647–5227) is located on the plaza level of the Department of Transportation Nassif Building at the street address stated in **ADDRESSES.** Comments will be available in the AD docket shortly after the DMS receives them.

Discussion

The Civil Aviation Authority (CAA), which is the airworthiness authority for the United Kingdom, recently notified us that an unsafe condition might exist on certain RRD Tay 650–15 series turbofan engines. The CAA advises that the spline flanks on the HPC shaft and HPT shaft may be developing excessive wear. The amount of wear is directly related to the amount of relative movement between the HPC and an immobilized HPT. You can detect wear by inspecting the engine to determine the amount of relative movement between the HPC and an immobilized HPT. On-wing and in-shop inspections found excessive spline flank wear on HPC shafts and HPT shafts that incorporated Service Bulletin (SB) No. TAY–72–1327 (hard coated abutment face) and HPC shafts and HPT shafts that did not incorporate SB No. TAY–72–1327.

Relevant Service Information

We have reviewed and approved the technical contents of RRD SB No. TAY–72–1485, Revision 2, dated March 21, 2003 that describes procedures for inspecting the flanks on the HPC shaft and HPT shaft for wear. The CAA classified the initial Rolls-Royce plc (RR) SB as mandatory and issued airworthiness directive CAA 001–01–2002, dated January 11, 2002 in order to ensure the airworthiness of these RR engines in the United Kingdom. Subsequently, the certification responsibility was transferred to RRD and Revision 1 and Revision 2 were reclassified to "Recommended" by the Luftfahrt-Bundesamt (LBA), which is the aviation authority for Germany.

Differences Between This Proposed AD and the Manufacturer's Service Information

The RRD SB No. TAY–72–1485, Revision 2, dated March 21, 2003 specifies compliance times based on the date of receipt of the SB. We have mandated compliance times based on the effective date of this proposed AD.

At initial inspection, if the HPC shaft or HPT shaft has accumulated 3,000 flight cycles or more, RRD SB No. TAY–72–1485, dated January 11, 2002, specifies compliance within 12 months. At initial inspection, if the HPC shaft or HPT shaft has accumulated 3,000 flight cycles or more, we specify compliance within six months from the effective date of the final rule.

FAA's Determination and Requirements of the Proposed AD

This engine model, manufactured in Germany, is type-certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. In keeping with this bilateral airworthiness agreement, the CAA and LBA have kept us informed of the situation described above. We have examined the findings of the CAA and LBA, reviewed all available information, and determined that AD action is necessary for products

of this type design that are certificated for operation in the United States. We are proposing this AD, which would require inspecting the spline flanks on the HPC shaft and HPT shaft for wear. The proposed AD would require you to use the service information described previously to perform these actions.

Costs of Compliance

There are about 390 RRD Tay 650–15 series turbofan engines of the affected design in the worldwide fleet. We estimate that 172 engines installed on airplanes of U.S. registry would be affected by this proposed AD. We also estimate that it would take about 4 work hours per engine to perform the proposed actions, and that the average labor rate is $65 per work hour. Based on these figures, we estimate the total cost of the proposed AD to U.S. operators, per inspection cycle, to be $44,720. We also estimate, for the HPC shaft of 172 engines to be replaced at teardown, with a parts cost of approximately $13,862 per shaft, the total cost of the proposed AD to U.S. operators to be $2,384,264.

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. Would 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 proposal and placed it in the AD Docket. You may get a copy of this summary at the address listed under **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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 Federal Aviation Administration (FAA) amends § 39.13 by adding a new airworthiness directive (AD) to read as follows:

Roll-Royce Deutschland Ltd & Co KG (RRD) (Formerly Rolls-Royce plc): Docket No. FAA–2004–19157; Directorate Identifier 2004–NE–30–AD.

Comments Due Date

(a) The FAA must receive comments on this AD action by December 3, 2004.

Affected ADs

(b) None.

Applicability

(c) This AD applies to RRD Tay 650–15 series turbofan engines. These engines are installed on, but not limited to, Fokker F100 airplanes.

Unsafe Condition

(d) This AD results from a number of occurrences of excessive high pressure compressor (HPC) and high pressure turbine (HPT) shaft spline wear and spline flank wear discovered during on-wing and in-shop inspections. We are issuing this AD to prevent spline disengagement resulting in an overspeed event, which could lead to an uncontained engine failure and possible damage to 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.

Initial Visual Inspection of the HPC Shaft and HPT Shaft Splines

(f) Within the compliance times specified in Table 1 of this AD, perform initial inspections of the HPC shaft splines and HPT shaft splines of RRD Tay 650–15 series turbofan engines. Use paragraph 3.A. of Accomplishment Instructions of RRD Service Bulletin (SB) No. TAY–72–1485, Revision 2, dated March 21, 2003, to do the inspections. Calculate spline wear using Appendix 1, paragraph 4.K., of RRD SB No. TAY–72–1485, Revision 2, dated March 21, 2003.

TABLE 1.—HPC SHAFT SPLINES AND HPT SHAFT SPLINES INSPECTION SCHEDULE

Current shaft life	Action
(1) If the HPC shaft or HPT shaft has accumulated 3,000 cycles-since-new (CSN) or more on the effective date of this AD.	Inspect HPC shaft splines and HPT shaft splines for wear within six months after the effective date of this AD, unless previously done.
(2) If the HPC shaft or HPT shaft has accumulated fewer than 3,000 CSN on the effective date of this AD.	Wait until the HPC shaft or HPT shaft has accumulated 3,000 flight cycles, then inspect the HPC shaft splines and HPT shaft splines for wear within 300 cycles-since-last visual inspection (CSLI) or remainder of 12 months from the effective date of this AD, whichever is greater.

(g) Disposition the HPC shaft, HPT shaft, or engine as specified in Table 2 of this AD.

TABLE 2.—VISUAL INSPECTION CRITERIA

Inspection limits	Disposition
(1) If spline wear is 0.1 inch or greater	Remove engine from service within 50 cycles-since-last visual inspection CSLI).
(2) If spline wear is greater than or equal to 0.06 inch but less than 0.1 inch.	Remove engine from service within 500 CSLI.
(3) If spline wear is greater than or equal to 0.03 inch but less than 0.06 inch..	Inspect HPC shaft and HPT shaft using the intervals in paragraph (h)(1) of this AD.

TABLE 2.—VISUAL INSPECTION CRITERIA—Continued

Inspection limits	Disposition
(4) If spline wear is less than 0.03 inch	Inspect HPC shaft and HPT shaft using the intervals in paragraph (h)(2) of this AD.

Repetitive Visual Inspection of the HPC Shaft and HPT Shaft Splines

(h) Perform repetitive inspections of the HPC shaft splines and HPT shaft splines of RRD Tay 650–15 series turbofan engines. Use paragraph 3.A. of Accomplishment Instructions with Appendix 1 of RRD SB No. TAY–72–1485, Revision 2, dated March 21, 2003, to do the inspections. Calculate spline wear using Appendix 1, paragraph 4.K., of RRD SB No. TAY–72–1485, Revision 2, dated March 21, 2003.

(1) If wear measured in paragraph (f) of this AD was greater than or equal to 0.03 inch but less than 0.06 inch, repetitively inspect HPC shaft and HPT shaft within 1,000 cycles-since-last visual inspection (CSLI).

(2) If wear measured in paragraph (f) of this AD was less than 0.03 inch, repetitively inspect HPC shaft and HPT shaft within 5,500 CSLI.

(i) Disposition the HPC shaft, HPT shaft, or engine as specified in Table 2 of this AD.

Previous Credit

(j) Previous credit is allowed for performing the initial inspections in paragraph (f) of this AD, that were done using the Accomplishment Instructions of one of the following, before the effective date of this AD:

(1) SB No. TAY–72–1485, dated January 11, 2002;

(2) SB No. TAY–72–1485, Revision 1, dated January 29, 2003; and

(3) SB No. TAY–72–1485, Revision 2, dated March 21, 2003.

Material Incorporated by Reference

(k) None.

Related Information

(l) Civil Aviation Authority (CAA) airworthiness directive 001–01–2002, dated January 11, 2002, also addresses the subject of this AD.

Issued in Burlington, Massachusetts, on September 24, 2004.

Francis A. Favara,

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

[FR Doc. 04–22192 Filed 10–1–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–19228; Directorate Identifier 2004–NM–77–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 707 Airplanes and Model 720 and 720B 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 all Boeing Model 707 airplanes and Model 720 and 720B series airplanes. This proposed AD would require repetitive inspections of the left and right support ribs for the main landing gear (MLG) trunnion, related investigative/corrective actions if necessary, and other specified actions. This proposed AD is prompted by reports of in-service cracking of the support ribs for the MLG trunnion. We are proposing this AD to detect and correct corrosion and cracking of the support ribs for the MLG trunnion, which could result in collapse of the MLG.

DATES: We must receive comments on this proposed AD by November 18, 2004.

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 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: 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.

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–2004–19228; Directorate Identifier 2004–NM–77–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 of in-service cracking of the support ribs for the main landing gear (MLG) trunnion on Boeing Model 707 airplanes and Model 720 and 720B series airplanes. Investigation revealed that the cracking was caused by stress corrosion. This condition, if not corrected, could result in collapse of the MLG.

Relevant Service Information

We have reviewed Boeing 707 Alert Service Bulletin A3510, dated January 15, 2004. Part I of the Accomplishment Instructions of the alert service bulletin describes procedures for doing a repetitive detailed inspection of the left and right support ribs for the MLG trunnion and related investigative/corrective and other specified actions. The inspection areas include both sides of the rib flanges, the web, the flange radius, and the support rib. The procedures include:

- Removing all corrosion inhibiting compound and sealant from the inspection areas.
- Removing the finish and blending the area smooth if deterioration, discoloration, blistering, wear, scratches, or raised rough/cracked areas in the surface finish are found.
- Contacting Boeing if blending into the base metal is necessary.
- Mechanically removing any corrosion.
- Contacting Boeing for repair information if any cracking is found.
- Applying cadmium plating to all areas where the surface finish was removed.
- Applying corrosion inhibitor to all exposed surfaces of the support fitting for the MLG trunnion.

Part II of the Accomplishment Instructions of the alert service bulletin includes procedures for doing a repetitive HFEC inspection of the left and right support ribs for the MLG trunnion, and corrective and other specified actions. The inspection areas include both sides of the web flange, the flange radius, the area around all bolt heads/nuts and fastener heads/collars for the upper and lower chords, and the rib around the edge of the support fitting for the MLG trunnion. The corrective and other specified actions include:

- Removing all corrosion inhibiting compound and sealant from the inspection areas.
- Contacting Boeing for repair information if any cracking is found.
- Applying cadmium plate to all areas where the surface finish was removed.
- Applying corrosion inhibitor to all exposed surfaces of the support fitting for the MLG trunnion, both sides of the flange radius of the upper and lower chords, and the rib supports.

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 repetitive inspections for corrosion and cracking of the left and right support ribs for the main landing gear (MLG) trunnion, related investigative/corrective actions if necessary, and other specified actions. The proposed AD would require you to use the service information described previously to perform these actions, except as discussed under "Differences Between the Proposed AD and Service Information."

Differences Between the Proposed AD and Service Information

The alert service bulletin specifies that the manufacturer may be contacted for disposition of certain repair conditions. This proposed AD would require the repair of those conditions in accordance with a method that we have approved or in accordance with data meeting the type certification basis of the airplane approved by a Boeing Company Designated Engineering Representative whom we have authorized to make such findings.

Costs of Compliance

This proposed AD would affect about 227 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
Inspection, per inspection cycle	6	$65	None	$390, per inspection cycle	32	$12,480, per inspection cycle.

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–2004–19228; Directorate Identifier 2004–NM–77–AD.

Comments Due Date

(a) The Federal Aviation Administration (FAA) must receive comments on this AD action by November 18, 2004.

Affected ADs

(b) None.

Applicability

(c) This AD applies to all Boeing Model 707–100 long body, –200, –100B long body, and –100B short body series airplanes; and Model 707–300, –300B, –300C, and –400 airplanes; and Model 720 and 720B series airplanes; certificated in any category.

Unsafe Condition

(d) This AD was prompted by reports of in-service cracking of the support ribs for the main landing gear (MLG) trunnion. We are proposing this AD to detect and correct corrosion and cracking of the support ribs for the MLG trunnion, which could result in collapse of the MLG.

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 "alert service bulletin," as used in this AD, means the Accomplishment Instructions of Boeing 707 Alert Service Bulletin A3510, dated January 15, 2004.

Repetitive Detailed Inspection and Corrective Action

(g) Within 6 months after the effective date of this AD: Do a detailed inspection for corrosion and cracking of the left and right support ribs of the MLG trunnion. Do the inspection in accordance with all of the actions in Part I of the alert service bulletin. Repeat the inspection thereafter at intervals not to exceed 6 months.

(h) If any corrosion or cracking is found during any inspection required by paragraph (g) of this AD: Before further flight, do all applicable related investigative and corrective actions, and the other specified actions, in accordance with the alert service bulletin; except, where the alert service bulletin specifies to contact Boeing, before further flight, repair in accordance with a method approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA; or in accordance with data meeting the type certification basis of the airplane approved by a Boeing Designated Engineering Representative (DER) who has been authorized by the Manager, Seattle ACO, to make such findings. For a repair method to be approved by the Manager, Seattle ACO, as required by this paragraph, the approval letter must specifically reference this AD.

Repetitive High Frequency Eddy Current (HFEC) Inspection and Corrective Action

(i) Within 12 months after the effective date of this AD: Do a HFEC inspection for cracking of the left and right support ribs of the MLG trunnion. Do the inspection in accordance with all of the actions in Part II of the alert service bulletin. Repeat the inspection thereafter at intervals not to exceed 12 months.

(j) If cracking is found during any inspection required by paragraph (i) of this AD: Before further flight, repair the cracked area in accordance with a method approved by the Manager, Seattle ACO; or in accordance with data meeting the type certification basis of the airplane approved by a Boeing 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 refer to this AD.

Alternative Methods of Compliance (AMOCs)

(k)(1) The Manager, Seattle ACO, 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.

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

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–22268 Filed 10–1–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–19227; Directorate Identifier 2003–NM–95–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A300 B2 and B4 Series Airplanes; Model A300 B4–600, A300 B4–600R, C4–605R Variant F, and A300 F4–600R (Collectively Called A300–600) Series Airplanes; and Model A310 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede an existing airworthiness directive (AD) that applies to certain Airbus Model A300 B2 and B4 series airplanes; Model A300 B4–600, A300 B4–600R, C4–605R Variant F, and A300 F4–600R (collectively called A300–600) series airplanes; and Model A310 series airplanes. The existing AD currently requires replacement of the transformer rectifier units (TRUs) in the avionics compartment with new, improved TRUs. This proposed AD would require replacement of the TRUs installed according to the existing AD with different TRUs that are improved. This proposed AD is prompted by analysis that has revealed that certain diodes installed in the TRUs are the main factor contributing to the continuing TRU failures. We are proposing this AD to prevent failure of the TRUs. Failure of multiple TRUs could result in loss of the thrust reversers, autothrottle, flaps, and various systems (wing/cockpit window anti-ice, trim tank pumps, and windshield wipers) on the airplane; or display of incorrect information to the flightcrew.

DATES: We must receive comments on this proposed AD by November 3, 2004.

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.
- 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 Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France.

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: Tim Backman, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2797; fax (425) 227–1149.

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–2004–19227; Directorate Identifier 2003–NM–95–AD" at the beginning 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 received 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 our docket 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 the 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

On August 31, 2000, we issued AD 2000–18–07, amendment 39–11892 (65 FR 54407, September 8, 2000), for certain Airbus Model A300, A300–600, and A310 series airplanes. That AD requires replacement of the transformer rectifier units (TRUs) in the avionics compartment with new, improved TRUs (having part number (P/N) F11QY3121). That AD was prompted by issuance of mandatory continuing airworthiness information by a foreign civil airworthiness authority. We issued that AD to prevent failure of the TRUs. Failure of multiple TRUs could result in loss of the thrust reversers, autothrottle, flaps, and various systems (wing/cockpit window anti-ice, trim tank pumps, and windshield wipers) on the airplane; or incorrect information being displayed to the flightcrew.

Actions Since Existing AD Was Issued

Since we issued AD 2000–18–07, the Direction Générale de l'Aviation Civile (DGAC), which is the airworthiness authority for France, has informed the FAA that failures have continued to occur on the TRUs having P/N F11QY3121, which were installed according to French airworthiness directive 1999–435–296(B), dated November 3, 1999. (French airworthiness directive 1999–435–296(B) is the parallel French airworthiness directive to AD 2000–18–07.) Analysis of these failures by the airplane manufacturer has revealed that certain diodes installed in the TRUs having P/N F11QY3121 are the main factor contributing to the continuing TRU failures.

Relevant Service Information

Airbus has issued Service Bulletins A300–24–0099, A300–24–6082, and A310–24–2088, all Revision 01, all dated December 18, 2003. These service bulletins describe procedures for replacing existing TRUs, having P/N F11QY3121, with new, improved TRUs, having P/N F11QY3714. Accomplishing the actions specified in the service information is intended to adequately address the unsafe condition. The DGAC mandated the service information and issued French airworthiness directive 2003–082R1, dated March 31, 2004, to ensure the continued airworthiness of these airplanes in France.

The Airbus service bulletins refer to Thales Service Bulletin F11QY3121–24–003, dated October 15, 2002, as an additional source of service information for modifying the existing TRUs to the improved configuration. Thales Service Bulletin F11QY3121–24–003 specifies that Thales Service Bulletins F11QY3121–24–001, dated February 2, 1998; and F11QY3121–24–002, dated October 5, 2000; must be done prior to or concurrent with Thales Service Bulletin F11QY3121–24–003. Those service bulletins modify TRUs having P/N F11QY3121 to include Amendments A and B, respectively. Thales Service Bulletin F11QY3121–24–003 modifies TRU P/Ns F11QY3121 with Amendments A and B, to P/N F11QY3714 (which is the P/N for the improved parts that the Airbus service bulletins recommend installing).

FAA's Determination and Requirements of the Proposed AD

These airplane models are manufactured in France and are type certificated for operation in the United States under the provisions of section

21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the DGAC has kept the FAA informed of the situation described above. We have examined the DGAC's findings, evaluated all pertinent information, and determined that AD action is necessary for airplanes of this type design that are certificated for operation in the United States.

Therefore, we are proposing this AD, which would supersede AD 2000–18–07 to require replacing existing TRUs with new, improved TRUs. The proposed AD would require you to use the Airbus service information described previously to perform these actions.

Difference Between the French Airworthiness Directive and This Proposed AD

The applicability of French airworthiness directive 2003–082R1 excludes airplanes on which Airbus Service Bulletin A300–24–0099 (for Model A300 B2 and B4 series airplanes), A300–24–6082 (for Model A300–600 series airplanes), or A310–24–2088 (for Model A310 series airplanes), has been accomplished in service. However, we have not excluded those airplanes from the applicability of this proposed AD. Rather, this proposed AD would include a requirement to accomplish the actions specified in those service bulletins. Such a requirement ensures that the actions specified in the service bulletins and that would be required by this proposed AD are accomplished on all affected airplanes. Operators must continue to operate the airplane in the configuration that would be required by this proposed AD unless an alternative method of compliance is approved.

Clarification of Inspections Referenced in Thales Service Bulletin

The Accomplishment Instructions of Thales Service Bulletin F11QY3121–24–003 specify to "complete implementation of the [Service Information Letter] SIL F11QY3121–24–004." We reviewed that Thales Service Information Letter (SIL), which contains recommendations about TRU overhaul. We have coordinated this issue with Airbus, and they have clarified that it was not their intent to require the recommendations in the SIL. Therefore, this proposed AD does not require doing the SIL.

Explanation of Change to Applicability

We have revised the applicability of the existing AD to identify model designations as published in the most recent type certificate data sheet for the affected models.

Costs of Compliance

This proposed AD would affect about 165 airplanes of U.S. registry.

The new proposed actions would take about 2 work hours per airplane, at an average labor rate of $65 per work hour. The parts manufacturer would provide required parts free of charge. Based on these figures, the estimated cost of the new actions specified in this proposed AD for U.S. operators is $21,450, or $130 per airplane.

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 removing 39–11892 (65 FR 54407, September 8, 2000) and adding the following new airworthiness directive (AD):

Airbus: Docket No. FAA–2004–19227; Directorate Identifier 2003–NM–95–AD.

Comments Due Date

(a) The Federal Aviation Administration must receive comments on this AD action by November 3, 2004.

Affected ADs

(b) This AD supersedes AD 2000–18–07, amendment 39–11892.

Applicability

(c) This AD applies to Model A300 B2 and B4 series airplanes; Model A300 B4–600, A300 B4–600R, C4–605R Variant F, and A300 F4–600R (collectively called A300–600) series airplanes; and Model A310 series airplanes; certificated in any category; except those on which Airbus Modification 12540 has been accomplished.

Unsafe Condition

(d) This AD was prompted by analysis that has revealed that certain diodes installed in the transformer rectifier units (TRUs) are the main factor contributing to the continuing TRU failures. We are issuing this AD to prevent failure of multiple TRUs, which could result in loss of the thrust reversers, autothrottle, flaps, and various systems (wing/cockpit window anti-ice, trim tank pumps, and windshield wipers) on the airplane; or display of incorrect information to the flightcrew.

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 TRUs

(f) Within 36 months after the effective date of this AD, replace the existing TRUs, having P/N F11QY3121, in the avionics compartment with new, improved TRUs having P/N F11QY3714, according to the Accomplishment Instructions of Airbus Service Bulletin A300–27–0099 (for Model A300 B2 and B4 series airplanes), A300–24–6082 (for Model A300–600 series airplanes), or A310–24–2088 (for Model A310 series airplanes); all Revision 01; all dated December 18, 2003; as applicable.

Note 1: Airbus Service Bulletin A300–27–0099, A300–24–6082, or A310–24–2088; all Revision 01; refer to Thales Service Bulletin F11QY3121–24–003, dated October 15, 2002, as an additional source of service information for modifying the existing TRUs to the improved configuration. Thales Service Bulletin F11QY3121–24–003 specifies that Thales Service Bulletins F11QY3121–24–001, dated February 2, 1998; and F11QY3121–24–002, dated October 5, 2000; must be done to add Amendments A and B, respectively, to P/N F11QY3121 before the TRU can be modified to P/N F11QY3714 according to Thales Service Bulletin F11QY3121–24–003.

Note 2: The Accomplishment Instructions of Thales Service Bulletin F11QY3121–24–003 specify to "complete implementation of the [Service Information Letter] SIL F11QY3121–24–004." This AD does not require doing the Service Information Letter.

Actions Accomplished Previously

(g) Replacements done before the effective date of this AD according to Airbus Service Bulletin A300–27–0099 (for Model A300 B2 and B4 series airplanes), A300–24–6082 (for Model A300–600 series airplanes), or A310–24–2088 (for Model A310 series airplanes); dated October 11, 2002; as applicable; are acceptable for compliance with the corresponding action required by paragraph (a) of this AD.

Alternative Methods of Compliance (AMOCs)

(h) 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.

Related Information

(i) French airworthiness directive 2003–082R1, dated March 31, 2004, also addresses the subject of this AD.

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

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–22267 Filed 10–1–04; 8:45 am]

BILLING CODE 4910–13–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 261

[SW FRL–7823–9]

Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Proposed Exclusion

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule and request for comment.

SUMMARY: EPA is proposing to grant a petition submitted by Bayer Polymers (Bayer) to exclude (or delist) a certain solid waste generated by its Baytown, Texas, facility from the lists of hazardous wastes.

EPA used the Delisting Risk Assessment Software (DRAS) in the evaluation of the impact of the petitioned waste on human health and the environment.

EPA bases its proposed decision to grant the petition on an evaluation of waste-specific information provided by the petitioner. This proposed decision, if finalized, would exclude the petitioned waste from the requirements of hazardous waste regulations under the Resource Conservation and Recovery Act (RCRA).

If finalized, EPA would conclude that Bayer's petitioned waste is nonhazardous with respect to the original listing criteria and that the generation of K027, K104, K111, and K112 treated effluent from the facility's waste water treatment plant will not be hazardous at the point of generation because of the adequately reduces the likelihood of migration of constituents from this waste. EPA would also conclude that Bayer's process minimizes short-term and long-term threats from the petitioned waste to human health and the environment.

DATES: EPA will accept comments until November 3, 2004. EPA will stamp comments received after the close of the comment period as late. These late comments may not be considered in formulating a final decision. Your requests for a hearing must reach EPA by October 19, 2004. The request must contain the information prescribed in 40 CFR 260.20(d).

ADDRESSES: Please send three copies of your comments. You should send two copies to the Chief, Corrective Action and Waste Minimization Section (6PD–C), Multimedia Planning and Permitting Division, U. S. Environmental Protection Agency Region 6, 1445 Ross Avenue, Dallas, Texas 75202. You should send a third copy to the Texas Commission on Environmental Quality, P.O. Box 13087, Austin, TX 78712. Identify your comments at the top with this regulatory docket number: [R6–TXDEL–FY04–Bayer]. You may submit your comments electronically to Michelle Peace at *peace.michelle@epa.gov.*

You should address requests for a hearing to Ben Banipal, Chief, Corrective Action and Waste Minimization Section (6PD–C), Multimedia Planning and Permitting Division, U.S. Environmental Protection Agency Region 6, 1445 Ross Avenue, Dallas, Texas 75202.

FOR FURTHER TECHNICAL INFORMATION CONTACT: Michelle Peace (214) 665–7430.

SUPPLEMENTARY INFORMATION:

The information in this section is organized as follows:

I. Overview Information

A. What Action Is EPA Proposing?

EPA is proposing to grant the delisting petition submitted by Bayer to have its Outfall 007 Treated Effluent (K027, K104, K111, and K112 listed hazardous waste) excluded, or delisted, from the definition of a hazardous waste.

B. Why Is EPA Proposing To Approve This Delisting?

Bayer's petition requests a delisting for the treated effluent derived from the treatment of hazardous waste water listed as K027, K104, K111, and K112 and non-hazardous waste water identified as brine header waste water. Bayer does not believe that the petitioned waste meets the criteria for which EPA listed it. Bayer also believes no additional constituents or factors could cause the waste to be hazardous. EPA's review of this petition included consideration of the original listing criteria, and the additional factors required by the Hazardous and Solid Waste Amendments of 1984 (HSWA). See Section 3001(f) of RCRA, 42 U.S.C. 6921(f), and 40 CFR 260.22 (d)(1)–(4). In making the initial delisting

determination, EPA evaluated the petitioned waste against the listing criteria and factors cited in § 261.11(a)(2) and (a)(3). Based on this review, EPA agrees with the petitioner that the waste is nonhazardous with respect to the original listing criteria. (If EPA had found, based on this review, that the waste remained hazardous based on the factors for which the waste was originally listed, EPA would have proposed to deny the petition.) EPA evaluated the waste with respect to other factors or criteria to assess whether there is a reasonable basis to believe that such additional factors could cause the waste to be hazardous. EPA considered whether the waste is acutely toxic, the concentration of the constituents in the waste, their tendency to migrate and to bioaccumulate, their persistence in the environment once released from the waste, plausible and specific types of management of the petitioned waste, the quantities of waste generated, and waste variability. EPA believes that the petitioned waste does not meet the listing criteria and thus should not be a listed waste. EPA's proposed decision to delist waste from the Bayer facility is based on the information submitted in support of this rule, including descriptions of wastes and analytical data from the Baytown, Texas facility.

C. How Will Bayer Manage the Waste, if it Is Delisted?

Bayer currently discharges the treated effluent as permitted by its Texas Pollutant Discharge Elimination System (TPDES) permit. If the delisting exclusion is finalized, Bayer intends to dispose of the petitioned waste (*i.e.*, treated effluent) in the same manner. This delisting does not relieve Bayer of its responsibility to comply with and conduct all tests required by its TPDES permit. The waste would be delisted in the Outfall Tank prior to its discharge from Outfall 007.

D. When Would the Proposed Delisting Exclusion Be Finalized?

RCRA section 3001(f) specifically requires EPA to provide notice and an opportunity for comment before granting or denying a final exclusion. Thus, EPA will not grant the exclusion unless and until it addresses all timely public comments (including those at public hearings, if any) on this proposal.

RCRA section 3010(b)(1) at 42 USCA 6930(b)(1), allows rules to become effective in less than six months after EPA addresses public comments when the regulated facility does not need the six-month period to come into compliance. That is the case here, because this rule, if finalized, would reduce the existing requirements for persons generating hazardous wastes.

EPA believes that this exclusion should be effective immediately upon final publication because a six-month deadline is not necessary to achieve the purpose of section 3010(b), and a later effective date would impose unnecessary hardship and expense on this petitioner. These reasons also provide good cause for making this rule effective immediately, upon final publication, under the Administrative Procedure Act, 5 U.S.C. 553(d).

E. How Would This Action Affect the States?

Because EPA is issuing this exclusion under the Federal RCRA delisting program, only States subject to Federal RCRA delisting provisions would be affected. This would exclude States who have received authorization from EPA to make their own delisting decisions.

EPA allows the States to impose their own non-RCRA regulatory requirements that are more stringent than EPA's, under section 3009 of RCRA, 42 U.S.C. 6929. These more stringent requirements may include a provision that prohibits a Federally issued exclusion from taking effect in the State. Because a dual system (that is, both Federal (RCRA) and State (non-RCRA) programs) may regulate a petitioner's waste, EPA urges petitioners to contact the state regulatory authority to establish the status of their wastes under the State law. Delisting petitions approved by EPA Administrator under 40 CFR 260.22 are effective in the State of Texas only after the final rule has been published in the **Federal Register**.

II. Background

A. What Is the History of the Delisting Program?

EPA published an amended list of hazardous wastes from nonspecific and specific sources on January 16, 1981, as part of its final and interim final regulations implementing section 3001 of RCRA. EPA has amended this list several times and published it in §§ 261.31 and 261.32. EPA lists these wastes as hazardous because: (1) They typically and frequently exhibit one or more of the characteristics of hazardous wastes identified in Subpart C of Part 261 (that is, ignitability, corrosivity, reactivity, and toxicity) or (2) they meet the criteria for listing contained in § 261.11(a)(2) or (a)(3).

Individual waste streams may vary, however, depending on raw materials, industrial processes, and other factors. Thus, while a waste described in these regulations generally is hazardous, a specific waste from an individual facility meeting the listing description may not be hazardous.

For this reason, §§ 260.20 and 260.22 provide an exclusion procedure, called delisting, which allows persons to prove that EPA should not regulate a specific waste from a particular generating facility as a hazardous waste.

B. What Is a Delisting Petition, and What Does it Require of a Petitioner?

A delisting petition is a request from a facility to EPA or an authorized State to exclude wastes from the list of hazardous wastes. The facility petitions EPA because it does not believe the wastes should be hazardous under RCRA regulations.

In a delisting petition, the petitioner must show that wastes generated at a particular facility do not meet any of the criteria for which the waste was listed. The criteria for which EPA lists a waste are in Part 261 and further explained in the background documents for the listed waste.

In addition, under § 260.22, a petitioner must prove that the waste does not exhibit any of the hazardous waste characteristics (that is, ignitability, reactivity, corrosivity, and toxicity) and present sufficient information for EPA to decide whether factors other than those for which the waste was listed warrant retaining it as a hazardous waste. See Part 261 and the background documents for the listed waste.

Generators remain obligated under RCRA to confirm whether their waste remains nonhazardous based on the hazardous waste characteristics even if EPA has "delisted" the waste.

C. What Factors Must EPA Consider in Deciding Whether To Grant a Delisting Petition?

Besides considering the criteria in § 260.22(a) and section 3001(f) of RCRA, 42 U.S.C. 6921(f), and in the background documents for the listed wastes, EPA must consider any factors (including additional constituents) other than those for which EPA listed the waste, if a reasonable basis exists that these additional factors could cause the waste to be hazardous.

EPA must also consider as hazardous waste mixtures containing listed hazardous wastes and wastes derived from treating, storing, or disposing of listed hazardous waste. See § 261.3(a)(2)(iii) and (iv) and (c)(2)(i), called the "mixture" and "derived-from" rules, respectively. These wastes are also eligible for exclusion and remain hazardous wastes until

excluded. See 66 FR 27266 (May 16, 2001).

III. EPA's Evaluation of the Waste Information and Data

A. What Waste Did Bayer Petition EPA To Delist?

On June 25, 2003, Bayer petitioned EPA to exclude from the lists of hazardous waste contained in §§ 261.31 and 261.32, the treated effluent that is discharged pursuant to Bayer's TPDES permit. The discharge originates at Outfall 007 and is piped to the discharge location described as the "diffuser near Hog Island into the Houston Ship Channel." The waste stream is generated from the Bayer facility located in Baytown, Texas. The waste (EPA Hazardous Waste Nos. K027, K104, K111, and K112) is effluent, which has been treated at the facility's waste water treatment plant and is ultimately discharged to Outfall 007 in accordance with the facility's TPDES permit. Specifically, in its petition, Bayer requested that EPA grant an exclusion for 18,071.150 cubic yards (5.745 billion gallons) per calendar year of treated effluent resulting from the treatment of waste waters from the manufacturing processes at its facility.

B. Who Is Bayer and What Process Do They Use to Generate the Petition Waste?

Bayer produces plastics, coatings, polyurethanes, and industrial chemicals. Bayer is the first facility in the United States to employ Tower Biology, an onsite waste water treatment plant (the plant) process that uses bacteria to treat waste above ground to protect ground water resources. The waste waters treated at the plant are generated by the various manufacturing operations at the Baytown facility. Influent waste waters enter the plant via the "normal waste water header" or the "brine waste water header." The waste water entering the plant via the normal waste water header is placed in the primary clarifier. From the primary clarifier, the waste water is placed in a tank that feeds the waste water to a denitrification reactor prior to treatment in the biological oxidation towers. Following biological treatment, the waste water is run through a secondary clarifier. Waste water from the clarifier is sent to an activated carbon absorption system. Upon exiting the carbon absorption system, the waste water is fed to a series of filters. After filtration, the treated waste water is placed in an outfall tank for subsequent discharge under Bayer's TPDES discharge permit.

Influent waste waters that enter the plant via the "brine waste water header" are placed in dedicated brine tanks and a brine carbon absorption system. After filtration, the brine waste water is commingled in the outfall tank with the treated normal waste water prior to being discharged in accordance with the Bayer TPDES discharge permit.

Treatment of the waste waters, which result from the manufacturing process generates the effluent that is classified as K027, K104, K111, and K112 listed hazardous wastes pursuant to 40 CFR § 261.31. The 40 CFR Part 261 Appendix VII hazardous constituents which are the basis for listing K027, K104, K111, and K112 hazardous wastes are: toluene diisocyanate, aniline, benzene, diphenylamine, nitrobenzene, phenylenediamine, 2,4-dinitrotoluene, 2,4-toluenediamine, o-toluidine, and p-toluidine.

C. What Information Did Bayer Submit To Support This Petition?

To support its petition, Bayer submitted:

(1) Results of the total constituent analysis for volatile and semivolatile organics, pesticides, herbicides, dioxins/furans, PCBs and metals for six samples.

(2) Descriptions of the waste water treatment process and effluent.

D. What Were the Results of Bayer's Analyses?

EPA believes that the descriptions of Bayer's waste water treatment process, in addition to the analytical data submitted in support of the petition show that the treated effluent is nonhazardous. Analytical data from Bayer's treated effluent samples were used in the Delisting Risk Assessment Software. The data summaries for detected constituents are presented in Table 1. EPA has reviewed the sampling procedures used by Bayer and has determined they satisfy EPA's criteria for collecting representative samples of the variations in constituent concentrations in the treated effluent. The data submitted in support of the petition show that constituents in Bayer's waste is presently below health-based risk levels used in the delisting decision-making. EPA believes that Bayer has successfully demonstrated that the treated effluent is nonhazardous.

TABLE 1.—MAXIMUM TOTAL CONSTITUENT CONCENTRATIONS OF THE TREATED EFFLUENT AND CORRESPONDING DELISTING LIMITS [1]

Chemical name	Waste stream total concentration (mg/kg)	Maximum allowable concentration (mg/kg)
Phenylenediamine, m-	5.00E–02	8.79E–01
Bis(2-ethylhexyl)phthalate	1.94E–03	1.26E+03
Di-n-octyl phthalate	2.50E–03	4.54E+02
Dinitrotoluene, 2,4-	1.50E–03	4.51E–03
Diphenylamine	1.50E–03	1.18E+01
Dioxane, 1,4-	1.40E+00	1.76E+00
Pyrene	2.00E–03	3.90E+01
Fluoranthene	2.50E–03	2.46E+01
Cyanide	2.84E–02	4.60E–01
Aniline	2.56E–03	6.80E–01
Tetrachloroethane, 1,1,1,2-	1.00E–03	7.03E–01
Acetone	2.80E+00	1.46E+01
Chloroform	1.40E–02	7.70E–02
Benzene	3.00E–03	5.90E–02
Mercury	6.80E–04	3.23E–02
Nickel	9.16E–02	1.13E+01
Thallium	5.00E–03	3.34E–02
Antimony	7.10E–03	8.16E–02
Arsenic	8.20E–03	3.85E–01

TABLE 1.—MAXIMUM TOTAL CONSTITUENT CONCENTRATIONS OF THE TREATED EFFLUENT AND CORRESPONDING DELISTING LIMITS [1]—Continued

Chemical name	Waste stream total concentration (mg/kg)	Maximum allowable concentration (mg/kg)
Barium	1.04E–01	2.22E+01
Chromium	9.10E–03	1.53E+02
Copper	1.02E–01	3.62E+03
Vanadium	1.38E–02	8.38E+00
Zinc	8.33E–02	1.12E+02
Methylene chloride	1.00E–03	2.90E–02
Bromodichloromethane	2.00E–03	7.19E–02
Selenium	9.10E–03	2.30E–01
Methyl ethyl ketone	1.00E–02	8.79E+01
Di-n-butyl phthalate	2.08E–03	1.49E+02
Toluidine, o-	2.00E–03	1.71E–02
Acetophenone	8.90E–04	1.58E+01
Toluidine, p-	1.50E–03	2.15E–02
Toluene diisocyanate	<1.0 E–02	1.0E–02
Nitrobenzene	1.50E–03	7.88E–02
2,4 toluenediamine	<1.0 E–02	1.21E–03

[1] These levels represent the highest concentration of each constituent found in any one sample. These levels do not necessarily represent the specific levels found in one sample.

< Denotes that the constituent was below the detection limit. Concentrations reported below detect are not believed to be present in the waste.

E. How Did EPA Evaluate the Risk of Delisting This Waste?

For this delisting determination, we assumed that the most reasonable, worst case scenario would be if the effluent were disposed in a surface impoundment and we considered transport of waste constituents through ground water, surface water and air.

We evaluated Bayer's petitioned waste using the Agency's Delisting Risk Assessment Software (DRAS) to predict the concentration of hazardous constituents that might be released from the petitioned waste and to determine if the waste would pose a threat. The DRAS uses EPA's Composite Model for leachate migration with Transformation Products (EPACMTP) to predict the potential for release to groundwater from the wastes and subsequent routes of exposure to a receptor. From a release to ground water, we considered routes of exposure to a human receptor via ingestion of contaminated ground water, inhalation from ground water via showering and dermal contact while bathing. The DRAS program evaluates the subsequent routes of exposure to a human receptor from such releases through exposure pathways of fish ingestion and ingestion of drinking water. The DRAS also considers releases of waste particles and volatile emissions to air from the surface of an open impoundment. From a release to air, we considered as routes of exposure of inhalation of particulates and absorption into the lungs; ingestion of particulates eliminated from respiratory passages and subsequently swallowed, air deposition of particulates and subsequent ingestion of the soil/waste mixture; and inhalation of volatile constituents.

We used the maximum estimated waste volume and the maximum reported total concentration to estimate the constituent concentrations in the ground water, soil, surface water and/or air.

Assuming a cancer risk of 1×10^{-5} and a hazard quotient of one, the DRAS program back calculated a maximum allowable concentration level which did not exceed protective levels in the waste for each constituent at the given annual waste volume of 18,071,150 cubic yards (5.475 billion gallons).

F. What Did EPA Conclude About Bayer Analysis?

EPA concluded, after reviewing Bayer's waste water treatment process that no other hazardous constituents of concern, other than those for which tested, are likely to be present or formed as reaction products or by-products in Bayer's wastes. In addition, on the basis of explanations and analytical data provided by Bayer, pursuant to § 260.22, EPA concludes that the effluent does not exhibit any of the characteristics of ignitability, corrosivity, reactivity, or toxicity. See §§ 261.21, 261.22 ,261.23, and 261.24 respectively.

G. What Other Factors Did EPA Consider in Its Evaluation?

During the evaluation of this petition, EPA also considered the potential impact of the petitioned waste via non-ground water routes (*i.e.*, air emissions and surface runoff) for the treated effluent. With regard to airborne dispersion in particular, EPA believes that exposure to airborne contaminants from the petitioned waste is unlikely. No appreciable air releases are likely from the treated effluent under any likely disposal conditions. EPA evaluated the potential hazards resulting from the unlikely scenario of airborne exposure to hazardous constituents released from the waste water in an open surface impoundment. The results of this worst-case analysis indicated that there is no substantial present or potential hazard to human health and the environment from airborne exposure to constituents from the treated effluent waste water.

H. What Is EPA's Evaluation of This Delisting Petition?

The descriptions by Bayer of the hazardous waste process and analytical characterization, with the proposed verification testing requirements (as discussed later in this notice), provide a reasonable basis for EPA to grant the exclusion. The data submitted in support of the petition show that constituents in the waste are below the maximum allowable concentrations (See Table 1). EPA believes that the treated effluent generated by Bayer contains hazardous constituents at levels, which will present minimal short-term and long-term threats to human health and the environment.

Thus, EPA believes that it should grant to Bayer an exclusion for the treated effluent. EPA believes that the

data submitted in support of the petition shows the Bayer treated effluent to be nonhazardous.

EPA has reviewed the sampling procedures used by Bayer and has determined they satisfy EPA's criteria for collecting representative samples of variable constituent concentrations in the treated effluent. The data submitted in support of the petition show that constituents in Bayer's wastes are presently below the compliance-point concentrations used in the delisting decision-making process and would not pose a substantial hazard to the environment and the public. EPA believes that Bayer has successfully demonstrated that the treated effluent is nonhazardous.

EPA, therefore, proposes to grant an exclusion to Bayer, in Baytown, Texas, for the treated effluent described in its June 2003 petition. EPA's decision to exclude this waste is based on analysis performed on samples taken of the treated effluent.

If EPA finalizes the proposed rule, EPA will no longer regulate the treated effluent under Parts 262 through 268 and the permitting standards of Part 270.

IV. Next Steps

A. With What Conditions Must the Petitioner Comply?

The petitioner, Bayer, must comply with the requirements in 40 CFR Part 261, Appendix IX, Table 2 as amended by this notice. The text below gives the rationale and details of those requirements.

(1) Delisting Levels

This paragraph provides the levels of constituent concentrations that Bayer must test for in the treated effluent, below which these wastes would be considered nonhazardous.

EPA selected the set of inorganic and organic constituents specified in paragraph (1) and listed in 40 CFR Part 261, Appendix IX, Table 2, based on information in the petition. EPA compiled the inorganic and organic constituents list from descriptions of the manufacturing process used by Bayer, previous test data provided for the waste, and the respective health-based levels used in delisting decision-making. These delisting levels correspond to the allowable levels measured in the total concentrations of the treated effluent. The limits described here do not relieve Bayer of its duty to comply with discharge limits described in its TPDES permit for the effluent.

(2) Waste Holding and Handling

Waste classification as non-hazardous cannot begin until compliance with the limits set in paragraph (1) has occurred for two consecutive quarterly sampling events. For example, if Bayer is issued a final exclusion in August, the first quarter samples are due in November and the second quarter samples are due in February. If EPA deems that both the first and second quarter samples (a total of four) meet all the delisting limits, classification of the waste as non-hazardous cannot begin until March. If constituent levels in any sample taken by Bayer exceed any of the delisting levels set in paragraph (1), Bayer must do the following: (i) notify EPA in accordance with paragraph (6), and; (ii) manage and dispose the treated effluent per its TPDES discharge permit as hazardous waste generated under Subtitle C of RCRA. The delisting for the treated effluent applies only during periods of TPDES compliance.

(3) Verification Testing Requirements

Bayer must complete a verification testing program on the treated effluent to assure that the waste does not exceed the maximum levels specified in paragraph (1). If EPA determines that the data collected under this paragraph does not support the data provided for in the petition, the exclusion will not cover the tested waste. This verification program operates on two levels.

The first part of the quarterly verification testing program consists of testing a batch of treated effluent for specified indicator parameters as per paragraph (1). Each quarterly sampling event will consist of at least two samples of the treated effluent. Levels of constituents measured in the samples of the treated effluent that do not exceed the levels set forth in paragraph (1) can be considered nonhazardous after two consecutive quarters of sampling data meet the levels listed in paragraph (1).

The second part of the verification testing program is the annual testing of two representative composite samples of treated effluent for all constituents specified in paragraph (1).

If Bayer demonstrates for two consecutive quarters complete attainment of all specified limits, then Bayer may request approval of EPA to reduce the frequency of testing to annually. If, after review of performance of the treatment system, EPA finds that annual testing is adequately protective of human health and the environment, then EPA may authorize Bayer to reduce the quarterly comprehensive sampling frequency to an annual basis. If the annual testing of the waste does not meet the delisting levels in paragraph 1, Bayer must notify EPA according to the requirements in paragraph 6. EPA will then take the appropriate actions necessary to protect human health and the environment per paragraph 6. Bayer must provide sampling results that support the rationale that the delisting exclusion should not be withdrawn.

The exclusion is effective upon publication in the **Federal Register** but the change in waste classification as "non-hazardous" cannot begin until two consecutive quarters of verification sampling comply with the levels specified in paragraph 1. The waste classification as "non-hazardous" is also not authorized if Bayer fails to perform the quarterly and yearly testing as specified herein. Should Bayer fail to conduct the quarterly/yearly testing as specified herein, then disposal of treated effluent as delisted waste may not occur in the following quarter(s)/year(s) until Bayer obtains the written approval of EPA.

(4) Changes in Operating Conditions

Paragraph (4) would allow Bayer the flexibility of modifying its processes (for example, changes in equipment or change in operating conditions) to improve its treatment processes. However, Bayer must prove the effectiveness of the modified process and request approval from EPA. Bayer must manage wastes generated during the new process demonstration as hazardous waste through verification sampling within 30 days of start-up.

(5) Data Submittals

To provide appropriate documentation that the Bayer facility is managing the treated effluent, Bayer must compile, summarize, and keep delisting records on-site for a minimum of five years. It should keep all analytical data obtained through paragraph (3), including quality control information, for five years. Paragraph (5) requires that Bayer furnish these data upon request for inspection by any employee or representative of EPA or the State of Texas.

If the proposed exclusion is made final, then it will apply only to 18,071,150 cubic yards (5.475 billion gallons) per calendar year of treated effluent generated at the Bayer facility after successful verification testing.

EPA would require Bayer to submit additional verification data under any of the following circumstances:

(a) If Bayer significantly alters the manufacturing process treatment system except as described in paragraph (4).

(b) If Bayer uses any new manufacturing or production

process(es), or significantly changes the current process(es) described in its petition; or

(c) If Bayer makes any changes that could affect the composition or type of waste generated.

Bayer must submit a modification to the petition complete with full sampling and analysis for circumstances where the waste volume changes and/or additional waste codes are added to the waste stream.

Bayer must manage waste volumes greater than 18,071,150 cubic yards (5.475 billion gallons) per calendar year of treated effluent as hazardous waste until EPA grants a revised exclusion. When this exclusion becomes final, the management of the treated effluent by Bayer covered in this petition would be relieved from Subtitle C jurisdiction. Bayer may not classify the waste as non-hazardous until the revised exclusion is finalized.

(6) Reopener

The purpose of paragraph (6) is to require Bayer to disclose new or different information related to a condition at the facility or disposal of the waste, if it is pertinent to the delisting. Bayer must also use this procedure, if the waste sample in the annual testing fails to meet the levels found in paragraph (1). This provision will allow EPA to reevaluate the exclusion, if a source provides new or additional information to EPA. EPA will evaluate the information on which it based the decision to see, if it is still correct, or if circumstances have changed so that the information is no longer correct or would cause EPA to deny the petition, if presented.

This provision expressly requires Bayer to report differing site conditions or assumptions used in the petition in addition to failure to meet the annual testing conditions within 10 days of discovery. If EPA discovers such information itself or from a third party, it can act on it as appropriate. The language being proposed is similar to those provisions found in RCRA regulations governing no-migration petitions at § 268.6.

It is EPA's position that it has the authority under RCRA and the Administrative Procedures Act (APA), 5 U.S.C. § 551 (1978) *et seq.*, to reopen a delisting decision. EPA may reopen a delisting decision when it receives new information that calls into question the assumptions underlying the delisting.

EPA believes a clear statement of its authority in delistings is merited in light of EPA's experience. *See* Reynolds Metals Company at 62 FR 37694 (July 14, 1997) and 62 FR 63458 (December 1, 1997) where the delisted waste leached at greater concentrations into the environment than the concentrations predicted when conducting the TCLP, thus leading EPA to repeal the delisting. If an immediate threat to human health and the environment presents itself, EPA will continue to address these situations case-by-case. Where necessary, EPA will make a good cause finding to justify emergency rulemaking. *See* APA section 553(b).

B. What Happens, if Bayer Violates the Terms and Conditions?

If Bayer violates the terms and conditions established in the exclusion, EPA will start procedures to withdraw the exclusion. Where there is an immediate threat to human health and the environment, EPA will evaluate the need for enforcement activities on a case-by-case basis. EPA expects Bayer to conduct the appropriate waste analysis and comply with the criteria explained above in paragraph (1) of the exclusion.

V. Public Comments

A. How May I as an Interested Party Submit Comments?

EPA is requesting public comments on this proposed decision. Please send three copies of your comments. Send two copies to the Chief, Corrective Action and Waste Minimization Section, Multimedia Permitting and Planning Division, U.S. Environmental Protection Agency Region 6, 1445 Ross Avenue, Dallas, Texas 75202. Send a third copy to the Industrial Hazardous Waste Permits Division, Technical Evaluation Team, Texas Commission on Environmental Quality, P.O. Box 13087, Austin, TX 78711–3087. Identify your comments at the top with this regulatory docket number: R6–FY04–Bayer. You may submit your comments electronically to Michelle Peace at *peace.michelle@epa.gov.*

B. How May I Review the Docket or Obtain Copies of the Proposed Exclusion?

You may review the RCRA regulatory docket for this proposed rule at the U.S. Environmental Protection Agency Region 6, 1445 Ross Avenue, Dallas, TX 75202. It is available for viewing in EPA Freedom of Information Act Review Room from 9 a.m. to 4 p.m., Monday through Friday, excluding Federal holidays. Call (214) 665–6444 for appointments. The public may copy material from any regulatory docket at no cost for the first 100 pages and at fifteen cents per page for additional copies.

VI. Regulatory Impact

Under Executive Order 12866, EPA must conduct an "assessment of the potential costs and benefits" for all "significant" regulatory actions.

The proposal to grant an exclusion is not significant, since its effect, if promulgated, would be to reduce the overall costs and economic impact of EPA's hazardous waste management regulations. This reduction would be achieved by excluding waste generated at a specific facility from EPA's lists of hazardous wastes, thus enabling a facility to manage its waste as nonhazardous.

Because there is no additional impact from this proposed rule, this proposal would not be a significant regulation, and no cost/benefit assessment is required. The Office of Management and Budget (OMB) has also exempted this rule from the requirement for OMB review under Section (6) of Executive Order 12866.

VII. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, 5 U.S.C. 601–612, whenever an agency is required to publish a general notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis which describes the impact of the rule on small entities (that is, small businesses, small organizations, and small governmental jurisdictions). No regulatory flexibility analysis is required, however, if the Administrator or delegated representative certifies that the rule will not have any impact on small entities.

This rule, if promulgated, will not have an adverse economic impact on small entities since its effect would be to reduce the overall costs of EPA's hazardous waste regulations and would be limited to one facility. Accordingly, EPA hereby certifies that this proposed regulation, if promulgated, will not have a significant economic impact on a substantial number of small entities. This regulation, therefore, does not require a regulatory flexibility analysis.

VIII. Paperwork Reduction Act

Information collection and recordkeeping requirements associated with this proposed rule have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980 (Public Law 96 511, 44 U.S.C. 3501 *et seq.*) and have been assigned OMB Control Number 2050 0053.

IX. Unfunded Mandates Reform Act

Under section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA),

Public Law 104–4, which was signed into law on March 22, 1995, EPA generally must prepare a written statement for rules with Federal mandates that may result in estimated costs to State, local, and tribal governments in the aggregate, or to the private sector, of $100 million or more in any one year.

When such a statement is required for EPA rules, under section 205 of the UMRA EPA must identify and consider alternatives, including the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule. EPA must select that alternative, unless the Administrator explains in the final rule why it was not selected or it is inconsistent with law.

Before EPA establishes regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must develop under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, giving them meaningful and timely input in the development of EPA's regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising them on compliance with the regulatory requirements.

The UMRA generally defines a Federal mandate for regulatory purposes as one that imposes an enforceable duty upon state, local, or tribal governments or the private sector.

EPA finds that this delisting decision is deregulatory in nature and does not impose any enforceable duty on any State, local, or tribal governments or the private sector. In addition, the proposed delisting decision does not establish any regulatory requirements for small governments and so does not require a small government agency plan under UMRA section 203.

X. Executive Order 13045

The Executive Order 13045 is entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This order applies to any rule that EPA determines (1) is economically significant as defined under Executive Order 12866, and (2) the environmental health or safety risk addressed by the rule has 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 EPA. This proposed rule is not subject to E.O. 13045 because this is not an economically significant regulatory action as defined by Executive Order 12866.

XI. Executive Order 13084

Because this action does not involve any requirements that affect Indian tribes, the requirements of section 3(b) of Executive Order 13084 do not apply.

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly affects or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments.

If the mandate is unfunded, EPA must provide to the Office Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation.

In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments to have "meaningful and timely input" in the development of regulatory policies on matters that significantly or uniquely affect their communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

XII. National Technology Transfer and Advancement Act

Under Section 12(d) of the National Technology Transfer and Advancement Act, EPA is directed to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, materials specifications, test methods, sampling procedures, business practices, etc.) developed or adopted by voluntary consensus standard bodies. Where available and potentially applicable voluntary consensus standards are not used by EPA, the Act requires that EPA provide Congress, through the OMB, an explanation of the reasons for not using such standards.

This rule does not establish any new technical standards and thus, EPA has no need to consider the use of voluntary consensus standards in developing this final rule.

XIII. 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" are 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.'

Under section 6 of Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law unless EPA consults with State and local officials early in the process of developing the proposed regulation.

This action does not have federalism implication. It 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, because it affects only one facility.

Lists of Subjects in 40 CFR Part 261

Environmental protection, Hazardous waste, Recycling, Reporting and recordkeeping requirements.

Authority: Sec. 3001(f) RCRA, 42 U.S.C. 6921(f).

Dated: September 24, 2004.

Bill Luthans,

Acting Division Director, Multimedia Permitting and Planning Division.

For the reasons set out in the preamble, 40 CFR part 261 is proposed to be amended as follows:

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

1. The authority citation for part 261 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, 6922, and 6938.

2. In Table 2 of Appendix IX of part 261 add the following waste stream in alphabetical order by facility to read as follows:

Appendix IX to Part 261—Waste Excluded Under §§ 260.20 and 260.22

TABLE 2.—WASTE EXCLUDED FROM SPECIFIC SOURCES

Facility	Address	Waste description
*	*	*
Bayer Polymers	Baytown, TX	Outfall 007 treated effluent (EPA Hazardous Waste Nos. K027, K104, K111, and K112) generated at a maximum rate of 18,071,150 cubic yards (5.475 billion gallons) per calendar year after [publication date of the final rule] as it exits the Outfall Tank and disposed in accordance with the TPDES permit. The delisting levels set do not relieve Bayer of its duty to comply with the limits set in its TPDES permit. For the exclusion to be valid, Bayer must implement a verification testing program that meets the following Paragraphs: (1) Delisting Levels: All concentrations for those constituents must not exceed the maximum allowable concentrations in mg/kg specified in this paragraph. (A) Outfall No. 7 Treated Effluent Total Concentrations (mg/kg): Antimony—0.0816; Arsenic—0.385, Barium—22.2; Chromium—153.0; Copper—3620.0; Cyanide—0.46; Mercury—0.0323; Nickel—11.3; Selenium—0.23; Thallium—0.0334; Vanadium—8.38; Zinc—112.0; Acetone—14.6; Acetophenone—15.8; Aniline—0.680; Benzene—0.0590; Bis(2-ethylhexyl)phthalate—1260.0; Bromodichloromethane—0.0719; Chloroform—0.077; Di-n-octyl phthalate—454.0; 2,4-Dinitrotoluene—0.00451; Diphenylamine—11.8; 1,4-Dioxane—1.76; Di-n-butyl phthalate—149.0; Fluoranthene—24.6; Methylene chloride—0.029; Methyl ethyl ketone—87.9;Nitrobenzene—0.0788; m-phenylenediamine—0.879; Pyrene—39.0; 1,1,1,2-Tetrachloroethane—0.703; o-Toluidine—0.0171; p-Toluidine—0.215; 2,4-Toluenediamine—0.00121. Toluene diisocyanate—0.001. (2) Waste Holding and Handling: (A) Waste classification as non-hazardous cannot begin until compliance with the limits set in paragraph (1) for the treated effluent has occurred for two consecutive quarterly sampling events. The delisting for the treated effluent applies only during periods of TPDES compliance. (B) If constituent levels in any sample taken by Bayer exceed any of the delisting levels set in paragraph (1) for the treated effluent, Bayer must do the following: (i) notify EPA in accordance with paragraph (6) and (ii) manage and dispose the treated effluent as hazardous waste generated under Subtitle C of RCRA. (3) Quarterly Testing Requirements: Upon this exclusion becoming final, Bayer may perform quarterly analytical testing by sampling and analyzing the treated effluent as follows: (A)(i) Collect two representative composite samples of the treated effluent at quarterly intervals after EPA grants the final exclusion. The first composite samples may be taken at any time after EPA grants the final approval. Sampling should be performed in accordance with the sampling plan approved by EPA in support of the exclusion. (ii) Analyze the samples for all constituents listed in paragraph 1. Any composite sample taken that exceeds the delisting levels listed in paragraph (1) for the treated effluent must be disposed as hazardous waste in accordance with the applicable hazardous waste requirements its TPDES discharge permit. (iii) Within thirty (30) days after taking its first quarterly sample, Bayer will report its first quarterly analytical test data to EPA. If levels of constituents measured in the samples of the treated effluent do not exceed the levels set forth in paragraph (1) of this exclusion for two consecutive quarters, Bayer can manage and dispose the nonhazardous treated effluent according to all applicable solid waste regulations. (4) Annual Testing:

TABLE 2.—WASTE EXCLUDED FROM SPECIFIC SOURCES—Continued

Facility	Address	Waste description
		(i) If Bayer completes the quarterly testing specified in paragraph (3) above and no sample contains a constituent with a level which exceeds the limits set forth in paragraph (1), Bayer may begin annual testing as follows: Bayer must test two representative composite samples of the treated effluent for all constituents listed in paragraph (1) at least once per calendar year. (ii) The samples for the annual testing shall be a representative composite sample according to appropriate methods such as those found in SW–846 or other reliable sources (with the exception of analyses requiring the use of SW–846 methods incorporated by reference in 40 CFR 260.11, which must be used without substitution) for all constituents listed in paragraph (1). (iii) The samples for the annual testing taken for the second and subsequent annual testing events shall be taken within the same calendar month as the first annual sample taken. (4) Changes in Operating Conditions: If Bayer significantly changes the process described in its petition or starts any processes that generate(s) the waste that may or could affect the composition or type of waste generated as established under paragraph (1) (by illustration, but not limitation, changes in equipment or operating conditions of the treatment process), it must notify EPA in writing; it may no longer handle the wastes generated from the new process as nonhazardous until the wastes meet the delisting levels set in paragraph (1) and it has received written approval to do so from EPA. Bayer must submit a modification to the petition complete with full sampling and analysis for circumstances where the waste volume changes and/or additional waste codes are added to the waste stream. (5) Data Submittals: Bayer must submit the information described below. If Bayer fails to submit the required data within the specified time or maintain the required records on-site for the specified time, EPA, at its discretion, will consider this sufficient basis to reopen the exclusion as described in paragraph (6). Bayer must: (A) Submit the data obtained through paragraph 3 to the Chief, Corrective Action and Waste Minimization Section, Multimedia Planning and Permitting Division, U. S. Environmental Protection Agency Region 6, 1445 Ross Ave., Dallas, Texas 75202, within the time specified. All supporting data can be submitted on CD–ROM or some comparable electronic media. (B) Compile records of analytical data from paragraph (3), summarized, and maintained on-site for a minimum of five years. (C) Furnish these records and data when either EPA or the State of Texas request them for inspection. (D) Send along with all data a signed copy of the following certification statement, to attest to the truth and accuracy of the data submitted: "Under civil and criminal penalty of law for the making or submission of false or fraudulent statements or representations (pursuant to the applicable provisions of the Federal Code, which include, but may not be limited to, 18 U.S.C. § 1001 and 42 U.S.C. § 6928), I certify that the information contained in or accompanying this document is true, accurate and complete." As to the (those) identified section(s) of this document for which I cannot personally verify its (their) truth and accuracy, I certify as the company official having supervisory responsibility for the persons who, acting under my direct instructions, made the verification that this information is true, accurate and complete. If any of this information is determined by EPA in its sole discretion to be false, inaccurate or incomplete, and upon conveyance of this fact to the company, I recognize and agree that this exclusion of waste will be void as if it never had effect or to the extent directed by EPA and that the company will be liable for any actions taken in contravention of the company's RCRA and CERCLA obligations premised upon the company's reliance on the void exclusion." (6) Reopener

TABLE 2.—WASTE EXCLUDED FROM SPECIFIC SOURCES—Continued

Facility	Address	Waste description
		(A) If, anytime after disposal of the delisted waste Bayer possesses or is otherwise made aware of any environmental data (including but not limited to leachate data or ground water monitoring data) or any other data relevant to the delisted waste indicating that any constituent identified for the delisting verification testing is at level higher than the delisting level allowed by the Division Director in granting the petition, then the facility must report the data, in writing, to the Division Director within 10 days of first possessing or being made aware of that data. (B) If either the quarterly or annual testing of the waste does not meet the delisting requirements in paragraph 1, Bayer must report the data, in writing, to the Division Director within 10 days of first possessing or being made aware of that data. (C) If Bayer fails to submit the information described in paragraphs (5),(6)(A) or (6)(B) or if any other information is received from any source, the Division Director will make a preliminary determination as to whether the reported information requires EPA action to protect human health and/or the environment. Further action may include suspending, or revoking the exclusion, or other appropriate response necessary to protect human health and the environment. (D) If the Division Director determines that the reported information requires action by EPA, the Division Director will notify the facility in writing of the actions the Division Director believes are necessary to protect human health and the environment. The notice shall include a statement of the proposed action and a statement providing the facility with an opportunity to present information as to why the proposed EPA action is not necessary. The facility shall have 10 days from the date of the Division Director's notice to present such information. (E) Following the receipt of information from the facility described in paragraph (6)(D) or (if no information is presented under paragraph (6)(D)) the initial receipt of information described in paragraphs (5), (6)(A) or (6)(B), the Division Director will issue a final written determination describing EPA actions that are necessary to protect human health and/or the environment. Any required action described in the Division Director's determination shall become effective immediately, unless the Division Director provides otherwise.

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[FR Doc. 04–22235 Filed 10–1–04; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[FRL–7823–7]

Nebraska: Final Authorization of State Hazardous Waste Management Program Revision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Nebraska has applied to the EPA for final authorization of the changes to its hazardous waste program under the Resource Conservation and Recovery Act. The EPA proposes to grant final authorization to Nebraska. In the "Rules and Regulations" section of this **Federal Register**, the EPA is authorizing the changes by an immediate final rule. The EPA did not make a proposal prior to the immediate final rule because we believe this action is not controversial and do not expect comments that oppose it. We have explained the reasons for this authorization in the preamble to the immediate final rule. Unless we receive written comments which oppose this authorization during the comment period, the immediate final rule will become effective on the date it establishes, and we will not take further action on this proposal. If we receive comments that oppose this action, we will withdraw the immediate final rule and it will not take effect. We will then respond to public comments in a later final rule based on this proposal. You may not have another opportunity for comment. If you want to comment on this action, you must do so at this time.

DATES: Send your written comments by November 3, 2004.

ADDRESSES: Comments may be mailed to Lisa Haugen, Environmental Protection Agency, ARTD/RESP, 901 North 5th Street, Kansas City, Kansas 66101. Comments may also be submitted electronically or through hand delivery/courier; please follow the detailed instructions in the **ADDRESSES** section of the direct final rule which is located in the rules section of this **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Lisa V. Haugen at the above address, by phone at (913) 551–7877, or by e-mail at *haugen.lisa@epa.gov*.

SUPPLEMENTARY INFORMATION: For additional information, please see the immediate final rule published in the "Rules and Regulations" section of this **Federal Register**.

Dated: September 2, 2004.

William Rice,

Acting Regional Administrator, Region 7.

[FR Doc. 04–22253 Filed 10–1–04; 8:45 am]
BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 0, 2 and 101

[ET Docket No. 95–183; RM–8553; PP Docket No. 93–253; FCC 04–78]

37.0–38.6 GHz and 38.6–40.0 GHz Bands—Competitive Bidding

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; extension of comment period.

SUMMARY: In this document, the Federal Communications Commission is extending the comment and reply comment period for the Third Notice of Proposed Rulemaking (NPRM). The Commission finds that it is in the public interest to extend the time for the filing of comments and reply comments on the NPRM.

DATES: The time for filing comments on all issues raised in the NPRM, including Paperwork Reduction Act is extended to December 3, 2004, and the time for filing reply comments is extended January 3, 2005.

FOR FURTHER INFORMATION CONTACT: Charlie Oliver, 202–418–2487.

SUPPLEMENTARY INFORMATION: This is a summary of an Order released by the Commission, extending the time for filing comments and reply comments on the Third Notice of Proposed Rulemaking (NPRM), FCC 04–78, released on May 5, 2004. Comment due dates contained in the summary of the NPRM published in the **Federal Register**, 69 FR 52632, August 27, 2004, are inconsistent with comment due dates contained in the NPRM.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 04–22194 Filed 10–1–04; 8:45 am]

BILLING CODE 6712–01–P

OFFICE OF PERSONNEL MANAGEMENT

48 CFR Parts 2101, 2102, 2103, 2104, 2105, 2109, 2110, 2115, 2116, 2131, 2132, 2137, 2144, 2146, 2149, and 2152

RIN 3206–AI65

Federal Employees' Group Life Insurance; Federal Acquisition Regulation

AGENCY: Office of Personnel Management.

ACTION: Proposed regulations.

SUMMARY: The Office of Personnel Management (OPM) is issuing proposed regulations to amend the Federal Employees' Group Life Insurance (FEGLI) Acquisition Regulation. The proposed regulations incorporate changes in administrative policy and practices and make clarifying language changes.

DATES: OPM must receive comments on or before December 3, 2004.

ADDRESSES: Send written comments to Abby L. Block, Deputy Associate Director for Employee and Family Support Policy, Strategic Human Resources Policy Division, Office of Personnel Management, 1900 E Street NW., Washington, DC 20415; or deliver to OPM, Room 3425, 1900 E Street NW.; or FAX to (202) 606–0633.

FOR FURTHER INFORMATION CONTACT: Karen Leibach, (202) 606–0004.

SUPPLEMENTARY INFORMATION: On August 27, 1993, OPM issued the Life Insurance Federal Acquisition Regulation (LIFAR), 48 CFR chapter 21, which identifies basic and significant acquisition policies that are unique to the FEGLI Program. The proposed regulations explain changes in the FEGLI Program's policies, update Federal Acquisition Regulation (FAR) changes, and make clarifying changes to the language.

Some of the more significant changes in the regulations are:

LIFAR 2101.102(b), Authority, is modified to reflect the prior consolidation of 5 CFR parts 870 through 874 into one part, part 870. An identical change is also made in 2109.7001(a).

The revised regulation provides that both OPM and the Contractor, with the approval of OPM, may issue FEGLI literature to employees (2103.570(a)). The language clarifies that the FEGLI Program Booklet, along with valid election documents, serves as certification of coverage under the FEGLI Program. The Booklet alone does not suffice as certification of coverage.

Under revised 2110.7002, Contractor investment of FEGLI Program funds, the Contractor is not responsible for any actions regarding investment strategy to maximize investment income when and if such actions were directed by OPM. This modification protects the Contractor in the event it is requested to take an action that could have an adverse impact on its responsibility to manage and invest Program funds in a prudent manner. The same modification occurs in 2152.210–70(a).

Section 2131.109, Advance agreements, increases the threshold from $25,000 to $100,000 for precontract and nonrecurring costs of the Contractor. We consider this change reasonable in relation to the total cost of the FEGLI contract. We are making a similar change at 2131.205–32.

A new subparagraph, Administrative Expense Ceiling, is added to 2152.231–70 (Accounting and allowable cost). Calculated annually, the administrative expense ceiling is based on the Contractor's prior year's administrative expense ceiling and adjusted by the percent change in the Consumer Price Index for All Urban Consumers for the preceding 12 months. Both OPM and the Contractor will reexamine the base, including the prior year's actual expenses, if either party so requests.

During a continuation of services period, revised policy allows for a one-time negotiated increase in the administrative expense ceiling to handle phase-in/phase-out costs. All costs, including costs that exceed the revised ceiling, must be actual, allowable, allocable, and reasonable under FAR cost principles. Since indirect costs are charged against an annual administrative expense ceiling, the policy on indirect costs is modified (2131.203) to delete reference to a "dividend or retention formula." Under the ceiling, a separate annual limit for indirect costs is negotiated between OPM and the Contractor.

An OPM policy change adds an incentive fee the Contractor can earn for exceptional performance during a continuity of services period (2137.102 and 2152.237–70). The incentive fee cannot exceed the pro rata risk or service charge for the same period. A new factor, Transitional services, is added to the weighted guidelines at 2115.404–71 (Profit analysis factors) to reflect this change and is only applicable during a continuity of services period.

Also, during a continuity of services period, OPM will not initiate any changes to the LIFAR (2101.370). This does not, however, exempt the Contractor from complying with statutory changes that may take effect during such a period.

The proposed regulation establishes a letter of credit (LOC) account for the Contractor (2132.170), which will be credited on the first business day of each month with one-twelfth of the estimated annual premium payment. The December payment will be credited to the LOC account no later than the last business day of each calendar year. Interest earnings on the LOC account will be made available for drawdown by the Contractor. Withdrawals from the LOC account for benefit costs of $5,000 or more will be made on a claims-paid basis. Withdrawals from the LOC

account for benefit costs of less than $5,000 and other FEGLI Program disbursements will be made on a checks-presented basis.

The proposed regulation clarifies the start date of the 31-day grace period that follows the date premiums are due. Since OPM cannot credit the LOC account if the first of the month falls on a non-business day, the revised regulations: (1) Define "grace period" at 2102.101 as 31 days from and including the payment due date of the first business day of the month; and (2) provide that the annual estimated premium, which will be credited to the Contractor's LOC account in 12 equal monthly installments, is due and available for drawdown on the first business day of the month. The grace period is also referenced in 2149.002, Applicability, and 2152.249–70, Renewal and termination.

Also under 2152.249–70, Renewal and termination, the Contractor agrees to reinstate the contract if termination occurs as the result of the Government's failure to make premium payments before the grace period ends due to circumstances beyond the Government's control. In such situations, the Contractor will allow an additional 5 days after the expiration of the grace period for OPM to make payment to the Contractor. Notwithstanding the above, the Contractor and OPM can agree to continue the contract.

The proposed regulation states that the Contractor is not responsible for continued performance as a result of OPM's failure to make timely premium payments. Were such a circumstance to occur, it would be unfair to expect the Contractor to continue to make benefits payments on a regular basis and subsequently seek recovery from OPM (2137.102 and 2152.237–70). This Contractor protection is included in revised policy and contract clause provisions on Termination (2149.002(b)) and Renewal and termination (2152.249–70(b)).

We believe it is unnecessary to evaluate annually a Contractor's system of internal controls under a quality assurance program. Accordingly, the language at 2146.201 provides for periodic reviews. While subsequent reviews may be limited to changes in the Contractor's internal control system, the Contractor has an ongoing obligation to fully implement its internal control system at all times.

Our current policy on subcontracting requires advance approval of subcontracts or modifications that exceed $100,000. The proposed regulation increases the threshold to $550,000 (2144.102 and 2152.244–70(a)). We are also making this change in the Notice of significant events clause (2152.210–71(d)).

We are making a number of important additions and clarifying language changes to 2152.231–70, Accounting and allowable costs. We are defining cost as a chargeable cost against the contract which must meet separate cost principle tests for being actual, allowable, allocable, and reasonable. Conforming changes are being made to the definitions of "Administrative expenses" and "Investment income" so that they reference the definition of cost. We are changing the definition of "Benefits" under this section to include excess mortality charges, post-mortem conversion charges, conversion policies, and delayed settlement interest as part of payments made and costs incurred. The term "Overpayments" is being modified to "Overpayments recovered," since overpayment monies are an offset against benefits paid or incurred.

An expanded Definitions section at subpart 2102.1 includes terms used throughout the LIFAR. Editorial changes to the LIFAR correct typographical errors in the Code of Federal Regulations, provide for consistency throughout, and make the text more readable. Reference changes and updates are made to the FEGLI Clause Matrix at 2152.3 and other sections of the LIFAR, where applicable, to conform to changes in the FAR (chapter 1 of title 48, Code of Federal Regulations) since the original issuance of the LIFAR.

Executive Order 12866, Regulatory Review

This rule has been reviewed by the Office of Management and Budget in accordance with Executive Order 12866.

Regulatory Flexibility Act

I certify that these regulations will not have a significant economic impact on a substantial number of small entities because they affect only the Federal life insurance Contractor.

List of Subjects in 48 CFR Parts 2101, 2102, 2103, 2104, 2105, 2109, 2110, 2115, 2116, 2131, 2132, 2137, 2144, 2146, 2149, and 2152

Advertising, Government employees, Government procurement, Life insurance.

U.S. Office of Personnel Management.

Kay Coles James,

Director.

Accordingly, OPM proposes to amend 48 CFR chapter 21, as follows:

CHAPTER 21—OFFICE OF PERSONNEL MANAGEMENT, FEDERAL EMPLOYEES' GROUP LIFE INSURANCE FEDERAL ACQUISITION REGULATION

1. The authority citation for 48 CFR parts 2101, 2102, 2103, 2104, 2105, 2109, 2110, 2115, 2116, 2131, 2132, 2137, 2144, 2146, 2149, and 2152 continues to read as follows:

Authority: 5 U.S.C. 8716; 40 U.S.C. 486(c); 48 CFR 1.301.

PART 2101—FEDERAL ACQUISITION REGULATIONS SYSTEM

Subpart 2101.1—Purpose, Authority, Issuance

2. In section 2101.102 revise paragraph (b) to read as follows:

2101.102 Authority.

* * * * *

(b) The LIFAR does not replace or incorporate regulations found at 5 CFR part 870, which provide the substantive policy guidance for administration of the FEGLI Program under 5 U.S.C. chapter 87. The following is the order of precedence in interpreting a contract provision under the FEGLI Program:

(1) 5 U.S.C. chapter 87.

(2) 5 CFR part 870.

(3) 48 CFR chapters 1 and 21.

(4) The FEGLI Program contract.

Subpart 2101.3—Agency Acquisition Regulations

3. In section 2101.301 revise paragraph (b) to read as follows:

2101.301 Policy.

* * * * *

(b) OPM may issue internal procedures, instructions, directives, and guides to clarify or implement the LIFAR within OPM. Clarifying or implementing procedures, instructions, directives, and guides issued pursuant to this section of the LIFAR must:

(1) Be consistent with the policies and procedures contained in this chapter as implemented and supplemented from time to time; and

(2) Follow the format, arrangement, and numbering system of this chapter to the extent practicable.

4. In section 2101.370 add paragraph (e) to read as follows:

2101.370 Effective date of LIFAR amendments.

* * * * *

(e) OPM will not initiate any changes to the LIFAR during a continuity of services period, as discussed in 2152.237–70 of this chapter.

PART 2102—DEFINITIONS OF WORDS AND TERMS

Subpart 2102.1—Definitions

5. Revise section 2102.101 to read as follows:

2102.101 Definitions.

In this chapter, unless otherwise indicated, the following terms have the meaning set forth in this subpart.

Contract means a policy or policies of group life and accidental death and dismemberment insurance to provide the benefits specified by 5 U.S.C. chapter 87.

Contract price means premium.

Contract year means October 1 through September 30. Also referred to as *contract term.*

Contractor means an insurance company contracted to provide the benefits specified by 5 U.S.C. chapter 87.

Director means the Director of the Office of Personnel Management.

Employees' Life Insurance Fund means the trust fund established under 5 U.S.C. 8714.

Enrollee means the insured, or, where applicable, the assignee.

FEGLI Program means the Federal Employees' Group Life Insurance Program.

Fixed price with limited cost redetermination plus fixed fee contract means a contract which provides for:

(1) A fixed price during the contract year with a cost element that is adjusted at the end of the contract term based on costs incurred under the contract; and

(2) A profit or fee that is fixed at the beginning of the contract term. The amount of adjustment for costs is limited to the amount in the Employees' Life Insurance Fund. The fee will be in the form of either a risk charge or a service charge.

Grace period means 31 days from and including the payment due date of the first business day of the month.

Insurance company, as provided in 5 U.S.C. 8709, means a company licensed to transact life and accidental death and dismemberment insurance under the laws of all the States and the District of Columbia. It must have in effect, on the most recent December 31 for which information is available to the Office of Personnel Management, an amount of employee group life insurance equal to at least 1 percent of the total amount of employee group life insurance in the United States in all life insurance companies.

OPM means the United States Office of Personnel Management.

Premium means an amount intended to cover the estimated annual benefits and administrative costs plus a fixed service or risk charge, made available to the Contractor in 12 equal installments. At the end of the contract year, a reconciliation of premiums, benefits, and other costs is performed as a limited cost redetermination.

Reinsurer means a company that reinsures portions of the total amount of insurance under the contract as specified in 5 U.S.C. 8710 and is not an agent or representative of the Contractor.

Subcontract means a contract entered into by any subcontractor that furnishes supplies or services for performance of a prime contract under the FEGLI Program. Except for the purpose of FAR subpart 22.8—Equal Employment Opportunity, the term "subcontract" does not include a contract with a reinsurer under the FEGLI Program.

Subcontractor means any supplier, distributor, vendor, or firm that furnishes supplies or services to or for a prime Contractor under the FEGLI Program contract. Except for the purpose of FAR subpart 22.8—Equal Employment Opportunity, the term "subcontractor" does not include reinsurers under the FEGLI Program.

PART 2103—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTEREST

Subpart 2103.5—Other Improper Business Practices

6. In section 2103.570 revise paragraphs (a) and (b) to read as follows:

2103.570 Misleading, deceptive, or unfair advertising.

(a) OPM, or the Contractor with the approval of OPM, makes available to Federal employees a booklet describing the provisions of the FEGLI Program, which includes information about eligibility, enrollment, and general procedures. The booklet, along with valid election documents, serves as certification of the employee's coverage under the FEGLI Program. Any marketing/advertising directed specifically at Federal employees and life insurance contacts with Federal employees for the purpose of selling FEGLI Program coverage must be approved by OPM in advance.

(b) The Contractor is prohibited from making incomplete and/or incorrect comparisons or using disparaging or minimizing techniques to compare its other products or services to those of the FEGLI Program. The Contractor agrees that any advertising material authorized and released by the Contractor which mentions the FEGLI Program will be truthful and not misleading and will present an accurate statement of FEGLI Program benefits. The Contractor will use reasonable efforts to assure that agents selling its other products are aware of and abide by this prohibition.

* * * * *

PART 2104—ADMINISTRATIVE MATTERS

7. Add subpart 2104.9 consisting of section 2104.9001 to read as follows:

Subpart 2104.9—Taxpayer Identification Number

Sec.
2104.9001 Contract clause.

2104.9001 Contract clause.

The clause at 2152.204–70 must be inserted in all FEGLI Program contracts.

PART 2105—PUBLICIZING CONTRACT ACTIONS

Subpart 2105.70—Applicability

8. Revise section 2105.7001 to read as follows:

2105.7001 Applicability.

FAR part 5 has no practical application to the FEGLI Program because the requirements for eligible contractors (*i.e.,* qualified life insurance companies) are stated in 5 U.S.C. 8709.

PART 2106—COMPETITION REQUIREMENTS

Subpart 2106.70—Applicability

9. Revise section 2106.7001 to read as follows:

2106.7001 Applicability.

FAR part 6 has no practical application to the FEGLI Program because 5 U.S.C. chapter 87 exempts the FEGLI Program from competitive bidding.

PART 2109—CONTRACTOR QUALIFICATIONS

Subpart 2109.70—Minimum Standards for FEGLI Program Contractors

10. In section 2109.7001 revise paragraphs (a), (f), and (g) to read as follows:

2109.7001 Minimum standards for FEGLI Program Contractors.

(a) The Contractor must meet the requirements of chapter 87 of title 5, United States Code; part 870 of title 5, Code of Federal Regulations; chapter 1 of title 48, Code of Federal Regulations; and the standards in this subpart. The Contractor must continue to meet these and the following statutory and

regulatory requirements while under contract with OPM. Failure to meet these requirements and standards is cause for OPM's termination of the contract in accordance with part 2149 of this chapter.

* * * * *

(f) The Contractor agrees to enter into annual premium rate redeterminations with OPM.

(g) The Contractor must furnish such reasonable reports as OPM determines are necessary to administer the FEGLI Program. The cost of preparation of such reports will be considered an allowable expense within the administrative expense ceiling defined in 2152.231–70 of this chapter.

* * * * *

PART 2110—SPECIFICATIONS, STANDARDS, AND OTHER PURCHASE DESCRIPTIONS

Subpart 2110.70—Contract Specifications

11. Revise section 2110.7002 to read as follows:

2110.7002 Contractor investment of FEGLI Program funds.

(a) The Contractor is required to invest and reinvest all FEGLI Program funds on hand, including any attributable to the special contingency reserve (as used in 5 U.S.C. 8712), until needed to discharge promptly the obligations incurred under the contract. Within the constraints of safety and liquidity of investments, the Contractor must seek to maximize investment income. However, the Contractor will not be responsible for any actions taken at the direction of OPM.

(b) The Contractor is required to credit income earned from its investment of FEGLI Program funds to the FEGLI Program. Thus, the Contractor must be able to allocate investment income to the FEGLI Program in an appropriate manner. If the Contractor fails to invest funds on hand, properly allocate investment income, or credit any income due to the contract, for whatever reason, it must return or credit any investment income lost to OPM or the FEGLI Program, retroactive to the date that such funds should have been originally invested, allocated, or credited in accordance with the clause at 2152.210–70.

PART 2114—SEALED BIDDING

Subpart 2114.70—Applicability

12. Revise section 2114.7001 to read as follows:

2114.7001 Applicability.

FAR part 14 has no practical application to the FEGLI Program because 5 U.S.C. chapter 87 exempts the FEGLI Program from competitive bidding.

PART 2115—CONTRACTING BY NEGOTIATION

2115.106–270 [Redesignated as 2115.071]

13. Redesignate section 2115.106–270 as section 2115.071 and revise the title to read as "Specific retention periods: Contract clause."

2115.170 [Redesignated as 2115.070]

14. Redesignate section 2115.170 as section 2115.070.

15. Revise the title of subpart 2115.1, remove section 2115.106, and add a new section 2115.170 to read as follows:

Subpart 2115.1—Source Selection Processes and Techniques

2115.170 Applicability.

FAR subpart 15.1 has no practical application to the FEGLI Program because prospective contractors (insurance companies) are considered for inclusion in the FEGLI Program in accordance with criteria provided in 5 U.S.C. chapter 87, LIFAR 2109.7001, and LIFAR 2115.370.

16. Redesignate subpart 2115.4 as subpart 2115.2 and revise the title, redesignate section 2115.401 as section 2115.270, and revise paragraphs (a) and (c) to read as follows:

Subpart 2115.2—Solicitation and Receipt of Proposals and Information

2115.270 Applicability.

(a) FAR subpart 15.2 has no practical application to the FEGLI Program because 5 U.S.C. chapter 87 exempts the FEGLI Program from competitive bidding.

* * * * *

(c) Eligible contractors (*i.e.*, qualified life insurance companies) are identified in accordance with 5 U.S.C. 8709. Prospective contractors voluntarily come forth in accordance with procedures provided in 2115.370.

* * * * *

17. Redesignate subpart 2115.6 as subpart 2115.3, and redesignate section 2115.602 as section 2115.370, and revise the introductory paragraph to read as follows:

Subpart 2115.3—Source Selection

2115.370 Applicability.

FAR subpart 15.3 has no practical application to the FEGLI Program because prospective contractors (insurance companies) are considered for inclusion in the FEGLI Program in accordance with criteria provided in 5 U.S.C. chapter 87, LIFAR 2109.7001, and the following:

* * * * *

18. Redesignate subpart 2115.8 as subpart 2115.4 and revise the title, and redesignate section 2115.802 as section 2115.402 and revise it to read as follows:

Subpart 2115.4—Contract Pricing

2115.402 Policy.

Pricing of FEGLI Program premium rates is governed by 5 U.S.C. 8707, 8708, 8711, 8714a, 8714b, and 8714c. FAR subpart 15.4 will be implemented by applying cost analysis policies and procedures. To the extent that reasonable or good faith actuarial estimates are used for pricing, such estimates will be deemed acceptable and, if inaccurate, will not constitute defective pricing.

19. Redesignate section 2115.902 as section 2115.404–70, revise the title, and revise paragraph (b)(2) to read as follows:

2115.404–70 Profit.

* * * * *

(b) * * *

(2) Once agreement to relinquish the risk charge is made, the agreement may not be cancelled unless OPM and the Contractor mutually agree to reinstitute payment of a risk charge; or unless the Fund balance falls below the level defined in 2115.404–70(a) and 30 days' notice of cancellation is provided; or unless the Contractor or OPM provides notice of cancellation for any reason 1 year prior to the date cancellation is sought.

* * * * *

20. Redesignate section 2115.905 as section 2115.404–71 and revise it to read as follows:

2115.404–71 Profit analysis factors.

(a) The OPM Contracting Officer will apply a weighted guidelines method when developing the prenegotiation objective (service charge) for the FEGLI Program contract. In accordance with the factors defined in FAR 15.404–4(d), OPM will apply the appropriate weights derived from the ranges specified in paragraph (b) of this section and will determine the prenegotiation objective based on the total dollar amount of the Contractor's Basic and Option C (family optional insurance) claims paid in the previous contract year.

(1) *Contractor performance.* OPM will consider such elements as the accurate and timely processing of benefit claims,

the volume and validity of complaints received by OPM, effectiveness of internal controls systems in place, the timeliness and adequacy of reports on operations, and responsiveness to OPM offices, enrollees, beneficiaries, and Congress as measures of economical and efficient contract performance. This factor will be judged apart from the Contractor's *basic* responsibility for contract compliance and will be a measure of the extent and nature of the Contractor's contribution to the FEGLI Program through the application of managerial expertise and effort. Evidence of effective contract performance will receive a plus weight, and poor performance or failure to comply with contract terms and conditions a zero weight. Innovations of benefit to the FEGLI Program will generally receive a plus weight; documented inattention or indifference to effective operations, a zero weight.

(2) *Contract cost risk.* OPM will evaluate the Contractor's risk annually in relation to the amount in the Employees' Life Insurance Fund and will evaluate this factor accordingly.

(3) *Federal socioeconomic programs.* OPM will consider documented evidence of successful Contractor-initiated efforts to support such Federal socioeconomic programs as drug and substance abuse deterrents and other concerns of the type enumerated in FAR 15.404–4(d)(1)(iii) as a factor in negotiating profit. This factor will be related to the quality of the Contractor's policies and procedures and the extent of exceptional effort or achievement demonstrated. Evidence of effective support of Federal socioeconomic programs will result in a plus weight; indifference to Federal socioeconomic programs will result in a zero weight; and only deliberate failure to provide opportunities to persons and organizations that would benefit from these programs will result in a negative weight.

(4) *Capital investments.* This factor is generally not applicable to FEGLI Program contracts because facilities capital cost of money may be an allowable administrative expense. Generally, this factor will be given a weight of zero. However, special purpose facilities or investment costs of direct benefit to the FEGLI Program that are not recoverable as allowable or allocable administrative expenses may be taken into account in assigning a plus weight.

(5) *Cost control.* This factor is based on the Contractor's previously demonstrated ability to perform effectively and economically. In addition, consideration will be given to measures taken by the Contractor that result in productivity improvements and other cost containment accomplishments that will be of future benefit to the FEGLI Program. Examples are containment of costs associated with processing claims; success at preventing waste, loss, unauthorized use, or misappropriation of FEGLI Program assets; and success at limiting and recovering erroneous benefit payments.

(6) *Independent development.* Consideration will be given to independent Contractor-initiated efforts, such as the development of a unique and enhanced customer support system, that are of demonstrated value to the FEGLI Program and for which developmental costs have not been recovered directly or indirectly through allowable or allocable administrative expenses. This factor will be used to provide additional profit opportunities based upon an assessment of the Contractor's investment and risk in developing techniques, methods, practices, etc., having viability to the Program at large. Improvements and innovations recognized and rewarded under any other profit factor cannot be considered.

(7) *Transitional services.* This factor is based on the Contractor's performance of transitional activities during a continuity of services period as described in the clause at 2152.237–70 of this chapter. These are any activities apart from the normal servicing of the contract during an active contract term. Other than for a transitional period, the weight applied to this factor for any active contract term is zero.

(b) The weight ranges for each factor to be used in the weighted guidelines approach are set forth in the following table:

Profit factor	Weight ranges
1. Contractor performance.	0 to +.0005
2. Contract cost risk ...	+.000001 to +.00001
3. Federal socio-economic programs.	−.00003 to +.00003
4. Capital investment ..	0 to +.00001
5. Cost control	−.0002 to +.0002
6. Independent development.	0 to +.00003
7. Transitional services	0 to +.0007

Subpart 2115.9—[Removed]

20a. Remove subpart 2115.9.

PART 2116—TYPES OF CONTRACTS

Subpart 2116.2—Fixed Price Contracts

21. Revise section 2116.270 to read as follows:

2116.270 FEGLI Program contracts.

FEGLI Program contracts are fixed price with limited cost redetermination plus fixed fee. The premium paid to the Contractor is mutually agreed upon by OPM and the Contractor and is based on an estimate of benefits and administrative costs, plus the fixed service or risk charge, and is determined annually. Claims costs, including benefits and administrative expenses, in excess of premiums are paid up to the amount in the Employees' Life Insurance Fund. Payment for costs exceeding the amount in the Fund are the responsibility of the Contractor and reinsurers. The fee is fixed at the inception of each contract year. The fee does not vary with the actual costs but may be adjusted as a result of changes in the work to be performed under the contract. The fee is in the form of either a risk charge or a service charge.

(a) *Risk charge.* The risk charge will be determined as prescribed in 5 U.S.C. 8711(d) and 2115.404–70 of this chapter. It will consist of a negotiated amount which will reflect the risk assumed by the Contractor and the reinsurers and may be adjusted as a result of increased or decreased risk under the contract. When the applicable fee is a risk charge, no service charge will be paid for the same period of time.

(b) *Service charge.* The amount of the service charge will be determined using a weighted guidelines structured approach in accordance with 2115.404–71 of this chapter and negotiated with the Contractor at the beginning of the contract term. When the applicable fee is a service charge, no risk charge will be paid for the same period of time.

PART 2131—CONTRACT COST PRINCIPLES AND PROCEDURES

Subpart 2131.1—Applicability

22. Revise section 2131.109 to read as follows:

2131.109 Advance agreements.

FAR 31.109 is applicable to FEGLI Program contracts, except that precontract costs and nonrecurring costs that exceed $100,000 will not be allowed in the absence of an advance agreement between OPM and any potential FEGLI Contractor.

Subpart 2131.2—Contracts with Commercial Organizations

23. Revise section 2131.203 to read as follows:

2131.203 Indirect costs.

The provisions of FAR 31.203 apply to the allocation of indirect costs.

24. Revise section 2131.205–32 to read as follows:

2131.205–32 Precontract costs.

Precontract costs will be allowable in accordance with FAR part 31, but precontract costs that exceed $100,000 will not be allowable except to the extent allowable under an advance agreement negotiated in accordance with 2131.109 of this chapter.

25. Revise section 2131.205–38 to read as follows:

2131.205–38 Selling costs.

Selling costs are not allowable costs to FEGLI contracts except to the extent that they are attributable to conducting contract negotiations with the Government and for liaison activities involving ongoing contract administration, including the conduct of informational and enrollment activities as directed or approved by the Contracting Officer.

PART 2132—CONTRACT FINANCING

Subpart 2132.1—General

26. Revise section 2132.170 to read as follows:

2132.170 Recurring premium payments to Contractors.

(a) OPM will make payments on a letter of credit (LOC) basis. OPM and the Contractor will concur on an estimate of benefits and administrative costs plus the fixed service or risk charge for the forthcoming contract year, as specified in the contract. The annual premium to the Contractor, based on this estimate, will be credited to the Contractor's LOC account in 12 equal monthly installments due on the first business day of each month and available for drawdown. OPM will credit the Contractor's LOC account for the December payment no later than the last business day of each calendar year. Following the close of the contract year, a reconciliation of premiums, benefits, and other costs will be performed as a limited cost redetermination. In addition, interest distribution payments will be made available for Contractor drawdown from the LOC account. The Contractor will use the LOC account in accordance with guidelines issued by OPM.

(b) Withdrawals from the LOC account for benefit costs of $5,000 or more will be made on a claims-paid basis. Withdrawals from the LOC account for benefit costs of less than $5,000 and other FEGLI Program disbursements will be made on a checks-presented basis. Under a checks-presented basis, drawdown on the LOC is delayed until the checks issued for FEGLI Program disbursements are presented to the Contractor's bank for payment.

(c) Nothing in this section will affect the ability of the Contractor to hold the special contingency reserve established and maintained in accordance with the terms of 5 U.S.C. 8712.

Subpart 2132.7—Contract Funding

27. Revise section 2132.771 to read as follows:

2132.771 Non-commingling of FEGLI Program funds.

(a) FEGLI Program funds must be maintained in such a manner as to be separately identifiable from other assets of the Contractor. Cash and investment balances reported on the FEGLI Program Annual Financial Report must be supported by the Contractor's books and records.

(b) This requirement may be modified by the Contracting Officer in accordance with the clause at 2152.232–71 of this chapter when adequate accounting and other controls are in effect. If the requirement is modified, such modification will remain in effect until rescinded by OPM.

PART 2137—SERVICE CONTRACTING

Subpart 2137.1—Service Contracts—General

28. Revise section 2137.102 to read as follows:

2137.102 Policy.

(a) The services under this contract are of vital interest to the Government and must be continued without interruption in the event the contract is terminated, unless the termination occurs as a result of OPM's failure to pay premiums on a timely basis.

(b) The Contractor will be reimbursed for all reasonable phase-in and phase-out costs (*i.e.*, costs incurred within the agreed-upon period after contract termination that result from phase-in and phase-out operations). The Contractor also will receive a risk or service charge for the full period after contract termination during which services are continued, not to exceed a pro rata portion of the risk or service charge for the final contract year. In addition, OPM will pay the Contractor an incentive amount, not to exceed the pro rata risk or service charge for the continuity of services period (LIFAR 2152.237–70), based on exceptional performance during the transition period to a new Contractor. The Contracting Officer will use the weighted guidelines method described in 2115.404–71 of this chapter in determining the incentive amount. The amount of the risk or service charge will be based upon the accurate and timely processing of benefit claims, the volume and validity of customer service complaints, the timeliness and adequacy of reports on operations, and responsiveness to OPM offices, insured individuals, beneficiaries, and Congress.

PART 2144—SUBCONTRACTING POLICIES AND PROCEDURES

Subpart 2144.1—General

29. Revise section 2144.102 to read as follows:

2144.102 Policy.

For all FEGLI Program contracts, the Contracting Officer's advance approval will be required on subcontracts or modifications to subcontracts when the cost of that portion of the subcontract that is charged the FEGLI Program contract exceeds $550,000 and is at least 25 percent of the total cost of the subcontract.

PART 2146—QUALITY ASSURANCE

Subpart 2146.2—Contract Quality Requirements

30. In section 2146.201 revise paragraph (b) to read as follows:

2146.201 General.

* * * * *

(b) OPM will make an initial evaluation of the Contractor's system of internal controls under the quality assurance program required by 2146.270 of this chapter and will acknowledge in writing whether or not the system is consistent with the requirements set forth in this subpart. After the initial review, subsequent periodic reviews may be limited to changes in the Contractor's internal control guidelines. However, a limited review does not diminish the Contractor's obligation to apply the full internal control system.

31. In section 2146.270 revise paragraph (b) to read as follows:

2146.270 FEGLI Program quality assurance requirements.

* * * * *

(b) The Contractor must prepare overpayment recovery guidelines to include a system of internal controls.

* * * * *

PART 2149—TERMINATION OF CONTRACTS

32. Revise section 2149.002 to read as follows:

2149.002 Applicability.

(a) *Termination.* (1) Termination of FEGLI Program contracts is controlled by 5 U.S.C. 8709(c) and this chapter. The procedures for termination of FEGLI Program contracts are contained in FAR part 49. For the purpose of this part, "terminate" means to "discontinue" as used in 5 U.S.C. 8709(c).

(2) A life insurance contract entered into by OPM may be terminated by OPM at any time for default by the Contractor in accordance with the provisions of FAR parts 49 and 52.249–8. A life insurance contract entered into by OPM may be terminated by the Contractor at the end of the grace period, after default for nonpayment by OPM. Notwithstanding the preceding sentence, the Contractor will allow OPM an additional 5 days after the end of the grace period to make payment if the failure to make payment was inadvertent and/or due to circumstances beyond the Government's control.

(3) A life insurance contract entered into by OPM may be terminated for convenience of the Government 60 days after the Contractor's receipt of OPM's written notice to terminate.

(4) The Contractor may terminate its contract with OPM at the end of any contract year when notice of intent to terminate is given to OPM in writing at least 60 days prior to the end of the contract year (*i.e.*, no later than July 31).

(b) *Continuation of services.* The services under this contract are of vital interest to the Government and must be continued without interruption in the event the contract is terminated for the Contractor's default or OPM's convenience. Consequently, the contract termination procedures contained in this paragraph must be used in conjunction with 2137.102 of this chapter, 2137.110 of this chapter, and the provisions of the "Continuity of Services" clause at 2152.237–70 of this chapter. The Contractor is not required to continue performance subsequent to OPM's default for failure to pay premiums in accordance with the provisions of the clause at 2152.249–70(b).

(c) *Settlement.* The procedures for settlement of contracts after they are terminated are those contained in FAR part 49.

PART 2152—PRECONTRACT PROVISIONS AND CONTRACT CLAUSES

33. In section 2152.070 revise the listing under Section and Clause Title to read as follows:

2152.070 Applicable clauses.

* * * * *

Section and Clause Title

52.202–1 Definitions
52.203–3 Gratuities
52.203–5 Covenant against Contingent Fees
52.203–6 Restrictions on Subcontractor Sales to the Government
52.203–7 Anti-Kickback Procedures
52.203–12 Limitation on Payments To Influence Certain Federal Transactions
52.209–6 Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment
52.215–2 Audit and Records—Negotiation
52.215–10 Price Reduction for Defective Cost or Pricing Data
52.215–12 Subcontractor Cost or Pricing Data
52.215–15 Pension Adjustments and Asset Reversions
52.215–16 Facilities Capital Cost of Money
52.215–17 Waiver of Facilities Capital Cost of Money
52.215–18 Reversion or Adjustment of Plans for Postretirement Benefits (PRB) Other Than Pensions
52.219–8 Utilization of Small Business Concerns
52.222–1 Notice to the Government of Labor Disputes
52.222–3 Convict Labor
52.222–4 Contract Work Hours and Safety Standards Act—Overtime Compensation
52.222–21 Prohibition of Segregated Facilities
52.222–22 Previous Contracts and Compliance Reports
52.222–25 Affirmative Action Compliance
52.222–26 Equal Opportunity
52.222–29 Notification of Visa Denial
52.222–35 Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.222–36 Affirmative Action for Workers with Disabilities
52.222–37 Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.223–6 Drug-Free Workplace
52.227–1 Authorization and Consent
52.227–2 Notice and Assistance regarding Patent and Copyright Infringement
52.228–7 Insurance—Liability to Third Persons
52.232–9 Limitation on Withholding of Payments
52.232–17 Interest
52.232–23 Assignment of Claims
52.232–33 Payment by Electronic Funds Transfer—Central Contractor Registration
52.233–1 Disputes (Alternate I)
52.242–1 Notice of Intent To Disallow Costs
52.242–3 Penalties for Unallowable Costs
52.242–13 Bankruptcy
52.244–5 Competition in Subcontracting
52.245–2 Government Property (Fixed-Price Contracts)
52.246–4 Inspection of Services—Fixed Price
52.246–25 Limitation of Liability—Services
52.247–63 Preference for U.S.-Flag Air Carriers
52.249–2 Termination for Convenience of the Government (Fixed Price)
52.249–8 Default (Fixed Price Supply and Service)
52.249–14 Excusable Delays
52.251–1 Government Supply Sources
52.252–4 Alterations in Contract
52.252–6 Authorized Deviations in Clauses

34. Revise section 2152.203–70 to read as follows:

2152.203–70 Misleading, deceptive, or unfair advertising.

As prescribed in 2103.571, insert the following clause:

Misleading, Deceptive, or Unfair Advertising (Oct 2005)

The Contractor agrees that any advertising material authorized and released by the Contractor which mentions the FEGLI Program must be truthful and not misleading and must present an accurate statement of FEGLI Program benefits. The Contractor is prohibited from making incomplete and/or incorrect comparisons or using disparaging or minimizing techniques to compare its other products or services to those of the FEGLI Program. The Contractor agrees to use reasonable efforts to assure that agents selling its other products are aware of and abide by this provision. The Contractor agrees to incorporate this clause in all subcontracts as defined at LIFAR 2102.101.

(End of Clause)

35. Add a new section 2152.204–70 to read as follows:

2152.204–70 Taxpayer Identification Number.

As prescribed in 2104.9001, insert the following clause:

Taxpayer Identification Number (Oct 2005)

(a) Definitions.

Common parent, as used in this provision, means that corporate entity that owns or controls an affiliated group of corporations that files its Federal income tax returns on a consolidated basis, and of which the Contractor is a member.

Taxpayer Identification Number (TIN), as used in this provision, means the number required by the Internal Revenue Service (IRS) to be used by the Contractor in reporting income tax and other returns. The TIN is the Contractor's Social Security Number.

(b) The Contractor must submit the information required in paragraphs (d) through (f) of this clause to comply with debt collection requirements of 31 U.S.C. 7701(c) and 3325(d), reporting requirements of 26 U.S.C. 6041, 6041A, and 6050M, and implementing regulations issued by the IRS. The Contractor is subject to the payment reporting requirements described in FAR 4.904. The Contractor's failure or refusal to furnish the information will result in payment being withheld until the TIN is provided.

(c) The Government may use the TIN to collect and report on any delinquent amounts arising out of the Contractor's relationship

with the Government (31 U.S.C. 7701(c)(3)). The TIN provided hereunder may be matched with IRS records to verify its accuracy.

(d) Taxpayer Identification Number (TIN).

TIN: _____

(e) Type of organization.

☐ Corporate entity (tax-exempt);

☐ Other _____

(f) Common parent.

☐ Contractor is not owned or controlled by a common parent as defined in paragraph (a) of this clause.

☐ Name and TIN of common parent:

Name _____

TIN _____

(End of Clause)

36. In section 2152.210–70 revise the clause title date, and revise paragraphs (a), (c), and (d)(2) to read as follows:

2152.210–70 Investment income.

Investment Income (Oct 2005)

(a) The Contractor must invest and reinvest all FEGLI Program funds on hand until needed to discharge promptly the obligations incurred under the contract. Within the constraints of safety and liquidity of investments, the Contractor must seek to maximize investment income. However, the Contractor will not be responsible for any actions taken at the direction of OPM.

* * * * *

(c) When the Contracting Officer concludes that the Contractor failed to comply with paragraph (a) or (b) of this clause, the Contractor must pay to OPM the investment income that would have been earned, at the rate(s) specified in paragraph (d) of this clause, had it not been for the Contractor's noncompliance. *Failed to comply with paragraph (a) or (b) of this clause* means:

(1) Making any charges against the contract which are not actual, allowable, allocable, or reasonable; or

(2) Failing to credit any income due the contract and/or failing to place funds on hand, including premium payments and payments from OPM not needed to discharge promptly the obligations incurred under the contract, tax refunds, credits, deposits, investment income earned, uncashed checks, or other amounts owed OPM in income-producing investments and accounts.

(d) * * *

(2) Investment income lost by the Contractor as a result of failure to credit income due under the contract or failure to place funds on hand in income-producing investments and accounts must be paid from the date the funds should have been invested or appropriate income was not credited and will end on the earlier of:

(i) The date the amounts are returned to OPM;

(ii) The date specified by the Contracting Officer; or

(iii) The date of the Contracting Officer's final decision.

* * * * *

37. In section 2152.210–71 revise the clause title date, and revise paragraphs (a)(3), (a)(5), (a)(6), (a)(11), (b), and (d) to read as follows:

2152.210–71 Notice of significant events.

As prescribed in 2110.7004(b), insert the following clause:

Notice of Significant Events (Oct 2005)

(a) * * *

(3) Loss of 20 percent or more of FEGLI Program reinsurers in a contract year;

* * * * *

(5) The withdrawal of, or notice of intent to withdraw, by any State or the District of Columbia, its license to do life insurance business or any other change of life insurance status under State law;

(6) The Contractor's material default on a loan or other financial obligation;

* * * * *

(11) Any written exceptions, reservations, or qualifications expressed by the independent accounting firm contracted with by the Contractor to provide an audit opinion on the annual financial report required by OPM for the FEGLI Program. (Accounting firm employees must be members of the American Institute of Certified Public Accountants and must audit the report in accordance with Generally Accepted Government Auditing Standards or other requirements issued by OPM.)

(b) Upon learning of a significant event, OPM may institute action, in proportion to the seriousness of the event, to protect the interest of insureds, including, but not limited to—

(1) Directing the Contractor to take corrective action; or

(2) Making a downward adjustment to the weight in the "Contractor Performance" factor of the service charge.

* * * * *

(d) The Contractor agrees to insert this clause in any subcontract or subcontract modification when the amount of the subcontract or modification that is charged to the FEGLI Program contract exceeds $550,000 and is at least 25 percent of the total cost of the subcontract.

(End of Clause)

38. Revise section 2152.215–70 to read as follows:

2152.215–70 Contractor records retention.

As prescribed in 2115.071, insert the following clause:

Contractor Records Retention (Oct 2005)

Notwithstanding the provisions of FAR 52.215–2(f), "Audit and Records—Negotiation," the Contractor must retain and make available all records applicable to a contract term that support the annual financial report for a period of 5 years after the end of the contract term to which the records relate. Claim records must be maintained for 10 years after the end of the contract term to which the claim records relate. If the Contractor chooses to maintain paper documents in electronic format, the electronic version must be an exact replica of the paper document.

(End of Clause)

39. Revise section 2152.216–70 to read as follows:

2152.216–70 Fixed price with limited cost redetermination—risk charge.

As prescribed in 2116.270–1(a), insert the following clause when a risk charge is negotiated:

Fixed Price With Limited Cost Redetermination Plus Fixed Fee Contract—Risk Charge (Oct 2005)

(a) This is a fixed price with limited cost redetermination plus fixed fee contract, with the fixed fee in the form of a risk charge. OPM will pay the Contractor the risk charge as specified in a letter from the Contracting Officer.

(b) At the Contractor's request, OPM will furnish, during the third quarter of the current contract year, an accounting of the funds in the Employees' Life Insurance Fund as of the end of the second quarter of the contract year.

(End of Clause)

40. Revise section 2152.216–71 to read as follows:

2152.216–71 Fixed price with limited cost redetermination—service charge.

As prescribed in 2116.270–1(b), insert the following clause when a service charge is negotiated:

Fixed Price With Limited Cost Redetermination Plus Fixed Fee Contract—Service Charge (Oct 2005)

(a) This is a fixed price with limited cost redetermination plus fixed fee contract, with the fixed fee in the form of a service charge. OPM will pay the Contractor the service charge as specified in a letter from the Contracting Officer.

(b) At the Contractor's request, OPM will furnish, during the third quarter of the current contract year, an accounting of the funds in the Employees' Life Insurance Fund as of the end of the second quarter of the contract year.

(End of Clause)

41. In section 2152.224–70 revise the clause title date, and revise paragraph (a) to read as follows:

2152.224–70 Confidentiality of records.

* * * * *

Confidentiality of Records (Oct 2005)

(a) The Contractor will use the personal data on employees and annuitants that is provided by agencies and OPM, including social security numbers, for only those routine uses stipulated for the data and published in the **Federal Register** as part of OPM's notice of systems of records.

* * * * *

42. Revise section 2152.231–70 to read as follows:

2152.231–70 Accounting and allowable cost.

As prescribed in 2131.270, insert the following clause:

Accounting and Allowable Cost (Oct 2005)

(a) *Annual Financial Report.* (1) The Contractor must prepare annually a financial

report summarizing the financial operations of the FEGLI Program for the previous contract year. This report will be due to OPM in accordance with a date established by OPM's requirements.

(2) The Contractor must have the most recent financial report for the FEGLI Program audited by an independent public accounting firm, whose employees are members of the American Institute of Certified Public Accountants. The audit must be performed in accordance with Generally Accepted Government Auditing Standards or other requirements issued by OPM. The report by the independent accounting firm on its audit must be submitted to OPM along with the annual financial report.

(3) Based on the results of either the independent audit or a Government audit, the FEGLI contract may be:

(i) Adjusted by amounts found not to constitute chargeable costs; or

(ii) Adjusted for prior overpayments or underpayments.

(b) *Definition of costs.* (1) A cost is chargeable to the contract for a ontract term if it is:

(i) An actual, allowable, allocable, and reasonable cost;

(ii) Incurred with proper justification and accounting support;

(iii) Determined in accordance with subpart 31.2 of the Federal Acquisition Regulation (FAR) and subpart 2131.2 of the Federal Employees' Group Life Insurance Acquisition Regulation (LIFAR) applicable on October 1 of each year; and

(iv) Determined in accordance with the terms of this contract.

(2) In the absence of specific contract terms to the contrary, contract costs will be classified in accordance with the following criteria:

(i) *Benefits.* Claims costs consist of payments made and costs incurred (including delayed settlement interest) by the Contractor for life insurance, accidental death and dismemberment insurance, excess mortality charges, post-mortem conversion charges, and conversion policies on behalf of insured persons, less any overpayments recovered (subject to the terms of LIFAR 2131.205–3), refunds, or other credits received.

(ii)(A) *Administrative expenses.* Administrative expenses consist of chargeable costs as defined in paragraph (b)(1) of this clause incurred in the adjudication of claims or incurred in the Contractor's overall operation of the business. Unless otherwise provided in the contract, FAR, or LIFAR, administrative expenses include, but are not limited to, taxes, service charges to reinsurers, the cost of investigation and settlement of policy claims, the cost of maintaining records regarding payment of claims, and legal expenses incurred in the litigation of benefit payments. Administrative expenses exclude the expenses related to investment income in paragraph (b)(2)(iii) of this clause.

(B) *Administrative Expense Ceiling.* Each year an administrative expense ceiling for the following contract year is calculated based on the prior contract year's administrative expense ceiling, adjusted by the percentage change in the average monthly consumer Price Index for All Urban Consumers for the preceding 12 months. Administrative expenses are reimbursed up to the administrative expense ceiling or actual costs, whichever is less. Both parties will reexamine the base, including the prior year's actual expenses, at the request of either OPM or the Contractor. Within the administrative expense ceiling is a separately negotiated limit for indirect costs that may be charged against the ceiling for the contract year. The Contractor agrees to provide annually to the Contracting Officer a detailed report of direct and indirect administrative costs which form the basis for determining the limit on indirect costs for the following contract year. During a continuity of services period, OPM and the Contractor will negotiate a one-time increase in the administrative expense ceiling to cover phase-in/phase-out costs. Costs that exceed the revised ceiling must be submitted by the Contractor, in writing and in advance of their incurrence, to the Contracting Officer for approval.

(iii) *Investment income.* Investment income represents the amount earned by the Contractor after deducting chargeable investment expenses. Investment expenses are those chargeable contract costs, as defined in paragraph (b)(1) of this clause, which are attributable to the investment of FEGLI funds.

(c) *Certification of Annual Financial Report.* (1) The Contractor must certify the annual financial report in the form set forth in paragraph (c)(2) of this clause. The certificate must be signed by the chief executive officer for the Contractor's FEGLI Program operations and the chief financial officer for the Contractor's FEGLI Program operations and must be returned with the annual financial report.

(2) The certification required must be in the following form:

Certification of Annual Financial Report

This is to certify that I have reviewed this financial report and, to the best of my knowledge and belief, attest that:

1. The report was prepared in conformity with the guidelines issued by the Office of Personnel Management and fairly presents the financial results of this contract year in conformity with those guidelines;

2. The costs included in the report are actual, allowable, allocable, and reasonable in accordance with the terms of the contract and with the cost principles of the Federal Employees' Group Life Insurance Program Acquisition Regulation (LIFAR) and the Federal Acquisition Regulation (FAR);

3. Income, overpayments, refunds, and other credits made or owed in accordance with the terms of the contract and applicable cost principles have been included in the report.

(End of clause)

43. Revise section 2152.232–70 to read as follows:

2152.232–70 Payments.

As prescribed in 2132.171, insert the following clause:

Payments (Oct 2005)

(a) OPM will make available to the Contractor, in full settlement of its obligations under this contract, subject to adjustment based on actual claims and administrative cost, a fixed premium once per month on the first business day of the month. The premium is determined by an estimate of costs for the contract year as provided in Section ____ and is redetermined annually by mutual agreement of OPM and the Contractor. In addition, an annual reconciliation of premiums, benefits, and other costs is performed, and additional payment by OPM or reimbursement by the Contractor is paid as necessary.

(b) If OPM fails to fund the Letter of Credit (LOC) account for the full amount of premium due by the due date, a grace period of 31 days will be granted to OPM for providing any premium due, unless OPM has previously given written notice to the Contractor that the contract is to be discontinued. The contract will continue in force during the grace period.

(c) If OPM fails to fund the LOC account for any premiums within the grace period, the contract may be terminated at the end of the 31st day of the grace period in accordance with LIFAR 2149.002(a)(2). If during the grace period OPM presents written notice to the Contractor that the contract is to be terminated before the expiration of the grace period, the contract will be terminated the later of the date of receipt of such written notice by the Contractor or the date specified by OPM for termination. In either event, OPM will be liable to the Contractor for all premiums then due and unpaid.

(d) In accordance with LIFAR 2143.205 and LIFAR 2252.243–70, Changes, if a change is made to the contract that increases or decreases the cost of performance of the work under this contract, the Contracting Officer will make an equitable adjustment to the payments under this contract.

(e) In the event this contract is terminated in accordance with LIFAR part 2149, the special contingency reserve held by the Contractor will be available to pay the necessary and proper charges against this contract after other Program assets held by the Contractor are exhausted.

(End of Clause)

44. Revise section 2152.232–71 to read as follows:

2152.232–71 Non-commingling of FEGLI Program funds.

As prescribed in 2132.772, insert the following clause:

Non-Commingling of Funds (Oct 2005)

(a) The Contractor must maintain FEGLI Program funds in such a manner as to be separately identifiable from other assets of the Contractor.

(b) The Contractor may request a modification of paragraph (a) of this clause from the Contracting Officer. The modification must be requested, and approved by the Contracting Officer, in advance of any change, and the Contractor must demonstrate that accounting techniques have been established that clearly measure

FEGLI Program cash and investment income (*i.e.*, subsidiary ledgers). Reconciliations between amounts reported and actual amounts shown in accounting records must be provided as supporting schedules to the annual financial report.

(End of Clause)

45. In section 2152.237–70 revise the clause title date, and revise paragraphs (a), (c), and (d) to read as follows:

2152.237–70 Continuity of services.

* * * * *

Continuity of Services (Oct 2005)

(a) The Contractor recognizes that the services under this contract are vital to the Government and must be continued without interruption. The Contractor further recognizes that upon contract expiration or termination, including termination by the Contractor for OPM's failure to make timely premium payments, a successor, either the Government or another Contractor, may continue them. The Contractor agrees to furnish phase-in training and exercise its best efforts and cooperation to effect an orderly and efficient transition to a successor.

* * * * *

(c) The Contractor must allow as many experienced personnel as practicable to remain on the job during the transition period to help the successor maintain the continuity and consistency of the services required by this contract. The Contractor also must, except if prohibited by applicable law, disclose necessary personnel records and allow the successor to conduct onsite interviews with these employees. If selected employees are agreeable to the change, the Contractor must release them at a mutually agreeable date and negotiate transfer of their earned fringe benefits to the successor.

(d) The Contractor will be reimbursed for all reasonable phase-in, phase-out costs (*i.e.*, costs incurred within the agreed period after contract termination that result from phase-in and phase-out operations) in accordance with the provisions of the administrative expense ceiling in the clause at 2152.231–70(b)(2)(ii)(B) and a risk charge or a service charge (profit) not to exceed a pro rata portion of the risk or service charge under this contract. The amount of profit will be based upon the accurate and timely processing of benefit claims, the volume and validity of complaints received by OPM, the timeliness and adequacy of reports on operations, and responsiveness to OPM offices, enrollees, beneficiaries, and Congress. In setting the final profit figure, obstacles overcome by the Contractor during the phase-in and phase-out period will be taken into consideration. OPM will pay an incentive amount to the Contractor not to exceed the pro rata risk or service charge for the continuity of services period, if the Contractor has performed exceptionally during the transition period to a new Contractor. The Contracting Officer uses the weighted guidelines method described in LIFAR 2115.404–71 in determining the incentive amount.

(End of Clause)

46. In section 2152.243–70 revise the clause title date, and revise paragraphs (a)(1), (a)(2), and (c) to read as follows:

2152.243–70 Changes.

* * * * *

Changes (Oct 2005)

(a) * * *

(1) Description of services to be performed;

(2) Time of performance (*i.e.*, hours of the day, days of the week, etc.);

* * * * *

(c) The Contractor must assert its right to an adjustment under this clause within 30 days from the date of receipt of the written order. However, if the Contracting Officer decides that the facts justify it, the Contracting Officer may receive and act upon a proposal submitted before final payment of the contract.

* * * * *

47. In section 2152.244–70 revise the clause title date, and revise paragraphs (a) and (f) to read as follows:

2152.244–70 Subcontracts.

* * * * *

Subcontracts (October 2005)

(a) The Contractor must notify the Contracting Officer reasonably in advance of entering into any subcontract or subcontract modification, or as otherwise specified by this contract, when the cost of that portion of the subcontract that is charged the FEGLI Program contract exceeds $550,000 and is at least 25 percent of the total cost of the subcontract.

* * * * *

(f) No subcontract placed under this contract will provide for payment on a cost-plus-a-percentage-of-cost basis. Any fee payable under cost reimbursement type subcontracts will not exceed the fee limitations in FAR 15.404–4(c)(4)(i). Any profit or fee payable under a subcontract will be in accordance with the provisions of Section _____.

* * * * *

48. In section 2152.246–70 revise the clause title date, and revise paragraph (b) to read as follows:

2152.246–70 Quality assurance requirements.

* * * * *

Quality Assurance Requirements (Oct 2005)

* * * * *

(b) The Contractor must keep complete records of its quality assurance procedures and the results of their implementation and make them available to an authorized Government entity during contract performance and for 5 years after the end of the contract term to which the records relate.

* * * * *

49. In section 2152.249–70 revise the clause title date, and revise paragraphs (b) and (d) to read as follows:

2152.249–70 Renewal and termination.

* * * * *

Renewal and Termination (Oct 2005)

* * * * *

(b) This contract may be terminated by OPM at any time in accordance with FAR part 49 and FAR 52.249–8 for default by the Contractor. This contract terminates at the end of the grace period if the Government does not fund the LOC account for any of the premium due to the Contractor (see LIFAR 2149.002(a)(2)). However, the Contractor and OPM may agree to continue the contract. In addition, the Contractor agrees to reinstate the contract if termination: (1) Arose out of the Government's inadvertent failure to fund the LOC account for the amount of the premium payment prior to the expiration of the grace period as defined in LIFAR 2102.101, and/or (2) was due to circumstances beyond the Government's control, provided that the LOC account is funded in the amount of the premium payment due to the Contractor within 5 days after the expiration of the grace period. In the event of such reinstatement, OPM will equitably adjust the payments due under the contract to compensate the Contractor for any increased costs of performance that result from the Government's failure to fund the LOC account prior to the expiration of the grace period and/or such reinstatement.

* * * * *

(d) Upon termination of the contract for Contractor's default or OPM's convenience, the Contractor agrees to assist OPM with an orderly and efficient transition to a successor in accordance with LIFAR 2137.102, LIFAR 2137.110, and the provisions of the "Continuity of Services" clause at 2152.237–70. The Contractor is not required to continue performance subsequent to OPM's failure to fund the LOC account for premiums due under paragraph (b) of this clause.

* * * * *

Subpart 2152.3—Provision and Clause Matrix

50. In section 2152.370 revise the FEGLI Program Clause Matrix to read as follows:

2152.370 Use of the matrix.

* * * * *

FEGLI PROGRAM CLAUSE MATRIX

Clause No.	Text reference	Title	Use status
FAR 52.202–1	FAR 2.201	Definitions	M
FAR 52.203–3	FAR 3.202	Gratuities	M
FAR 52.203–5	FAR 3.404	Covenant against Contingent Fees	M
FAR 52.203–6	FAR 3.503–2	Restrictions on Subcontractor Sales to the Government	M
FAR 52.203–7	FAR 3.502–3	Anti-Kickback Procedures	M
FAR 52.203–12	FAR 3.808	Limitation on Payments to Influence Certain Federal Transactions.	M
2152.203–70	2103.571	Misleading, deceptive, or unfair advertising	M
2152.204–70	2104.9001	Taxpayer Identification Number	M
FAR 52.209–6	FAR 9.409(b)	Protecting the Government's Interest when Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment.	M
2152.209–71	2109.409(b)	Certification regarding debarment, suspension, proposed debarment and other responsibility matters.	M
2152.210–70	2110.7004(a)	Investment income	M
2152.210–71	2110.7004(b)	Notice of significant events	M
FAR 52.215–2	FAR 15.209(b)	Audit and Records—Negotiation	M
FAR 52.215–10	FAR 15.408(b)	Price Reduction for Defective Cost or Pricing Data	M
FAR 52.215–12	FAR 15.408(d)	Subcontractor Cost or Pricing Data	M
FAR 52.215–15	FAR 15.408(g)	Pension Adjustments and Asset Reversions	M
FAR 52.215–16	FAR 15.408(h)	Facilities Capital Cost of Money	M
FAR 52.215–17	FAR 15.408(i)	Waiver of Facilities Capital Cost of Money	A
FAR 52.215–18	FAR 15.408(j)	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) other than Pensions.	A
2152.215–70	2115.071	Contractor records retention	M
2152.216–70	2116.270–1(a)	Fixed price with limited cost redetermination—risk charge	A
2152.216–71	2116.270–1(b)	Fixed price with limited cost redetermination—service charge	A
FAR 52.219–8	FAR 19.708(a)	Utilization of Small Business Concerns	M
FAR 52.222–1	FAR 22.103–5(a)	Notice to the Government of Labor Disputes	M
FAR 52.222–3	FAR 22.202	Convict Labor	M
FAR 52.222–4	FAR 22.305	Contract Work Hours and Safety Standards Act—Overtime Compensation.	M
FAR 52.222–21	FAR 22.810(a)(1)	Prohibition of Segregated Facilities	M
FAR 52.222–22	FAR 22.810(a)(2)	Previous Contracts and Compliance Reports	M
FAR 52.222–25	FAR 22.810(d)	Affirmative Action Compliance	M
FAR 52.222–26	FAR 22.810(e)	Equal Opportunity	M
FAR 52.222–29	FAR 22.810(g)	Notification of Visa Denial	A
FAR 52.222–35	FAR 22.1310(a)(1)	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans.	M
FAR 52.222–36	FAR 22.1408(a)	Affirmative Action for Workers with Disabilities	M
FAR 52.222–37	FAR 22.1310(b)	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans.	M
FAR 52.223–6	FAR 23.505	Drug-Free Workplace	M
2152.224–70	2124.104–70	Confidentiality of records	M
FAR 52.227–1	FAR 27.201–2(a)	Authorization and Consent	M
FAR 52.227–2	FAR 27.202–2	Notice and Assistance regarding Patent and Copyright Infringement.	A
FAR 52.228–7	FAR 28.311–1	Insurance—Liability to Third Persons	M
2152.231–70	2131.270	Accounting and allowable cost	M
FAR 52.232–9	FAR 32.111(c)(2)	Limitation on Withholding of Payments	M
FAR 52.232–17	FAR 32.617(a) and (b)	Interest	M
FAR 52.232–23	FAR 32.806(a)(1)	Assignment of Claims	A
FAR 52.232–33	FAR 32.1110(a)(1)	Payment by Electronic Funds Transfer—Central Contractor Registration.	M
2152.232–70	2132.171	Payments	M
2152.232–71	2132.772	Non-commingling of FEGLI Program funds	M
2152.232–72	2132.806	Approval for assignment of claims	M
FAR 52.233–1	FAR 33.215	Disputes (Alternate I)	M
2152.237–70	2137.110	Continuity of services	M
FAR 52.242–1	FAR 42.802	Notice of Intent to Disallow Costs	M
FAR 52.242–3	FAR 42.709–6	Penalties for Unallowable Costs	M
FAR 52.242–13	FAR 42.903	Bankruptcy	M
2152.243–70	2143.205	Changes	M
FAR 52.244–5	FAR 44.204(c)	Competition in Subcontracting	M
2152.244–70	2144.204	Subcontracts	M
FAR 52.245–2	FAR 45.106(b)(1)	Government Property (Fixed-Price Contracts)	M
FAR 52.246–4	FAR 46.304	Inspection of Services—Fixed Price	M
FAR 52.246–25	FAR 46.805	Limitation of Liability—Services	M
2152.246–70	2146.270–1	Quality assurance requirements	M
FAR 52.247–63	FAR 47.405	Preference for U.S.-Flag Air Carriers	M

FEGLI PROGRAM CLAUSE MATRIX—Continued

Clause No.	Text reference	Title	Use status
FAR 52.249–2	FAR 49.502(b)(1)(i)	Termination for Convenience of the Government (Fixed-Price)	M
FAR 52.249–8	FAR 49.504(a)(1)	Default (Fixed Price Supply and Service)	M
FAR 52.249–14	FAR 49.505(d)	Excusable Delays	M
2152.249–70	2149.505–70	Renewal and termination	M
FAR 52.251–1	FAR 51.107	Government Supply Sources	A
FAR 52.252–4	FAR 52.107(d)	Alterations in Contract	M
FAR 52.252–6	FAR 52.107(f)	Authorized Deviations in Clauses	M

[FR Doc. 04–21922 Filed 10–1–04; 8:45 am]
BILLING CODE 6325–39–P

Notices

Federal Register
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Monday, October 4, 2004

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

Animal and Plant Health Inspection Service

[Docket No. 04–098–1]

Notice of Request for Extension of Approval of an Information Collection

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request an extension of approval of an information collection associated with environmental monitoring.

DATES: We will consider all comments that we receive on or before December 3, 2004.

ADDRESSES: You may submit comments by any of the following methods:

- EDOCKET: Go to *http://www.epa.gov/feddocket* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once you have entered EDOCKET, click on the "View Open APHIS Dockets" link to locate this document.
- Postal Mail/Commercial Delivery: Please send four copies of your comment (an original and three copies) to Docket No. 04–098–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 04–098–1.
- E-mail: Address your comment to *regulations@aphis.usda.gov*. Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and "Docket No. 04–098–1" on the subject line.
- Agency Web Site: Go to *http://www.aphis.usda.gov/ppd/rad/cominst.html* for a form you can use to submit an e-mail comment through the APHIS Web site.

Reading Room: You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

Other Information: You may view APHIS documents published in the **Federal Register** and related information, including the names of groups and individuals who have commented on APHIS dockets, on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html*.

FOR FURTHER INFORMATION CONTACT: For information regarding environmental monitoring, contact Mr. Ronald Berger, Environmental Monitoring, Pest Detection and Management Programs, PPQ, APHIS, 4700 River Road Unit 150, Riverdale, MD 20737; (301) 734–5105. For copies of more detailed information on the information collection, contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734–7477.

SUPPLEMENTARY INFORMATION:

Title: Environmental Monitoring Form.

OMB Number: 0579–0117.

Type of Request: Extension of approval of an information collection.

Abstract: The mission of the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture is to protect the health and value of American animal and plant resources. In carrying out this mission, APHIS ensures appropriate consideration of the potential environmental effects of its programs.

In accordance with the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and the regulations that implement this Act (contained in 40 CFR parts 1500–1508), APHIS engages in environmental monitoring for certain activities that we conduct to control or eradicate certain pests and diseases. We monitor those activities that have the greatest potential for harm to the human environment to ensure that the mitigation measures developed to avoid that harm are enforced and effective. In many cases, monitoring is required where APHIS programs are conducted close to habitats of endangered and threatened species. This monitoring is developed in coordination with the U.S. Department of the Interior, Fish and Wildlife Service, in compliance with the Endangered Species Act (50 U.S.C. 17.11 and 17.12).

APHIS field personnel and State cooperators jointly use APHIS Form 2060, Environmental Monitoring Form, to collect information concerning the effects of pesticide use in these sensitive habitats. The goal of environmental monitoring is to track the potential impact that APHIS activities may have on the environment and to use this knowledge in making any necessary adjustments in future program actions.

We are asking the Office of Management and Budget (OMB) to approve our use of APHIS Form 2060 for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information 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 our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(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, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.*, permitting electronic submission of responses.

Estimate of burden: The public reporting burden for this collection of information is estimated to average 0.5 hours per response.

Respondents: Growers, appliers of pesticides, State department of agriculture personnel.

Estimated annual number of respondents: 150.

Estimated annual number of responses per respondent: 20.

Estimated annual number of responses: 3,000.

Estimated total annual burden on respondents: 1,500 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 28th day of September 2004.

Elizabeth E. Gaston,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E4–2470 Filed 10–1–04; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 04–097–1]

Notice of Request for Extension of Approval of an Information Collection

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request an extension of approval of an information collection associated with accrediting nongovernment facilities to perform services related to the export certification of plants or plant products.

DATES: We will consider all comments that we receive on or before December 3, 2004.

ADDRESSES: You may submit comments by any of the following methods:

- EDOCKET: Go to *http://www.epa.gov/feddocket* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once you have entered EDOCKET, click on the "View Open APHIS Dockets" link to locate this document.
- Postal Mail/Commercial Delivery: Please send four copies of your comment (an original and three copies) to Docket No. 04–097–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road, Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 04–097–1.
- E-mail: Address your comment to *regulations@aphis.usda.gov*. Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and "Docket No. 04–097–1" on the subject line.
- Agency Web Site: Go to *http://www.aphis.usda.gov/ppd/rad/cominst.html* for a form you can use to submit an e-mail comment through the APHIS Web site.

Reading Room: You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

Other Information: You may view APHIS documents published in the **Federal Register** and related information, including the names of groups and individuals who have commented on APHIS dockets, on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html.*

FOR FURTHER INFORMATION CONTACT: For information regarding the accreditation program, contact Mr. Michael Ward, Accreditation Program Manager, Phytosanitary Issues Management, PPQ, APHIS, 4700 River Road, Unit 140, Riverdale, MD 20737; (301) 734–8262. For copies of more detailed information on the information collection, contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734–7477.

SUPPLEMENTARY INFORMATION:

Title: Accreditation of Nongovernment Facilities.

OMB Number: 0579–0130.

Type of Request: Extension of approval of an information collection.

Abstract: The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA), among other things, provides export certification services to assure other countries that the plants and plant products they are receiving from the United States are free of plant pests specified by the receiving country. This activity is authorized by the Plant Protection Act (7 U.S.C. 7701–7772).

The export certification regulations, which are contained in 7 CFR part 353, describe the procedures for obtaining certification for plants and plant products offered for export or reexport. Our regulations do not require that we engage in export certification activities; however, we perform this work as a service to exporters who are shipping plants or plant products to countries that require phytosanitary certification as a condition of entry.

After assessing the condition of the plants or plant products intended for export (*i.e.*, after conducting a phytosanitary inspection), an inspector will issue an internationally recognized phytosanitary certificate, a phytosanitary certificate for reexport, or an export certificate for processed plant products. Laboratory testing of plant or plant product samples is an important component of the certification process.

The regulations allow nongovernment facilities (such as commercial laboratories and private inspection services) to be accredited by APHIS to perform specific laboratory testing or phytosanitary inspections that could serve as the basis for issuing Federal phytosanitary certificates, phytosanitary certificates for reexport, or export certificates for processed plant products.

The accreditation process requires the use of several information collection activities to ensure that nongovernment facilities applying for accreditation possess the necessary qualifications.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information 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 our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(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, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.*, permitting electronic submission of responses.

Estimate of burden: The public reporting burden for this collection of information is estimated to average 3.4482 hours per response.

Respondents: U.S. growers, shippers, and exporters; State and plant health protection authorities.

Estimated annual number of respondents: 15.

Estimated annual number of responses per respondent: 5.8.

Estimated annual number of responses: 87.

Estimated total annual burden on respondents: 300 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 28th day of September, 2004.

Elizabeth E. Gaston,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E4–2474 Filed 10–1–04; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 04–039–2]

Mile-A-Minute Weed; Availability of an Environmental Assessment and Finding of No Significant Impact

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that an environmental assessment and finding of no significant impact have been prepared by the Animal and Plant Health Inspection Service relative to issuing a permit for the environmental release of the nonindigenous weevil *Rhinoncomimus latipes* Korotyaev (Coleoptera: Curculionidae), a potential biological control agent of mile-a-minute weed (*Polyganum perfoliatum*). The environmental assessment documents our review and analysis of environmental impacts associated with, and alternatives to, issuing a permit for the environmental release of the weevil in the continental United States. Based on its finding of no significant impact, the Animal and Plant Health Inspection Service has determined that an environmental impact statement need not be prepared.

ADDRESSES: Copies of the environmental assessment and finding of no significant impact are available for public inspection in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Robert Flanders, Branch Chief, Biological and Technical Services, Pest Permit Evaluations, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737–1236; (301) 734–5930.

SUPPLEMENTARY INFORMATION:

Background

Mile-a-minute weed (*Polygonum perfoliatum* L. [Polygonaceae]) is an annual vine that is indigenous to Asia. Since it was accidentally introduced into Pennsylvania via imported nursery stock in the 1930s, it has become established throughout the northeastern United States. The weed grows rapidly, with stems that can extend up to 6 meters. Its stems, petioles, and leaf veins are covered with downward-curving barbs that aid the plant in climbing and supporting itself on other plants.

Large, dense patches of mile-a-minute weed develop during the summer. As the vines climb over and cover other plants, they block available sunlight, which can reduce the population of native plant species in affected areas. Mile-a-minute weed can also interfere with Christmas tree farms, pine plantations, and reforestation projects by smothering tree seedlings. Nursery and horticultural crops that are not regularly tilled can also be affected by mile-a-minute weed. The Animal and Plant Health Inspection Service (APHIS) and several States list mile-a-minute weed as a noxious weed.

On June 1, 2004, we published in the **Federal Register** (69 FR 30865–30866, Docket No. 04–039–1) a notice in which we announced the availability, for public review and comment, of an environmental assessment documenting our review and analysis of environmental impacts associated with issuing a permit for the release of the nonindigenous weevil *Rhinoncomimus latipes* Korotyaev (Coleoptera: Curculionidae) as a biological control agent of mile-a-minute weed in the continental United States. Research suggests that larval feeding by this weevil has the potential to kill small mile-a-minute weed plants and stunt and reduce seed production by larger plants. Alternatives to issuing the permit were also examined in the environmental assessment, and included no action, herbicides, mechanical control, and cultural control.

We solicited comments on the environmental assessment for 30 days ending on July 1, 2004. We received one comment by that date, from a private citizen. The commenter objected to APHIS programs and activities in general, but did not address the environmental assessment. Therefore, we are making no changes to the environmental assessment based on this comment.

The environmental assessment and finding of no significant impact may be viewed on the Internet at *http://www.aphis.usda.gov/ppq/*. In the middle of that page, click on "Document/Forms Retrieval System." At the next screen, click on the triangle beside "Permits—Environmental Assessments." A list of documents will appear; the environmental assessment and finding of no significant impact for mile-a-minute weed are document number 0037. You may request paper copies of the environmental assessment and finding of no significant impact by calling or writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. Please refer to the title of the environmental assessment and finding of no significant impact when requesting copies. The environmental assessment and finding of no significant impact are also available for review in our reading room (information on the location and hours of the reading room is listed under the heading **ADDRESSES** at the beginning of this notice).

The environmental assessment and finding of no significant impact have been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Done in Washington, DC, this 28th day of September 2004.

Elizabeth E. Gaston,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E4–2473 Filed 10–1–04; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 04–076–1]

Monsanto Co.; Availability of Petition and Environmental Assessment for Determination of Nonregulated Status for Cotton Genetically Engineered for Tolerance to the Herbicide Glyphosate

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service has received a petition from Monsanto Company seeking a determination of nonregulated status for cotton designated as MON 88913, which has been genetically engineered for tolerance to the herbicide glyphosate. The petition has been submitted in accordance with our regulations concerning the introduction of certain genetically engineered organisms and products. In accordance with those regulations, we are soliciting public comments on whether this cotton presents a plant pest risk. We are also making available for public comment an environmental assessment for the proposed determination of nonregulated status.

DATES: We will consider all comments we receive on or before December 3, 2004.

ADDRESSES: You may submit comments by any of the following methods:

- Postal Mail/Commercial Delivery: Please send four copies of your comment (an original and three copies) to Docket No. 04–076–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 04–076–1.
- E-mail: Address your comment to *regulations@aphis.usda.gov*. Your comment must be contained in the body of your message; do not send attached files.
- Agency Web Site: Go to *http://www.aphis.usda.gov/ppd/rad/cominst.html* for a form you can use to submit an e-mail comment through the APHIS Web site.
- Federal eRulemaking Portal: Go to *http://www.regulations.gov* and follow the instructions for locating this docket and submitting comments.

Reading Room: You may read the petition, the environmental assessment, and any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

Other Information: You may view APHIS documents published in the **Federal Register** and related information, including the names of groups and individuals who have commented on APHIS dockets, on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html*.

FOR FURTHER INFORMATION CONTACT: Mr. Michael Blanchette, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737–1236; (301) 734–5141. To obtain copies of the petition or the environmental assessment, contact Ms. Terry Hampton at (301) 734–5715; e-mail: *TerryA.Hanpton@aphis.usda.gov*. The petition and environmental assessment are also available on the Internet at *http://www.aphis.usda.gov/brs/aphisdocs/04_08601p.pdf* and *http://www.aphis.usda.gov/brs/aphisdocs/04_08601p_ea.pdf*.

SUPPLEMENTARY INFORMATION: The regulations in 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests," regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered organisms and products are considered "regulated articles."

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. Paragraphs (b) and (c) of § 340.6 describe the form that a petition for a determination of nonregulated status must take and the information that must be included in the petition.

On March 26, 2004, APHIS received a petition from Monsanto Company of St. Louis, MO, (Monsanto), requesting a determination of nonregulated status under 7 CFR part 340 for cotton (*Gossypium hirsutum* L.) designated as MON 88913, which has been genetically engineered for tolerance to the herbicide glyphosate. The Monsanto petition states that the subject cotton should not be regulated by APHIS because it does not present a plant pest risk.

As described in the petition, MON 88913 has been genetically engineered to express a 5-enolpyruvyshikimate-3-phosphate synthase protein from *Agrobacterium* sp. strain CP4 (CP4 EPSPS), which confers tolerance to the herbicide glyphosate. Expression of the added genes is controlled in part by gene sequences derived from the plant pathogens figwort mosaic virus and cauliflower mosaic virus. The *Agrobacterium tumefaciens* transformation method was used to transfer the added genes into the recipient upland cotton variety Coker 312.

MON 88913 cotton has been considered a regulated article under the regulations in 7 CFR part 340 because it contains gene sequences from plant pathogens. In the process of reviewing the notifications for field trials of the subject cotton, APHIS determined that the vectors and other elements were disarmed and that the trials, which were conducted under conditions of reproductive and physical confinement or isolation, would not present a risk of plant pest introduction or dissemination.

In § 403 of the Plant Protection Act (7 U.S.C. 7701–7772), plant pest is defined as any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product: A protozoan, a nonhuman animal, a parasitic plant, a bacterium, a fungus, a virus or viroid, an infectious agent or other pathogen, or any article similar to or allied with any of the foregoing. APHIS views this definition very broadly. The definition covers direct or indirect injury, disease, or damage not just to agricultural crops, but also to plants in general, for example, native species, as well as to organisms that may be beneficial to plants, for example, honeybees, rhizobia, etc.

The U.S. Environmental Protection Agency (EPA) is responsible for the regulation of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136 *et seq.*). FIFRA requires that all pesticides, including herbicides, be registered prior to distribution or sale, unless exempt by EPA regulation. In cases in which genetically modified plants allow for a new use of a pesticide or involve a different use pattern for the pesticide, EPA must approve the new or different use. Accordingly, Monsanto has submitted glyphosate residue data and proposed labeling to EPA for the

expanded use of Roundup UltraMAX(®) herbicide on MON 88913.

When the use of the pesticide on the genetically modified plant would result in an increase in the residues in a food or feed crop for which the pesticide is currently registered, or in new residues in a crop for which the pesticide is not currently registered, establishment of a new tolerance or a revision of the existing tolerance would be required. Residue tolerances for pesticides are established by EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended (21 U.S.C. 301 *et seq.*), and the Food and Drug Administration (FDA) enforces tolerances set by EPA under the FFDCA. EPA has previously established an exemption from the requirement for a tolerance for the CP4 EPSPS protein in or on all raw agricultural commodities.

FDA published a statement of policy on foods derived from new plant varieties in the **Federal Register** on May 29, 1992 (57 FR 22984–23005). The FDA statement of policy includes a discussion of FDA's authority for ensuring food safety under the FFDCA, and provides guidance to industry on the scientific considerations associated with the development of foods derived from new plant varieties, including those plants developed through the techniques of genetic engineering. Monsanto has begun consultation with FDA on the food and feed safety and nutritional assessment of the subject cotton.

To provide the public with documentation of APHIS' review and analysis of the environmental impacts and plant pest risk associated with a proposed determination of nonregulated status for Monsanto's 88913 cotton, an environmental assessment (EA) has been prepared. The EA was prepared in accordance with (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

In accordance with § 340.6(d) of the regulations, we are publishing this notice to inform the public that APHIS will accept written comments regarding the petition for a determination of nonregulated status from interested persons for a period of 60 days from the date of this notice. We are also soliciting written comments from interested persons on the EA prepared to examine any environmental impacts of the proposed determination for the subject cotton. The petition and the EA and any comments received are available for public review, and copies of the petition and the EA are available as indicated in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

After the comment period closes, APHIS will review the data submitted by the petitioner, all written comments received during the comment period, and any other relevant information. After reviewing and evaluating the comments on the petition and the EA and other data and information, APHIS will furnish a response to the petitioner, either approving the petition in whole or in part, or denying the petition. APHIS will then publish a notice in the **Federal Register** announcing the regulatory status of Monsanto's glyphosate-tolerant MON 88913 cotton and the availability of APHIS' written decision.

Authority: 7 U.S.C. 1622n and 7701–7772; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 28th day of September 2004.

Elizabeth E. Gaston,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E4–2471 Filed 10–1–04; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 04–040–2]

Old World Climbing Fern; Availability of an Environmental Assessment and Finding of No Significant Impact

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that an environmental assessment and finding of no significant impact have been prepared by the Animal and Plant Health Inspection Service relative to issuing a permit for the environmental release of the nonindigenous moth *Cataclysta camptozonale* (Hampson) (Lepidoptera: Crambidae), a potential biological control agent of Old World climbing fern (*Lygodium microphyllum*). The environmental assessment documents our review and analysis of environmental impacts associated with, and alternatives to, issuing a permit for the environmental release of the moth in Florida. Based on its finding of no significant impact, the Animal and Plant Health Inspection Service has determined that an environmental impact statement need not be prepared.

ADDRESSES: Copies of the environmental assessment and finding of no significant impact are available for public inspection in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Robert Flanders, Branch Chief, Biological and Technical Service, Pest Permit Evaluations, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737–1236; (301) 734–5930.

SUPPLEMENTARY INFORMATION:

Background

Old World climbing fern, *Lygodium microphyllum* (Cav.) R. Br. (Lygodiaceae), is a climbing fern that has a large native range that extends through much of the Old World tropics. It has become established in central and southern peninsular Florida where it grows in a number of wetland and mesic (having a moderate supply of moisture) habitats including hammocks, cypress swamps, flatwoods, bayheads, and disturbed sites.

The climbing fern is a highly invasive, exotic weed that climbs over plants, including tall trees, to form massive walls of vegetation. It also forms thick mats on the ground that smother native plants. New infestations can arise great distances from existing populations because the weed produces millions of spores that are spread by wind and other physical carriers. A single spore is capable of starting a new infestation.

In Florida, the potential distribution of this weed includes all habitats from Lake Okeechobee south. It also has the potential to invade the Gulf Coast of Mexico and southern Texas.

On July 1, 2004, we published in the **Federal Register** (69 FR 39894–39895, Docket No. 04–040–1) a notice in which we announced the availability, for public review and comment, of an environmental assessment documenting our review and analysis of environmental impacts associated with issuing a permit for the release of the nonindigenous moth *Cataclysta camptozonale* (Hampson) (Lepidoptera: Crambidae) as a biological control agent of Old World climbing fern in the State of Florida. Larvae of the moth feed on the leaves of *L. microphyllum* for

approximately 11 to 12 days and older larvae spin a loose web of silk on leaves of the weed and pupate. Research suggests that the moth is host specific to only a few *Lygodium* species. Alternatives to issuing the permit were also examined in the environmental assessment, and included no action, herbicides, mechanical control, and flooding.

We solicited comments on the environmental assessment for 30 days ending on August 2, 2004. We received five comments by that date. Four of the commenters supported the recommendations of the environmental assessment. The fifth commenter objected to APHIS' performance and programs in general, but did not address the environmental assessment. Therefore, we are making no changes to the environmental assessment in response to this comment.

The environmental assessment and finding of no significant impact may be viewed on the Internet at *http://www.aphis.usda.gov/ppq/*. In the middle of that page, click on "Document/Forms Retrieval System." At the next screen, click on the triangle beside "Permits—Environmental Assessments." A list of documents will appear; the environmental assessment and finding of no significant impact for Old World climbing fern are document number 0038. You may request paper copies of the environmental assessment and finding of no significant impact by calling or writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. Please refer to the title of the environmental assessment and finding of no significant impact when requesting copies. The environmental assessment and finding of no significant impact are also available for review in our reading room (information on the location and hours of the reading room is listed under the heading **ADDRESSES** at the beginning of this notice).

The environmental assessment and finding of no significant impact have been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Done in Washington, DC, this 28th day of September 2004 .

Elizabeth E. Gaston,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E4–2472 Filed 10–1–04; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Forest Service

Payette National Forest, ID; Revision of Travel Plan

AGENCY: USDA, Forest Service.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The Forest Service gives notice of the intent to prepare an environmental impact statement (EIS) to revise the Payette National Forest Travel Plan. The proposed action would designate a site-specific transportation system and prohibit indiscriminant cross-country traffic. The EIS will analyze the effects of the proposed action and alternatives. The Payette National Forest invites written comments and suggestions on the scope of analysis and the issues to address. The agency gives notice of the National Environmental Policy Act (NEPA) analysis and decision-making process on the proposal so interested and affected members of the public may participate and contribute to the final decision.

DATES: Comments need to be received in writing by December 7, 2004.

ADDRESSES: Send written comments to: Travel Plan Revision, Forest Supervisor's Office, Payette National Forest, P.O. Box 1026, McCall, ID 83638, fax (208) 634–0744.

FOR FURTHER INFORMATION CONTACT: Questions about the proposed project and scope of analysis should be directed to Ana Egnew, Land Management Planner, Payette National Forest, P.O. Box 1026, McCall, ID 83638, or by phone to (208) 634–0624.

SUPPLEMENTARY INFORMATION:

Purpose and Need

The need for revision of the Travel Plan was identified in the 2003 Payette National Forest Land and Resource Plan (Forest Plan) (p. III–63), and in the Forest Service proposed rule (for Travel Management (July 15, 2004); specifically, to establish a system of roads and trails and areas designated for motor vehicle use and to prohibit the use of motor vehicles off the designated system. The purpose of the revision is to (1) meet Forest Plan and national direction, (2) designate a reasonable system of roads, trails, and over-snow use areas, (3) balance management considerations with recreation demands, (4) reduce impacts to Forest resources, and (5) reduce recreation user conflicts. The analysis will be conducted across the 13 Management Areas that comprise the 1,583,681 acres of the Payette National Forest outside designated Wilderness.

The Proposed Action

The proposed action would revise the current Travel Plan by designating a site-specific transportation system for snow-free and over-snow travel. Motorized snow-free travel off the transportation system would be prohibited on 1,583,681 acres (an increase of 544,863 acres).

The transportation system for snow-free travel would include:

- 1,505 miles of open roads (reduction of 14 miles)
- 612 miles of seasonally open roads (reduction of 28 miles)
- 76 miles of trail open to All-Terrain Vehicles (ATVs) (increase of 22 miles)
- 546 miles of trail open to 2-wheel motorized use (reduction of 98 miles)
- 621 miles of trail open to non-motorized travel (increase of 87 miles)
- 2.7 miles of undetermined road added to the system.

The transportation system for over-snow travel would include:

- 183 miles of open road (unchanged)
- 1,106,480 acres open to motorized activities (reduction of 17,400 acres)
- 477,801 acres reserved for non-motorized over-snow activities

Responsible Official

The responsible official is the Forest Supervisor of the Payette National Forest.

Decision To Be Made

The decision to be made is: whether to adopt the proposed revision to the Travel Plan, in whole, or in part, or to adopt another alternative, and with what mitigation measures and management requirements.

Issues

Preliminary issues identified by the Forest Service interdisciplinary team include effects to: water quality and wetlands; threatened, endangered, sensitive, and management indicator fish species and habitat; threatened, endangered, sensitive, and management indicator wildlife species and habitat; rare plants; and recreation opportunities.

Range of Alternatives

A range of reasonable alternatives will be considered. The no-action alternative will serve as a baseline for comparison of alternatives. The proposed action will be considered along with additional alternatives developed that meet the purpose and need and address significant issues identified during scoping. Alternatives may allow different locations, types, and seasons of travel activities.

Public Participation

Public participation will be important at several points during the analysis. This notice of intent initiates the scoping process. The scoping process will identify issues to be analyzed in detail and lead to the development of alternatives to the proposal.

The Forest Service is seeking information and comments from other Federal, State, and local agencies; Tribal governments; organizations; and individuals who may be interested in or affected by the proposed action. Comments received in response to this notice, including the names and addresses of those who comment, will be part of the project record and available for public review.

Public meetings are scheduled during the 60-day scoping period and following issuance of the draft EIS. The public scoping meetings are: September 30, in Riggins, Salmon River High School; October 6 in Weiser, Vendome Conference Center; October 12 in McCall, Forest Supervisor's Office; October 14 in Council, Adams County Fairground Exhibit Hall; and October 21 in New Meadows, New Meadows Ranger District Office. All meetings are 4:30 p.m. to 7 p.m.

The second major opportunity for public input is with the draft EIS. The draft EIS will be filed with the Environmental Protection Agency (EPA) and is anticipated to be available for public review during the summer of 2005. The comment period on the draft EIS will be 60 days. It is important that those interested in travel management on the Payette National Forest participate at that time.

The Forest Service believes it is important to give reviewers notice of several court rulings related to public participation in the environmental review process. First, reviewers of draft EISs must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions (*Vermont Yankee Nuclear Power Corp.*, v. *NRDC*, 435 U.S. 519, 553 (1978)). Also, environmental objections that could be raised at the draft EIS stage, but that are not raised until completion of the final EIS, may be waived or dismissed by the courts (*City of Angoon* v. *Hodel*, 803 F .2d 1016, 1002 (9th Cir. 1986), and *Wisconsin Heritages, Inc.*, v. *Harris*, 490 F. Supp. 1334, 1338 (E.D. Wis. 1980)). Because of these court rulings, it is important that those interested in this proposed action participate by the close of the 60-day comment period so substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider them and respond to them in the final EIS.

To assist the Forest Service in identifying and considering issues raised by the proposed action, comments on the draft EIS should be as specific as possible. It is also helpful if comments refer to specific pages or chapters of the draft EIS. Comments may also address the adequacy of the draft EIS or the merits of the alternatives formulated and discussed in the statement. (Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act 40 CFR 1503.3 in addressing these points.)

After the 60-day comment period ends on the draft EIS, the Forest Service will analyze comments received and address them in the final EIS. The final EIS is scheduled to be released in December 2005. In the final EIS, the Forest Service will respond to substantive comments received during the comment period. The Responsible Official (Forest Supervisor, Payette National Forest) will document the decision and rationale in a Record of Decision (ROD). The decision will be subject to review under Forest Service appeal regulations at 36 CFR part 215.

Dated: September 24, 2004.

Mark J. Madrid,

Forest Supervisor.

[FR Doc. 04–22190 Filed 10–1–04; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Forest Service

Meeting of the Land Between the Lakes Advisory Board

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Land Between the Lakes Advisory Board will hold a meeting on Thursday, October 28, 2004. Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. App. 2.

The meeting agenda includes the following:

(1) Welcome/Introductions/Agenda;
(2) Advisory Board Membership;
(3) Land and Resource Management Plan Update;
(4) Conservation Education;
(5) Four Threats;
(6) Tour of Turkey Bay;
(7) Board Discussion of Comments Received;
(8) LBL Updates.

The meeting is open to the public. Written comments are invited and may be mailed to: William P. Lisowsky, Area Supervisor, Land Between The Lakes, 100 Van Morgan Drive, Golden Pond, Kentucky 42211. Written comments must be received at Land Between The Lakes by October 20, 2004, in order for copies to be provided to the members at the meeting. Board members will review written comments received, and at their request, oral clarification may be requested at a future meeting.

DATES: The meeting will be held on Thursday, October 28, 2004, 8:30 a.m. to 3:15 p.m., c.s.t.

ADDRESSES: The meeting will be held at the USDA Forest Service Administrative Building, Land Between the Lakes, and will be open to the public.

FOR FURTHER INFORMATION CONTACT: Sharon Byers, Advisory Board Liaison, Land Between the Lakes, 100 Van Morgan Drive, Golden Pond, Kentucky 42211, (270) 924–2002.

SUPPLEMENTARY INFORMATION: None.

Dated: September 24, 2004.

William P. Lisowsky,

Area Supervisor, Land Between the Lakes.

[FR Doc. 04–22256 Filed 10–1–04; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Forest Service

Notice of Southwest Idaho Resource Advisory Committee Meeting

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: Pursuant to the authorities in the Federal Advisory Committee Act (Public Law 92–463) and under the Secure Rural Schools and Community Self-Determination Act of 2000 (Public Law 106–393), the Boise and Payette National Forests' Southwest Idaho Resource Advisory Committee will conduct a business meeting, which is open to the public.

DATES: Wednesday, October 20, 2004, beginning at 10:30 a.m.

ADDRESSES: Idaho Counties Risk Management Program Building, 3100 South Vista Avenue, Boise, Idaho.

SUPPLEMENTARY INFORMATION: Agenda topics will include review and approval of project proposals, and it is an open public forum.

FOR FURTHER INFORMATION CONTACT: Doug Gochnour, Designated Federal Officer, at (202) 392–6681 or e-mail *dgochnour@fs.fed.us*.

Dated: September 28, 2004.

Richard A. Smith,

Forest Supervisor, Boise National Forest.

[FR Doc. 04–22257 Filed 10–1–04; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Rural Business-Cooperative Service

Maximum Portion of Guarantee Authority Available for Fiscal Year 2005

AGENCY: Rural Business-Cooperative Service, USDA.

ACTION: Notice.

SUMMARY: As set forth in 7 CFR 4279.107 (b) and 4279.119 (b)(4), each fiscal year the Agency shall establish a limit on the maximum portion of guarantee authority available for that fiscal year that may be used to guarantee loans with a guarantee fee of 1 percent or guaranteed loans with a guarantee percentage exceeding 80 percent.

Allowing the guarantee fee to be reduced to 1 percent or exceeding the 80 percent guarantee on certain guaranteed loans that meet the conditions set forth in 7 CFR 4279.107 and 4279.119 will increase the Agency's ability to focus guarantee assistance on projects which the Agency has found particularly meritorious, such as projects in rural communities that remain persistently poor, which experience long-term population decline and job deterioration, are experiencing trauma as a result of natural disaster, or are experiencing fundamental structural changes in the economic base.

Not more than 12 percent of the Agency's quarterly apportioned guarantee authority will be reserved for loan requests with a guarantee fee of 1 percent, and not more than 15 percent of the Agency's quarterly apportioned guarantee authority will be reserved for guaranteed loan requests with a guaranteed percentage exceeding 80 percent. Once the above quarterly limits have been reached, all additional loans guaranteed during the remainder of that quarter will require a 2 percent guarantee fee and not exceed an 80 percent guarantee limit. As an exception to this paragraph and for the purposes of this notice, loans developed by the North American Development Bank (NADBank) Community Adjustment and Investment Program (CAIP) will not count against the 15 percent limit. Up to 50 percent of CAIP loans may have a guaranteed percentage exceeding 80 percent. The funding authority for CAIP loans is not derived carryover or recovered funding authority of the B&I Guaranteed Loan Program.

Written requests by the Rural Development State Office for approval of a guaranteed loan with a 1 percent guarantee fee or a guaranteed loan exceeding 80 percent must be forwarded to the National Office, Attn: Director, Business and Industry Division, for review and consideration prior to obligation of the guaranteed loan. The Administrator will provide a written response to the State Office confirming approval or disapproval of the request.

EFFECTIVE DATE: October 4, 2004.

FOR FURTHER INFORMATION CONTACT: Fred Kieferle, Processing Branch Chief, Business and Industry Division, Rural Business-Cooperative Service, USDA, Stop 3224, 1400 Independence Avenue, SW., Washington, DC 20250–3224, telephone (202) 720–7818.

SUPPLEMENTARY INFORMATION: This action has been reviewed and determined not to be a rule or regulation as defined in Executive Order 12866.

Dated: September 22, 2004.

Peter J. Thomas,

Administrator.

[FR Doc. 04–22217 Filed 10–1–04; 8:45 am]

BILLING CODE 3410–XY–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Information Collection To Be Submitted to the Office of Management and Budget (OMB) for Approval Under the Paperwork Reduction Act; Nonprofit Agency Recordkeeping Requirements

AGENCY: Committee for Purchase from People Who Are Blind or Severely Disabled.

ACTION: Notice; request for comments.

SUMMARY: The Committee for Purchase from People Who Are Blind or Severely Disabled (The Committee) will submit the collection of information listed below to OMB for approval under the provisions of the Paperwork Reduction Act. This notice solicits comments on that collection of information.

DATES: Submit your written comments on the information collection on or before December 3, 2004.

ADDRESSES: Mail your comments on the requirement to Janet Yandik, Information Management Specialist, Committee for Purchase from People Who Are Blind or Severely Disabled, 1421 Jefferson Davis Highway, Jefferson Plaza 2, Suite 10800, Arlington, VA, 22202–3259; fax (703) 603–0655; or e-mail *rulecomments@jwod.gov*.

FOR FURTHER INFORMATION CONTACT: Anissa Craghead, Regulatory Affairs Specialist, Committee for Purchase from People Who Are Blind or Severely Disabled, 1421 Jefferson Davis Highway, Jefferson Plaza 2, Suite 10800, Arlington, VA, 22202–3259; phone (703) 603–0033; fax (703) 603–0655; or e-mail *acraghead@jwod.gov*.

SUPPLEMENTARY INFORMATION: The Office of Management and Budget (OMB) regulations at 5 CFR part 1320, which implement provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities (*see* 5 CFR 1320.8(d)). The Committee plans to submit a request to OMB to renew its approval of the collection of information for nonprofit agency responsibilities related to recordkeeping. The Committee is requesting a 3-year term of approval for this information collection activity.

Federal agencies 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 number for this collection of information is 3037–0005.

The Javits-Wagner-O'Day (JWOD) Act of 1971 (41 U.S.C. 46–48c) is the authorizing legislation for the JWOD Program. The JWOD Program creates jobs and training opportunities for people who are blind or who have other severe disabilities. Its primary means of doing so is by requiring Government agencies to purchase selected products and services from nonprofit agencies employing such individuals. The JWOD Program is administered by the Committee. Two national, independent organizations, National Industries for the Blind (NIB) and NISH, help State and private nonprofit agencies participate in the JWOD Program.

The implementing regulations for the JWOD Act, which are located at 41 CFR Chapter 51, detail the recordkeeping requirements imposed on nonprofit agencies participating in the JWOD

Program. Section 51–2.4 of the regulations describes the criteria that the Committee must consider when adding a product or service to its Procurement List. One of these criteria is that a proposed addition must demonstrate a potential to generate employment for people who are blind or severely disabled. The Committee decided that evidence that employment will be generated for those individuals consists of recordkeeping that tracks direct labor and revenues for products or services sold through a JWOD Program contract. This recordkeeping can be done on each individual JWOD project or by product or service family.

In addition, § 51–4.3 of the regulations requires that nonprofit agencies keep records on direct labor hours performed by each worker and keep an individual record or file for each blind or severely disabled individual documenting that individual's disability and capabilities for competitive employment. The records that nonprofit agencies must keep in accordance with § 51–4.3 of the regulations constitute the bulk of the hour burden associated with this OMB control number.

This information collection renewal request seeks approval for the Committee to continue to ensure compliance with recordkeeping requirements established by the authority of the JWOD Act and set forth in the Act's implementing regulations and to ensure that the Committee has the ability to confirm the suitability of products and services on its Procurement List. The recordkeeping requirements described in this document are the same as those currently imposed on nonprofit agencies participating in the JWOD Program.

Title: Nonprofit Agency Responsibilities, 41 CFR 51–2.4 and 51–4.3.

OMB Control Number: 3037–0005.

Description of Collection: Recordkeeping.

Description of Respondents: Nonprofit agencies participating in the JWOD Program.

Annual Number of Respondents: About 650 nonprofit agencies will annually participate in recordkeeping.

Total Annual Burden Hours: The recordkeeping burden is estimated to average 5 hours per respondent. Total annual burden is 3,250 hours.

We invite comments concerning this renewal on: (1) Whether the collection of information is necessary for the proper performance of our agency's functions, including whether the information will have practical utility; (2) the accuracy of our estimate of the burden of the 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.

Dated: September 28, 2004.

Sheryl D. Kennerly,

Director, Information Management.

[FR Doc. 04–22179 Filed 10–1–04; 8:45 am]

BILLING CODE 6353–01–P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Delaware, Connecticut, District of Columbia, Maryland, Pennsylvania, Rhode Island, Vermont, Virginia, and West Virginia Advisory Committees and Subcommittees

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights that a briefing by conference call of the Connecticut, Delaware, District of Columbia, Maryland, Pennsylvania, Rhode Island, Vermont, Virginia, and West Virginia Advisory Committees will convene at 11 a.m. and adjourn at 11:45 a.m., Friday, October 8, 2004. The purpose of the briefing is to listen to a presentation by Professor Gavin Clarkson on the use of Native American racial imagery for sports mascots.

This conference call is available to the public through the following call-in number: 1–800–497–7708, access code: 26575717. Any interested member of the public may call this number and listen to the meeting. Callers can expect to incur charges for calls not initiated using the supplied call-in number or over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls using the call-in number over land-line connections. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–977–8339 and providing the Service with the conference call number and access code.

To ensure that the Commission secures an appropriate number of lines for the public, persons are asked to register by contacting Barbara de La Viez of the Eastern Regional Office at (202) 376–7533 by 4 p.m. on Wednesday, October 6, 2004.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, September 29, 2004.

Ivy L. Davis,

Chief, Regional Programs Coordination Unit.

[FR Doc. 04–22270 Filed 10–1–04; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Sunshine Act Notice

AGENCY: U.S. Commission on Civil Rights.

DATE AND TIME: Friday, October 8, 2004, 9:30 a.m.

PLACE: U.S. Commission on Civil Rights, 624 9th Street, NW., Room 540, Washington, DC 20425.

STATUS:

Agenda

I. Approval of Agenda
II. Approval of Minutes of September 17, 2004 Meeting
III. Announcements
IV. Staff Director's Report
V. State Advisory Committee Appointments for Montana, North Dakota, Ohio, Utah, and Washington
VI. "Redefining Rights in America: The Civil Rights Record of the George W. Bush Administration, 2001–2004" Report
VII. Future Agenda Items
11 a.m. Briefing on Voting and Election Reform: Is America Ready to Vote?

FOR FURTHER INFORMATION CONTACT: Les Jin, Press and Communications (202) 376–7700.

Debra A. Carr,

Deputy General Counsel.

[FR Doc. 04–22301 Filed 9–29–04; 4:30 pm]

BILLING CODE 6335–01–M

DEPARTMENT OF COMMERCE

Bureau of the Census

[Docket Number 040916269–4269–01]

Notice of Data Sharing Activity

AGENCY: Bureau of the Census, Department of Commerce.

ACTION: Notice of determination.

SUMMARY: The Bureau of the Census (Census Bureau) will provide certain business data from its Business Register and its 2002 Economic Census to the Bureau of Economic Analysis (BEA) for statistical purposes exclusively. Through the use of these shared data, the BEA expects to improve the quality of data collected by the Census Bureau

under the authority of Title 13 of the United States Code (U.S.C.), and collected by the BEA under the authority of the International Investment and Trade in Services Survey Act by identifying data-quality issues arising from reporting differences in the Census Bureau and BEA surveys. The Census Bureau and BEA will publish nonconfidential aggregate reports (public use) that have cleared the BEA and Census Bureau disclosure review.

DATES: The Census Bureau will make certain business data collected from the 2002 Economic Census, as discussed in this notice, available to BEA on October 4, 2004.

FOR FURTHER INFORMATION CONTACT: Requests for additional information on this proposed program should be directed to Mr. Julius Smith, Jr., Chief, Special Studies Branch, Manufacturing and Construction Division, U.S. Census Bureau, 4700 Silver Hill Road, Washington, DC 20233–6900, by phone at (301) 763–7662, by fax at (301) 457–1318 or by e-mail at *julius.smith.jr@census.gov*.

SUPPLEMENTARY INFORMATION:

Background

The CIPSEA (Pub. L. 107–347, Subtitle V; 44 U.S.C. 3501 *et seq.*) and the International Investment and Trade in Services Survey Act (Pub. L. 94–472 as amended; 22 U.S.C. 3101–3108) allow the BEA and the Census Bureau to share certain business data for exclusively statistical purposes. Section 524(d) of the CIPSEA requires a **Federal Register** notice announcing the intent to share data (allowing 60 days for public comment). On June 30, 2004 (69 FR 39408), the Census Bureau published in the **Federal Register** a notice of this proposed data-sharing activity and requested comments on the subject. The Census Bureau did not receive any public comments.

Shared Data

The Census Bureau will provide the BEA with certain business data from its Business Register and collected from the 2002 Economic Census. The BEA also will share data from its 2002 Foreign Direct Investment in the United States survey. The BEA issued a separate notice addressing this issue.

The BEA will use these data for statistical purposes exclusively. Through record linking, the BEA expects to improve the quality of data collected under the authority of Title 13 of the U.S.C. and the International Investment and Trade in Services Survey Act by identifying data-quality issues arising from reporting differences in the Census Bureau and the BEA surveys.

Statistical Purposes for the Shared Data

The data from the Business Register and from the 2002 Economic Census are used to estimate employment, payroll, and receipt data of U.S. companies. Statistics from the census are published in separate data publications. All data are collected under Sections 131 and 224 of Title 13 of the U.S.C.

Data Access and Confidentiality

Title 13 of the U.S.C. protects the confidentiality of these data. The data may be seen only by persons sworn to uphold the confidentiality of the information. Access to the shared data will be restricted to specifically authorized personnel and will be provided for statistical purposes only. All BEA employees with access to these data will become Census Bureau Special Sworn Status Employees-meaning that they, under penalty of law, must uphold the data's confidentiality. To further safeguard the confidentiality of the data, the Census Bureau has conducted an Information Technology Security Review of the BEA. The results of this project are subject to disclosure review. Disclosure review is a process conducted to verify that the data to be released do not reveal any confidential information.

Dated: September 29, 2004.

Charles Louis Kincannon,

Director, Bureau of the Census.

[FR Doc. 04–22216 Filed 10–1–04; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–357–812]

Honey From Argentina: Corrected Final Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Correction to final results of antidumping duty administrative review.

EFFECTIVE DATE: October 4, 2004.

FOR FURTHER INFORMATION CONTACT: Brian J. Sheba or Robert M. James, Antidumping and Countervailing Duty Operations Office Seven, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230, telephone: (202) 482–0145 or (202) 482–0649, respectively.

Background

On May 27, 2004, the Department of Commerce (the Department) published in the **Federal Register** its notice of final results of the antidumping duty administrative review of honey from Argentina for the period May 11, 2001 through November 30, 2002. *See Honey from Argentina: Final Results of Antidumping Duty Administrative Review*, 69 FR 30283 (May 27, 2004). Subsequent to the final results, the Department has discovered a typographical error in its "all others" cash deposit rate. The Department mistakenly used the "all others" rate in the investigation final determination, rather than the corrected "all others" rate published in the antidumping duty order. *See Notice of Final Determination of Sales at Less Than Fair Value; Honey From Argentina*, 66 FR 50611 (Oct. 4, 2001), *Notice of Amended Final Determination of Sales at Less Than Fair Value; Honey From Argentina*, 66 FR 58434 (Nov. 21, 2001), and *Notice of Antidumping Duty Order; Honey From Argentina*, 66 FR 63672 (Dec. 10, 2001).

We now correct the final results of the 2001-2002 antidumping duty administrative review of honey from Argentina as noted above. As a result of this correction, the "all others" cash deposit rate is 30.24 percent *ad valorem*.

These amended final results are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Tariff Act.

Dated: September 28, 2004.

James J. Jochum,

Assistant Secretary for Import Administration.

[FR Doc. E4–2477 Filed 10–1–04; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–896]

Preliminary Determination of Sales at Less Than Fair Value and Postponement of the Final Determination: Magnesium Metal From the People's Republic of China

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: October 4, 2004.

FOR FURTHER INFORMATION CONTACT: Lilit Astvatsatrian or Laurel LaCivita, Import Administration, International Trade

Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–6412 or 482–4243.

Preliminary Determination

We preliminarily determine that magnesium metal from the People's Republic of China ("PRC") is being, or is likely to be, sold in the United States at less than fair value ("LTFV"), as provided in section 733 of the Tariff Act of 1930, as amended ("the Act"). The estimated margins of sales at LTFV are shown in the "Suspension of Liquidation" section of this notice.

Case History

On February 27, 2004, the Department of Commerce ("Department") received a petition on imports of magnesium metal from the PRC, filed in proper form by the U.S. Magnesium Corporation LLC, United Steelworkers of America, Local 8319, and Glass, Molders, Pottery, Plastics & Allied Workers International, Local 374 (collectively, "Petitioners") on behalf of the domestic industry and workers producing magnesium metal. *See Petition for the Imposition of Antidumping Duties: Magnesium Metal from the People's Republic of China*, dated February 27, 2004 ("the Petition"). This investigation was initiated on March 25, 2004. *See Initiation of Antidumping Duty Investigation: Magnesium Metal from the People's Republic of China*, 69 FR 15293 (March 25, 2004) ("*Notice of Initiation*").

On April 16, 2004, and April 26, 2004, the Department requested quantity and value ("Q&V") information from a total of one hundred and forty-two producers of magnesium metal in the PRC which were identified in the petition and for which the Department was able to locate contact information. On April 16, 2004, the Department also sent the Government of the PRC a letter requesting assistance in locating all known Chinese producers/exporters of magnesium metal who exported magnesium metal to the United States during the period of investigation ("POI"), July 1, 2003, through December 31, 2003.

On April 26, 2004, the Department received Q&V responses from two Chinese producers/exporters of magnesium metal, the RSM companies ("RSM") and Tianjin Magnesium International Co., Ltd. ("Tianjin"). The Government of the PRC did not respond to the Department's April 16, 2004, letter requesting assistance in identifying producers and exporters of the subject merchandise in the PRC.

On April 30, 2004, the Department determined that India, Pakistan, Indonesia, Sri Lanka, the Philippines, Morocco, and Egypt are countries comparable to the PRC in terms of economic development. *See Memorandum from Ron Lorentzen, Acting Director, Office of Policy to Robert Bolling, Program Manager, Group III, Office 9: Antidumping Duty Investigation of Magnesium Metal from the People's Republic of China (PRC): Request for a List of Surrogate Countries*, dated April 30, 2004 ("*Office of Policy Surrogate Countries Memorandum*").

On May 6, 2004, we issued Sections A, C, D, and E of our questionnaire to Tianjin and RSM, the only two companies that responded to our request for Q&V information. In addition, on May 6, 2004, we issued a Section A, C, D, and E questionnaire to the Government of the PRC through the Ministry of Commerce and the Chinese Embassy in Washington, DC.

On May 17, 2004, the United States International Trade Commission ("ITC") issued its affirmative preliminary determination that there is a reasonable indication that an industry in the United States is materially injured by reason of imports from China and Russia of pure magnesium and magnesium alloy. The ITC's determination was published in the **Federal Register** on May 21, 2004. *See Investigation Nos. 731–TA–1071–1072 (Preliminary), Magnesium from China and Russia*, 69 FR 29329 (May 21, 2004).

On May 19, 2004, the Department issued its respondent selection memorandum, officially selecting RSM and Tianjin as the two mandatory respondents in this investigation. *See Memorandum from Laurel LaCivita, Senior Case Analyst, Office IX, to Edward Yang, Office Director, Office IX, Antidumping Duty Investigation of Magnesium Metal from the People's Republic of China: Selection of Respondents for the Antidumping Duty Investigation of Magnesium Metal from the People's Republic of China*, dated May 19, 2004 ("Respondent Selection Memorandum").

On May 10, 2004, the Department requested that the parties submit comments on surrogate country selection. On May 24, 2004, we received comments regarding our selection of a surrogate country from the Petitioners. On June 2, 2004, we received comments regarding our selection of a surrogate country from RSM and Tianjin. Petitioners argued that India is the appropriate surrogate country for this investigation because India is at a comparable level of economic development with the PRC based on gross national income ("GNI") and contains the only producer of primary magnesium located in any of the countries identified by the Department as surrogate countries.

RSM and Tianjin provided information identifying Kazakhstan, Russia, and Brazil as potential surrogate countries in this investigation and contended that, according to the World Bank, Kazakhstan, Russia, and Brazil each have a per-capita GNI comparable to that of the PRC. RSM and Tianjin stated further that, according to the World Bank, neither India nor any of the other countries named in the *Office of Policy Surrogate Countries Memorandum* is at a stage of economic development comparable to the PRC.

We received rebuttal comments concerning the selection of a surrogate country from Petitioners and respondents on June 14, 2004, June 28, 2004, and July 9, 2004.

We provided a one-week extension until June 1, 2004 to all interested parties that requested an extension for submitting a response to our Section A questionnaire. Additionally, we provided an extension until June 16, 2004, to all mandatory respondents to respond to sections C, D, and E of the questionnaire. For a detailed discussion on specific mandatory respondent extensions, please see the company-specific section for each mandatory respondent below.

On June 3, 2004, we received a Section A questionnaire response from Beijing Guangling Jinghua Science & Technology Co., Ltd. ("Guangling"), which requested a separate rate.

On June 2, 2004, and June 4, 2004, we received a request from Petitioners, RSM, and Tianjin, respectively, to extend the deadline for supplying surrogate-value information until two weeks after the submission of Section D data. On July 6, 2004, we extended the time period for interested parties to provide surrogate values for factors of production until July 12, 2004. On July 8, 2004, RSM and Tianjin requested an extension until two weeks after the Department decided the surrogate country to submit their surrogate-value information.

On June 17, 2004, RSM requested that the Department excuse it from reporting certain U.S. further-manufacturing activities. On June 21, 2004, we informed RSM that we did not have sufficient information on the record to exempt it from reporting sales and cost for merchandise further manufactured in the United States and requested RSM to report the further-manufactured

downstream sales of its affiliate by June 28, 2004. On June 22, 2004, RSM requested additional guidance concerning the information the Department required it to provide in order to grant RSM an exemption from responding to the Section E questionnaire (for a detailed discussion of this issue, please see the RSM company-specific section below).

On June 28, 2004, Petitioners made a timely request pursuant to 19 CFR 351.205(e) for a fifty-day postponement of the preliminary determination or until September 24, 2004. On July 21, 2004, the Department published a postponement of the preliminary antidumping duty determination on magnesium metal from the PRC. *See Notice of Postponement of the Preliminary Determinations in Antidumping Duty Investigations of Magnesium Metal from the People's Republic of China and the Russian Federation* 69 FR 43561 (July 21, 2004).

On August 3, 2004, the Department determined that India was the appropriate surrogate country to use in this investigation. *See Memorandum to Laurie Parkhill, Office Director, from Laurel LaCivita and Lilit Astvatsatrian, Case Analysts, through Robert Bolling, Program Manager: Antidumping Duty Investigation on Magnesium Metal from the People's Republic of China*, dated August 3, 2004 ("*Surrogate-Country Selection Memorandum*"). We received comments regarding our selection of India as the surrogate country from interested parties (for a detailed discussion of the comments regarding the surrogate country, please see the "Surrogate Country" section below). On August 3, 2004, we informed Petitioners, RSM, and Tianjin that the due date for submitting surrogate-value information was August 10, 2004. On August 6, 2004, RSM and Tianjin requested that the Department extend the deadline for submitting surrogate-value information until September 1, 2004. On August 9, 2004, we extended the deadline for submitting surrogate-value information until August 17, 2004. We then extended the deadline for submitting surrogate-value information until August 19, 2004. On August 19, 2004, Petitioners, RSM and Tianjin submitted surrogate-value comments. Petitioners filed rebuttal comments concerning RSM and Tianjin Magnesium's August 19, 2004, submission on August 30, 2004. RSM and Tianjin submitted additional, unsolicited surrogate-value information on September 10, 2004, and September 13, 2004. On September 10, 2004, and September 14, 2004, Petitioners objected to RSM's and Tianjin's September 10, 2004, and September 13, 2004, submissions of surrogate-value information, and requested that the Department withdraw them from the record. On September 16, 2004, we responded that we would not use RSM's and Tianjin's surrogate-value submissions of September 10, 2004, and September 13, 2004, for the preliminary determination of this investigation, but would consider the information for the final determination. *See Memorandum to The File from Laurel LaCivita Senior Case Analyst, Through Robert Bolling, Program Manager, AD/CVD Enforcement, Magnesium Metal from the People's Republic of China: Untimely Submissions of Surrogate Value Information*, dated September 16, 2004.

Company-Specific Chronology

As described above, the Department staggered its issuance of sections of the antidumping questionnaire to the mandatory respondents. Upon receipt of the various responses, the Petitioners provided comments and the Department issued supplemental questionnaires. The chronology of this stage of the investigation varies by respondent. Therefore, the Department has separated by company the following discussion of its information-gathering process after issuance of the questionnaire.

RSM

RSM submitted its Section A questionnaire response on June 4, 2004. On June 17, 2004, RSM requested that the Department excuse it from reporting certain further-manufacturing activities in the United States, arguing that the value added in the United States "exceeds substantially" the value of the imported subject merchandise and that there were sufficient sales to unaffiliated U.S. customers upon which to conduct a constructed-export-price ("CEP") analysis. On June 21, 2004, the Department responded that it did not have sufficient information to exempt RSM from reporting its sales of further-manufactured merchandise in the United States. On June 22, 2004, RSM requested further guidance concerning the types of information that the Department needed to grant its request. Petitioners submitted comments concerning RSM's June 22, 2004, request on June 23, 2004, claiming that RSM did not explain fully its affiliations with Toyota Tsusho America, Inc. ("TAI"), its affiliated reseller in the United States, and its further-manufacturer in the United States. Petitioners claimed further that RSM applied an incorrect methodology to determine the value added in the United States. On June 25, 2004, RSM responded that it need only address the value-added arguments in Petitioners' June 23, 2004, submission. RSM submitted its Section C and D questionnaire responses on June 21, 2004. On June 25, 2004, Petitioners submitted comments on RSM's Section A response. RSM submitted its Section E questionnaire response on June 29, 2004. Petitioners submitted deficiency comments on RSM's Section C and D questionnaire responses on July 2, 2004, and on RSM's Section E questionnaire response on July 13, 2004. The Department issued a supplemental questionnaire concerning Sections A–E of RSM's questionnaire responses on July 23, 2004. RSM submitted a supplemental section A through E questionnaire response on August 20, 2004. The Department issued a second supplemental questionnaire covering RSM on September 2, 2004. RSM provided its second supplemental questionnaire response on September 15, 2004. On September 21, 2004, the Department provided a memorandum to the file explaining that, although it was not rejecting RSM's September 15, 2004, submission, it would not be able to use the information provided in its second supplemental questionnaire response for the preliminary determination. *See Memorandum from Laurel LaCivita, Senior Case Analyst, to the File, through Robert Bolling, Program Manager, AD/CVD Enforcement, Magnesium Metal from the People's Republic of China: The Use of RSM's September 14, 2004 Second Supplemental Section A, C & D Questionnaire Response for the Preliminary Determination*, dated September 20, 2004.

Tianjin

On June 4, 2004, Tianjin submitted its Section A questionnaire response. On June 18, 2004, Tianjin submitted its response to Section C of the Department's May 6, 2004, questionnaire. On June 21, 2004, Tianjin submitted its response to Section D of the Department's questionnaire. On July 2, 2004, Petitioners submitted deficiency comments on Tianjin's responses to Sections A, C, and D of the questionnaire. On July 23, 2004, the Department issued a supplemental Sections A, C, and D questionnaire. On August 13, 2004, Tianjin submitted its response to the supplemental Sections A, C, and D questionnaire. On August 23, 2004, the Department issued a second supplemental Sections A, C, and D questionnaire. On September 2, 2004, Tianjin submitted its response to the second supplemental Sections A, C, and D questionnaire. On September 3, 2004,

Tianjin provided corrected versions of certain exhibits included in its September 2, 2004, submission. On September 13, 2004, Tianjin submitted electronic copies of its supplemental Sections A–D questionnaire responses.

Guangling Jinghua

Guangling Jinghua submitted its Section A response on June 3, 2004. Petitioners provided comments on Guangling Jinghua's Section A response on July 8, 2004. The Department issued a supplemental Section A questionnaire on August 12, 2004. Guangling provided its supplemental Section A response on August 26, 2004.

Postponement of Final Determination

Section 735(a) of the Act provides that a final determination may be postponed until no later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise or, in the event of a negative preliminary determination, a request for such postponement is made by the Petitioners. The Department's regulations at 19 CFR 351.210(e)(2) require that requests by respondents for postponement of a final determination be accompanied by a request for an extension of the provisional measures from a four-month period to not more than six months.

On September 14, 2004, RSM requested that, in the event of an affirmative preliminary determination in this investigation, the Department postpone its final determination by 60 days until 135 days after the publication of the preliminary determination. Accordingly, because we have made an affirmative preliminary determination and the requesting parties account for a significant proportion of the exports of the subject merchandise, we have postponed the final determination until no later than 135 days after the date of publication of the preliminary determination and are extending the provisional measures accordingly.

Period of Investigation

The period of investigation ("POI") is July 1, 2003, through December 31, 2003. This period corresponds to the two most recent fiscal quarters prior to the month of the filing of the petition (February 27, 2003). *See* 19 CFR 351.204(b)(1).

Scope of Investigation

The products covered by this investigation are primary and secondary alloy magnesium metal, regardless of chemistry, raw material source, form, shape, or size. Magnesium is a metal or alloy containing by weight primarily the element magnesium. Primary magnesium is produced by decomposing raw materials into magnesium metal. Secondary magnesium is produced by recycling magnesium-based scrap into magnesium metal. The magnesium covered by this investigation includes blends of primary and secondary magnesium.

The subject merchandise includes the following alloy magnesium metal products made from primary and/or secondary magnesium including, without limitation, magnesium cast into ingots, slabs, rounds, billets, and other shapes, and magnesium ground, chipped, crushed, or machined into raspings, granules, turnings, chips, powder, briquettes, and other shapes: products that contain 50 percent or greater, but less than 99.8 percent, magnesium, by weight, and that have been entered into the United States as conforming to an "ASTM Specification for Magnesium Alloy" [1] and thus are outside the scope of the existing antidumping orders on magnesium from the PRC (generally referred to as "alloy" magnesium).

The scope of this investigation excludes the following merchandise: (1) All forms of pure magnesium, including chemical combinations of magnesium and other material(s) in which the pure magnesium content is 50 percent or greater, but less that 99.8 percent, by weight, that do not conform to an "ASTM Specification for Magnesium Alloy" [2]; (2) magnesium that is in liquid or molten form; and (3) mixtures containing 90 percent or less magnesium in granular or powder form, by weight, and one or more of certain non-magnesium granular materials to make magnesium-based reagent mixtures, including lime, calcium metal, calcium silicon, calcium carbide, calcium carbonate, carbon, slag coagulants, fluorspar, nephaline syenite, feldspar, alumina (Al203), calcium aluminate, soda ash, hydrocarbons, graphite, coke, silicon, rare earth metals/mischmetal, cryolite, silica/fly ash, magnesium oxide, periclase, ferroalloys, dolomite lime, and colemanite.[3]

The merchandise subject to this investigation is classifiable under items 8104.19.00 and 8104.30.00 of the Harmonized Tariff Schedule of the United States ("HTSUS"). Although the HTSUS items are provided for convenience and customs purposes, the written description of the merchandise under investigation is dispositive.

Selection of Respondents

Section 777A(c)(1) of the Act directs the Department to calculate individual dumping margins for each known exporter and producer of the subject merchandise. Section 777A(c)(2) of the Act gives the Department discretion, when faced with a large number of exporters/producers, to limit its examination to a reasonable number of such companies if it is not practicable to examine all companies. Where it is not practicable to examine all known producers/exporters of subject merchandise, this provision permits the Department to investigate either (1) a sample of exporters, producers, or types of products that is statistically valid based on the information available to the Department at the time of selection or (2) exporters/producers accounting for the largest volume of the merchandise under investigation that can reasonably be examined. Only two of the twenty-four exporters identified in the petition responded to the Department's questionnaire. Therefore, the Department determined that it has the resources available to investigate all responding parties in this investigation and that there is no reason to limit the number of respondents to be examined in this investigation pursuant to section 777A(c)(2) of the Act. *See Respondent Selection Memorandum* at 3. Consequently, in this investigation, we have examined both Tianjin and RSM,

[1] The meaning of this term is the same as that used by the American Society for Testing and Materials in its *Annual Book of ASTM Standards: Volume 01.02 Aluminum and Magnesium Alloys.*

[2] This material is already covered by existing antidumping orders. *See Antidumping Duty Orders: Pure Magnesium from the People's Republic of China, the Russian Federation and Ukraine; Amended Final Determination of Sales at Less Than Fair Value: Antidumping Duty Investigation of Pure Magnesium from the Russian Federation*, 60 FR 25691 (May 12, 1995); *Antidumping Duty Order: Pure Magnesium in Granular Form from the People's Republic of China*, 66 FR 57936 (Nov. 19, 2001).

[3] This third exclusion for magnesium-based reagent mixtures is based on the exclusion for reagent mixtures in the 2000–2001 investigations of magnesium from the PRC, Israel, and Russia. *See Final Determination of Sales at Less Than Fair Value: Pure Magnesium in Granular Form From the People's Republic of China*, 66 FR 49345 (September 27, 2001); *Final Determination of Sales at Less Than Fair Value: Pure Magnesium From Israel*, 66 FR 49349 (September 27, 2001); *Final Determination of Sales at Not Less Than Fair Value: Pure Magnesium From the Russian Federation*, 66 FR 49347 (September 27, 2001). These mixtures are not magnesium alloys because they are not chemically combined in liquid form and cast into the same ingot.

the only two exporters of subject merchandise who responded to the Department's Q&V questionnaire. The two Chinese producers/exporters (Tianjin and RSM) accounted for a significant percentage of all exports of the subject merchandise from the PRC during the POI and were selected as mandatory respondents. *See Respondent Selection Memorandum* at 3.

Non-Market-Economy Country

For purposes of initiation, the Petitioners submitted LTFV analyses for the PRC as a non-market economy. *See Notice of Initiation* at 15295. In every case conducted by the Department involving the PRC, the PRC has been treated as an Non-Market-Economy ("NME") country. In accordance with section 771(18)(C)(i) of the Act, any determination that a foreign country is an NME country shall remain in effect until revoked by the administering authority. *See also Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, From the People's Republic of China: Preliminary Results 2001–2002 Administrative Review and Partial Rescission of Review,* 68 FR 7500 (February 14, 2003). Therefore, we have treated the PRC as an NME country for purposes of this preliminary determination.

Surrogate Country

When the Department is investigating imports from an NME, section 773(c)(1) of the Act directs it to base normal value ("NV"), in most circumstances, on the NME producer's factors of production valued in a surrogate market-economy country or countries considered to be appropriate by the Department. In accordance with section 773(c)(4) of the Act, in valuing the factors of production, the Department shall utilize, to the extent possible, the prices or costs of factors of production in one or more market-economy countries that are at a level of economic development comparable to that of the NME country and are significant producers of comparable merchandise. The sources of the surrogate values we have used in this investigation are discussed under the NV section below.

The Department determined that India, Pakistan, Indonesia, Sri Lanka, the Philippines, Morocco, and Egypt are countries comparable to the PRC in terms of economic development. *See Office of Policy Surrogate Countries Memorandum.* Customarily, we select an appropriate surrogate country based on the availability and reliability of data from the countries.

The Department received arguments from interested parties on the surrogate country. Petitioners argue that India is the appropriate surrogate country for this investigation because India is at a comparable level of economic development with the PRC based on gross national income ("GNI"). Petitioners contend that the Department has consistently found that India meets these statutory requirements for a surrogate country for the PRC, citing *Pure Magnesium and Alloy Magnesium* at 55425 and 55426 and *Pure Magnesium From the People's Republic of China: Preliminary Results of Antidumping Duty New Shipper Administrative Review,* 62 FR 55215, 55217 (October 23, 1997). Petitioners argue that India is a significant producer of aluminum, which the Department has determined previously to be the product most comparable product to magnesium, citing *Pure Magnesium and Alloy Magnesium From the People's Republic Of China: Final Results of Antidumping Duty New Shipper Administrative Review,* 63 FR 3085, 3087 (January 21, 1998) ("Pure Magnesium New Shipper Review").

Respondents identified Kazakhstan, Russia, and Brazil as potential surrogate countries for the PRC in this investigation. Respondents argue that neither India nor the other countries identified in the Office of Policy's List of Surrogate Countries produce the subject merchandise nor comparable merchandise. Respondents claim further that, among the developing countries other than China, only Kazakhstan, Russia, and Brazil are significant producers and exporters of magnesium and magnesium alloys. *See* the *Selection of a Surrogate Country Memorandum* dated August 3, 2004, for a complete description of the interested parties surrogate-country arguments.

The Department found that none of the countries on the List of Surrogate Countries are significant producers of the subject merchandise, magnesium metal. In past cases, the Department has determined that aluminum is comparable merchandise to magnesium. *See Pure Magnesium and Alloy Magnesium* at 55425 and 55426 and *Pure Magnesium From the People's Republic of China: Preliminary Results of Antidumping Duty New Shipper Administrative Review,* 62 FR 55215, 55217 (October 23, 1997). The Department also adopted this decision in *Pure Magnesium From the People's Republic of China: Final Results of Antidumping Duty New Shipper Administrative Review,* 63 FR 3085, 3088 (January 21, 1998). In *Pure Magnesium and Alloy Magnesium,* the Department explained that, "{a}lthough the material inputs used to produce magnesium and aluminum are different, according to both U.S. Bureau of Mines and Department of Commerce experts, both (1) are light metals in terms of molecular weight; (2) are electricity-intensive products; (3) are produced using an electrolytic process, and (4) share some common end uses (*e.g.*, die casting)." Similarly, in the 1998 new shipper review of *Pure Magnesium* we determined that aluminum constituted comparable merchandise in the context of surrogate selection for magnesium for the reasons specified in *Pure Magnesium and Alloy Magnesium, supra.*

Consequently, we have made the following determination about the use of India as a surrogate country: (1) It is a significant producer of comparable merchandise, aluminum; (2) it is at a similar level of economic development pursuant to 733(c)(4) of the Act; and (3) we have reliable data from India that we can use to value the factors of production. *See Selection of a Surrogate Country Memorandum.* Thus, we have calculated NV using Indian prices when available and appropriate to value the factors of production of the magnesium metal producers. We have obtained and relied upon publicly available information wherever possible. *See Memorandum to the File from Laurel LaCivita, Lilit Astvatsatrian and Steven Winkates, Case Analysts, through Robert Bolling, Program Manager, and Laurie Parkhill, Office Director: Magnesium Metal from the People's Republic of China: Factors Valuation Memorandum for the Preliminary Determination,* dated September 24, 2004 ("Factor-Valuation Memorandum").

In accordance with 19 CFR 351.301(c)(3)(i), for the final determination in an antidumping investigation, interested parties may submit publicly available information to value the factors of production within 40 days after the date of publication of the preliminary determination.

Affiliation

Section 771(33) of the Act states that the Department considers the following entities to be affiliated: (A) Members of a family, including brothers and sisters (whether by whole or half blood), spouse, ancestors, and lineal descendants; (B) Any officer or director of an organization and such organization; (C) Partners; (D) Employer and employee; (E) Any person directly or indirectly owning, controlling, or holding with power to vote, 5 percent or more of the outstanding voting stock or shares of any organization and such

organization; (F) Two or more persons directly or indirectly controlling, controlled by, or under common control with, any person; and (G) Any person who controls any other person and such other person.

For purposes of affiliation, section 771(33) of the Act states that a person shall be considered to control another person if the person is legally or operationally in a position to exercise restraint or direction over the other person. In order to find affiliation between companies, the Department must find that at least one of the criteria listed above is applicable to the respondents.

The Statement of Administrative Action accompanying the Uruguay Round Agreements Act ("SAA"), H.R. Doc. 103–316 (1994), indicates that stock ownership is not the only evidentiary factor that the Department may consider to exercise restraint or direction to determine whether a person is in a position to control and that control may be established through corporate or family groupings. *See SAA* at 838. Thus, the statute and the *SAA* expressly envision affiliation based on family shareholdings, consistent with our practice. *See e.g., Certain Fresh Cut Flowers from Colombia; Final Results of Antidumping Duty Administrative Review*, 61 FR 42833, 42853 (August 19, 1996), and *Certain Welded Carbon Steel Pipes and Tubes from Thailand: Final Results of Antidumping Duty Administrative Review*, 62 FR 53808, 53810 (October 16, 1997). Moreover, as stated in its final regulations, the Department examines issues of affiliation by family groupings closely. *See Certain Welded Carbon Steel Pipes and Tubes From Thailand: Final Results of Antidumping duty Administrative Review*, 62 FR 53808, 53810 (October 16, 1997).

To the extent that the affiliation provisions in section 771(33) of the Act do not conflict with the Department's application of separate rates and the statutory NME provisions in section 773(c) of the Act, the Department will determine that exporters and/or producers are affiliated if the facts of the case support such a finding. *See Certain Preserved Mushrooms From the People's Republic of China: Preliminary Results of Sixth New Shipper Review and Preliminary Results and Partial Rescission of Fourth Antidumping Duty Administrative Review*, 69 FR 10410, 10413 (March 5, 2004) ("Mushrooms").

Following these guidelines, we have considered whether we should determine that the seven members of the RSM Group ("RSM"): Nanjing Yunhai Special Metals Co., Ltd. ("Yunhai Special"), Nanjing Welbow Metals Co., Ltd. ("Welbow"), Nanjing Yunhai Magnesium Co., Ltd. ("Yunhai Magnesium"), Shanxi Wenxi Yunhai Metals Co., Ltd. ("Wenxi Yunhai"), Shanxi Wenxi Bada Magnesium Co., Ltd. ("Bada Magnesium"), Yuncheng Wenxi Welfare Magnesium Plant ("Welfare Magnesium"), and Nanjing Yunhai Metals Plant ("Yunhai Metals") are affiliated and should be collapsed. Moreover, we considered whether these companies should be collapsed with China National Nonferrous Metals I/E Corp., Jiangsu Branch ("Jiangsu Metals"), and TAI, thus considering these companies as a single entity for the purposes of the antidumping investigation of magnesium metal from the People's Republic of China ("PRC"). *See Memorandum to Laurie Parkhill, Director, Office 8, NME/China Group, Through Robert Bolling, Program Manager, From Laurel LaCivita, Senior Case Analyst, Antidumping Duty Investigation of Magnesium Metal From the People's Republic of China: Affiliation and Collapsing of Members of the RSM Group and Its Affiliated U.S. Reseller, Toyota Tsusho America, Inc.*, dated September 24, 2004 ("Collapsing Memorandum").

In its original questionnaire responses, RSM also reported that its affiliated reseller in the United States made sales of subject merchandise to an affiliated further-manufacturer in the United States that incorporated the subject merchandise into steering wheel armatures. In its supplemental questionnaire response, RSM argued that TAI was not affiliated with its downstream further-manufacturer. Therefore, we considered whether TAI and its downstream further-manufacturer are affiliated for the purposes of this investigation. *See* the proprietary *Memorandum to Laurie Parkhill, Director, Office 8, NME/China Group, Through Robert Bolling, Program Manager, From Laurel LaCivita, Senior Case Analyst, Antidumping Duty Investigation of Magnesium Metal From the People's Republic of China: Affiliation and Collapsing of Members of the RSM Group and Its Affiliated U.S. Reseller, Toyota Tsusho America, Inc.*, dated September 24, 2004 ("Affiliation Memorandum").

RSM reported that the members of RSM Group that produced or exported the subject merchandise are Yunhai Special, Welbow, Yunhai Magnesium, Wenxi Yunhai, Bada Magnesium, Welfare Magnesium, and Yunhai Metals. In addition, in its original questionnaire response, RSM claimed that it was affiliated with its U.S. reseller, TAI, during the POI and that all of the U.S. sales made through TAI should be treated as CEP sales. In its supplemental response, however, RSM argued that TAI was affiliated with only one member of the RSM group, Yunhai Magnesium, through TAI's parent company. Consequently, RSM reclassified all of its U.S. sales, except those originating with Yunhai Magnesium, as export-price ("EP") sales.

Based on our examination of the evidence presented in RSM's questionnaire responses, we have determined that Yunhai Special, Wenxi Yunhai, Welbow, Yunhai Magnesium, Bada Magnesium, Welfare Magnesium, and Yunhai Metals are affiliated under sections 771(33)(B), (E), (F), and (G) of the Act. We found, however, that only Yunhai Special, Welbow, Yunhai Magnesium, and Wenxi Yunhai either produced the subject merchandise during the POI, or were capable of producing the subject merchandise. Thus, we determined that Yunhai Special, Welbow, Wenxi Yunhai, and Yunhai Magnesium are affiliated and should be collapsed and treated as a single entity for purposes of calculating a dumping margin in this investigation for the following reasons: (1) Yunhai Special controls a majority or near-majority of Welbow, Wenxi Yunhai, and Yunhai Magnesium based on stock-ownership; (2) Yunhai Special, Welbow, Wenxi Yunhai, and Yunhai Magnesium share the same general manager and a common board member; and (3) RSM reported that the operations of Yunhai Special and Welbow cannot be distinguished since the two companies share the same general manager, production facilities, and employees.

We also determined that Jiangsu Metals is affiliated with the RSM Group, under sections 771(33)(E) and (F) of the Act, because RSM reported that Jiangsu Metals, an exporter of the subject merchandise, held more than 5 percent of the outstanding stock in Yunhai Magnesium and is therefore affiliated with Yunhai Magnesium pursuant to section 771(33)(E) of the Act. In addition, we found that Jiangsu Metals and Yunhai Special both own shares of Yunhai Magnesium as joint-venture partners. Consequently, we determined that Jiangsu Metals and Yunhai Special are affiliated in accord with section 771(33)(F) of the Act.

We determined further that, in contrast to RSM's arguments in its supplemental questionnaire response, TAI is also affiliated with the RSM Group under sections 771(33)(E) and (F) of the Act because the role that TAI and its parent corporation play in RSM's sales process indicates that TAI is

legally and operationally in a position to exercise control over the RSM Group in accordance with section 771(33)(F) of the Act.

We did not analyze whether Jiangsu Metals, an affiliated exporter, meets the criteria for collapsing with the RSM group because the company did not produce the subject merchandise during the POI. As a result, we have not collapsed Jiangsu Metals with the members of the RSM group for the purposes of calculating the antidumping duty margin. We have considered Jiangsu Metals for a separate rate in its own right.

We examined the information on the record with respect to TAI and its further-manufacturer and determined that TAI was affiliated with its downstream further-manufacturer, under section 771(33)(E) and (F) of the Act, for several reasons. RSM reported that TAI and its further-manufacturer are both subsidiaries of the same parent corporation in Japan and, thus, are affiliated in accord with section 771(33)(E) of the Act. *See* the proprietary discussion of this issue in the *Affiliation Memorandum* at 3. RSM demonstrated further that the parent corporation's ownership share held a very substantial stock ownership share in both TAI and its further-manufacturer, and is therefore in a position to exercise control over both entities. Because we determined that TAI and its further-manufacturer are affiliated under sections 771(33)(E) and (F) of the Act, we have not used the sales of subject merchandise from TAI to its affiliated further-manufacturer in our margin analysis because such sales do not represent the sales to the first unaffiliated customer in the United States. *See Affiliation Memorandum.* We did not examine the downstream sales of the subject merchandise made by the affiliated further-manufacturer because we determined that the subject merchandise sold to the further-manufacturer was incorporated into products whose value exceeded substantially the value of the imported subject merchandise. *See Memorandum to the File, through Laurie Parkhill, Director, Office 8, NME/China Unit, and Robert Bolling, Program Manager, From Laurel LaCivita, Senior Case Analyst, Magnesium Metal From the People's Republic of China: The Use of RSM's Sales of Further-Manufactured Merchandise in the U.S. Market for the Preliminary Determination,* dated September 24, 2004.

Separate Rates

In proceedings involving NME countries, the Department begins with a rebuttable presumption that all companies within the country are subject to government control and, thus, should be assigned a single antidumping duty deposit rate. It is the Department's policy to assign all exporters of merchandise subject to investigation in an NME country this single rate unless an exporter can demonstrate that it is sufficiently independent so as to be entitled to a separate rate. The two mandatory respondents and the Section A respondent have provided company-specific information and each has stated that it meet the standards for the assignment of a separate rate.

We have considered whether each company based in the PRC is eligible for a separate rate. The Department's separate-rate test to determine whether the exporters are independent from government control does not consider, in general, macroeconomic/border-type controls, *e.g.*, export licenses, quotas, and minimum export prices, particularly if these controls are imposed to prevent dumping. The test focuses, rather, on controls over the investment, pricing, and output decision-making process at the individual firm level. *See Certain Cut-to-Length Carbon Steel Plate From Ukraine: Final Determination of Sales at Less Than Fair Value,* 62 FR 61754, 61757 (November 19, 1997), and *Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, From the People's Republic of China: Final Results of Antidumping Duty Administrative Review,* 62 FR 61276, 61279 (November 17, 1997).

To establish whether a firm is sufficiently independent from government control of its export activities to be entitled to a separate rate, the Department analyzes each entity exporting the subject merchandise under a test arising from the *Final Determination of Sales at Less Than Fair Value: Sparklers from the People's Republic of China,* 56 FR 20588 (May 6, 1991) ("*Sparklers*"), as amplified by *Final Determination of Sales at Less Than Fair Value: Silicon Carbide From the People's Republic of China,* 59 FR 22585 (May 2, 1994) ("*Silicon Carbide*"). In accordance with the separate-rates criteria, the Department assigns separate rates in NME cases only if respondents can demonstrate the absence of both *de jure* and *de facto* governmental control over export activities.

1. Absence of De Jure Control

The Department considers the following *de jure* criteria in determining whether an individual company may be granted a separate rate: (1) An absence of restrictive stipulations associated with an individual exporter's business and export licenses; (2) any legislative enactments decentralizing control of companies; and (3) other formal measures by the government decentralizing control of companies. *See Sparklers,* 56 FR at 20589.

Our analysis shows that the evidence on the record supports a preliminary finding of *de jure* absence of governmental control for Tianjin, Guangling Jinghua, Jiangsu Metals, and the RSM companies consisting of Yunhai Special, Welbow, Wenxi Yunhai, and Yunhai Magnesium based on the criteria listed above. *See Memorandum to Laurie Parkhill, Office Director, China/NME Group, through Robert Bolling, Program Manager, from Laurel LaCivita, Senior Case Analyst and Lilit Astvatsatrian, Case Analyst, Magnesium Metal from the People's Republic of China: Separate Rates Memorandum* ("*Separate-Rates Memorandum*"), dated September 24, 2004.

2. Absence of De Facto Control

Typically the Department considers the following four factors in evaluating whether each respondent is subject to de facto governmental control of its export functions: (1) Whether the export prices are set by or are subject to the approval of a governmental agency; (2) whether the respondent has authority to negotiate and sign contracts and other agreements; (3) whether the respondent has autonomy from the government in making decisions regarding the selection of management; and (4) whether the respondent retains the proceeds of its export sales and makes independent decisions regarding disposition of profits or financing of losses. *See Silicon Carbide,* 59 FR at 22586–87; *see also Final Determination of Sales at Less Than Fair Value: Furfuryl Alcohol From the People's Republic of China,* 60 FR 22544, 22545 (May 8, 1995). The Department has determined that an analysis of *de facto* control is critical in determining whether respondents are, in fact, subject to a degree of governmental control which would preclude the Department from assigning separate rates.

We determine that, for Tianjin, Guangling Jinghua, Jiangsu Metals, and the RSM companies consisting of Yunhai Special, Welbow, Wenxi Yunhai, and Yunhai Magnesium, the evidence on the record supports a preliminary finding of *de facto* absence of governmental control based on record statements and supporting documentation showing the following:

(1) Each exporter sets its own export prices independent of the government and without the approval of a government authority; (2) each exporter retains the proceeds from its sales and makes independent decisions regarding disposition of profits or financing of losses; (3) each exporter has the authority to negotiate and sign contracts and other agreements; and (4) each exporter has autonomy from the government regarding the selection of management.

Therefore, the evidence placed on the record of this investigation by Tianjin, Guangling Jinghua, Jiangsu Metals, and the RSM companies consisting of Yunhai Special, Welbow, Wenxi Yunhai, and Yunhai Magnesium demonstrates an absence of government control, both in law and in fact, with respect to each of the exporter's exports of the merchandise under investigation in accordance with the criteria identified in *Sparklers* and *Silicon Carbide*. As a result, for the purposes of this preliminary determination, we have granted separate, company-specific rates to the mandatory respondents and the Section A respondent which shipped magnesium metal to the United States during the POI. For a full discussion of this issue, please *see* the *Separate-Rates Memorandum*.

PRC-Wide Rate

The Department has data that indicates there were more exporters of magnesium metal from the PRC during the POI than those which responded to the Q&V questionnaire. *See Respondent Selection Memorandum* at 1. Although we issued the Q&V questionnaire to 142 known Chinese exporters of the subject merchandise, we received only two Q&V questionnaire responses, which were from the two mandatory respondents. Also, on May 6, 2004, we issued our complete questionnaire to the Chinese Government (*i.e.*, Ministry of Commerce). Although all exporters were given an opportunity to provide information showing they qualify for separate rates, not all of these other exporters provided a response to either the Department's Q&V questionnaire or its Section A questionnaire. Therefore, the Department determines preliminarily that there were exports of the merchandise under investigation from PRC producers/exporters that did not respond to the Department's questionnaire. We treated these PRC producers/exporters as part of the countrywide entity. Further, the Government of the PRC did not respond to the Department's questionnaire.

Section 776(a)(2) of the Act provides that, if an interested party (A) withholds information that has been requested by the Department, (B) fails to provide such information in a timely manner or in the form or manner requested, subject to subsections 782(c)(1) and (e) of the Act, (C) significantly impedes a proceeding under the antidumping statute, or (D) provides such information but the information cannot be verified, the Department shall, subject to subsection 782(d) of the Act, use facts otherwise available in reaching the applicable determination.

Pursuant to section 782(e) of the Act, the Department shall not decline to consider submitted information if all of the following requirements are met: (1) The information is submitted by the established deadline; (2) the information can be verified; (3) the information is not so incomplete that it cannot serve as a reliable basis for reaching the applicable determination; (4) the interested party has demonstrated that it acted to the best of its ability; and (5) the information can be used without undue difficulties.

Information on the record of this investigation indicates that there are numerous producers/exporters of magnesium metal in the PRC. As described above, all exporters were given the opportunity to respond to the Department's questionnaire. Based upon our knowledge of the volume of imports of subject merchandise from the PRC and the fact that information indicates that the responding companies did not account for all imports into the United States from the PRC, we have preliminarily determined that certain PRC exporters of magnesium metal failed to respond to our questionnaires. As a result, use of adverse facts available ("AFA") pursuant to section 776(a)(2)(A) of the Act is appropriate. Additionally, in this case, the Government of the PRC did not respond to the Department's questionnaire, thereby necessitating the use of AFA to determine the PRC-wide rate. *See Preliminary Determination of Sales at Less Than Fair Value, Affirmative Preliminary Determination of Critical Circumstances and Postponement of Final Determination: Certain Frozen Fish Fillets from the Socialist Republic of Vietnam*, 68 FR 4986 (January 31, 2003).

Section 776(b) of the Act provides that, in selecting from among the facts available, the Department may employ adverse inferences if an interested party fails to cooperate by not acting to the best of its ability to comply with requests for information. *See Final Determination of Sales at Less Than Fair Value: Certain Cold-Rolled Flat-Rolled Carbon-Quality Steel Products from the Russian Federation*, 65 FR 5510, 5518 (February 4, 2000). *See also* "Statement of Administrative Action" accompanying the URAA, H.R. Rep. No. 103–316, 870 (1994) ("SAA"). We find that, because the PRC-wide entity did not respond to our request for information, it has failed to cooperate to the best of its ability. Therefore, the Department preliminarily finds that, in selecting from among the facts available, an adverse inference is appropriate.

Section 776(b) of the Act authorizes the Department to use AFA information derived from the petition, the final determination from the LTFV investigation, a previous administrative review, or any other information placed on the record. As AFA, we have assigned to the PRC-wide entity a margin based on a calculated margin derived from information obtained in the course of the investigation and placed on the record of this proceeding. In this case, we have applied a rate of 177.62 percent.

Consequently, we are applying a single antidumping rate—the PRC-wide rate—to producers/exporters that failed to respond to the Q&V questionnaire or Section A questionnaire. This rate will also apply to exporters which did not demonstrate entitlement to a separate rate. *See, e.g., Final Determination of Sales at Less Than Fair Value: Synthetic Indigo from the People's Republic of China*, 65 FR 25706, 25707 (May 3, 2000). The PRC-wide rate applies to all entries of the merchandise under investigation except for entries from the two mandatory respondents and the Section A respondent.

Because this is a preliminary margin, the Department will consider all margins on the record at the time of the final determination for the purpose of determining the most appropriate final PRC-wide margin. *See Preliminary Determination of Sales at Less Than Fair Value: Saccharin from the People's Republic of China*, 67 FR 79049, 79054 (December 27, 2002).

Margin for Section A Respondent

Guangling Jinghua, the only exporter which submitted a response to Section A of the Department's antidumping questionnaire and had sales of the subject merchandise to the United States during the POI but was not selected as mandatory respondent in this investigation ("Section A respondent"), has applied for a separate rate and provided information for the Department to consider for this purpose. Therefore, we have established a weighted-average margin based on the rate we have calculated for the two mandatory respondents, excluding any

rates that are zero, *de minimis*, or based entirely on adverse facts available. That rate is 140.09 percent. Guangling Jinghua is identified by name in the "Suspension of Liquidation" section of this notice.

Date of Sale

Section 351.401(I) of the Department's regulations state that, "in identifying the date of sale of the subject merchandise or foreign like product, the Secretary normally will use the date of invoice, as recorded in the exporter or producer's records kept in the normal course of business." After examining the sales documentation placed on the record by the mandatory respondents, we preliminarily determine that date of purchase order is the most appropriate date of sale for RSM and Tianjin. In their submissions, RSM and Tianjin stated that they establish the date of sale on their purchase order date because all of their sales terms are finalized by the purchase order date. Additionally, RSM and Tianjin provided no evidence to suggest that their sales terms changed after the purchase order was established. Based on record evidence, we have determined that RSM's and Tianjin's sales terms did not change after the purchase-order date, and thus we have used purchase order date as the date of sale for the preliminary determination for RSM and Tianjin.

The Department intends to examine the date-of-sale issue at verification thoroughly and may reconsider its position for the final determination based on the results of verification.

Fair Value Comparisons

To determine whether sales of magnesium metal to the United States by the two mandatory respondents were made at less than fair value, we compared EP or CEP to NV, as described in the "Export Price," "U.S. Price," and "Normal Value" sections of this notice.

U.S. Price

In accordance with section 772(a) of the Act, we used EP for Tianjin, as appropriate, because the subject merchandise was first sold (or agreed to be sold) before the date of importation by the producer or exporter of the subject merchandise outside the United States to an unaffiliated purchaser in the United States or to an unaffiliated purchaser for exportation to the United States and because the use of CEP was not otherwise indicated. In accordance with section 772(b) of the Act, we used CEP for RSM and Jiangsu Metals because the subject merchandise was sold in the United States after the date of importation by a U.S. reseller affiliated with the producer. In addition, we did not use sales made by the U.S. reseller to an affiliated further-manufacturer because RSM reported that all of those sales were destined for further manufacturing in the United States where the value added substantially exceeded the value of the merchandise imported. *See Memorandum to The File, Through Laurie Parkhill, Director, Office 8, NME/China Unit, and Robert Bolling, Program Manager, From Laurel LaCivita, Senior Case Analyst, Magnesium Metal from the People's Republic of China: The Use of RSM's Sales of Further-Manufactured Merchandise in the U.S. Market for the Preliminary Determination*, dated September 24, 2004.

We calculated EP and CEP based on the packed F.O.B., C.I.F., or delivered price to unaffiliated purchasers in, or for exportation to, the United States. We made deductions, as appropriate, for any movement expenses (*e.g.*, foreign inland freight from the plant to the port of exportation, domestic brokerage, ocean freight, marine insurance, U.S. brokerage, and inland freight from warehouse to unaffiliated U.S. customer) in accordance with section 772(c)(2)(A) of the Act. For a detailed description of all adjustments, *see Memorandum to The File Through Robert Bolling, Program Manager, China/NME Group, from Lilit Astvatsatrian, Case Analyst, Analysis for the Preliminary Determination of Magnesium Metal from the People's Republic of China: Tianjin Magnesium International Co., Ltd. ("Tianjin"), dated September 24, 2004, and Memorandum to the File Through Robert Bolling, Program Manager, China/NME Group, From Laurel LaCivita, Senior Case Analyst, Analysis for the Preliminary Determination of Magnesium Metal from the People's Republic of China: the RSM Companies*, dated September 24, 2004.

In accordance with section 772(d)(1) of the Act and the *SAA* at 823–824, we calculated the CEP by deducting selling expenses associated with economic activities occurring in the United States, for which RSM includes U.S. customs duty.

We compared NV to weighted-average EPs and CEPs in accordance with section 777A(d)(1) of the Act. For RSM, in accordance with sections 772(d)(3) and 772(f) of the Act, we deducted CEP profit. For a detailed description of all adjustments, *see* the Company-Specific Analysis Memoranda dated September 24, 2004.

Normal Value

Section 773(c)(1) of the Act provides that the Department shall determine the NV using a factors-of-production methodology if the merchandise is exported from an NME and the information does not permit the calculation of NV using home-market prices, third-country prices, or constructed value under section 773(a) of the Act. The Department bases NV on the factors of production because the presence of government controls on various aspects of these economies renders price comparisons and the calculation of production costs invalid under its normal methodologies.

The Department's questionnaire requires that the respondent provide information regarding the weighted-average factors of production across all of the company's plants that produce the subject merchandise, not just the factors of production from a single plant. This methodology ensures that the Department's calculations are as accurate as possible. *See e.g., Final Determination of Sales at Less Than Fair Value and Critical Circumstances: Certain Malleable Iron Pipe Fittings From the People's Republic of China*, 68 FR 61395 (Oct. 28, 2003); Issues and Decision Memorandum, Comment 19 (Oct. 20, 2003). Therefore, for Tianjin, the Department calculated the factors of production using the weighted-average factor values for all of the facilities involved in producing the subject merchandise. For RSM and Jiangsu Metals, the Department used the weighted-average factor values reported for the RSM group members which it determined were affiliated and which it collapsed. *See* the *Collapsing Memorandum*.

Factor Valuations

In accordance with section 773(c) of the Act, we calculated NV based on factors of production reported by respondents for the POI. To calculate NV, we multiplied the reported per-unit factor-consumption rates by publicly available Indian surrogate values (except as discussed below). In selecting the surrogate values, we considered the quality, specificity, and contemporaneity of the data. As appropriate, we adjusted input prices by including freight costs to make them delivered prices. Specifically, we added to Indian import surrogate values a surrogate freight cost using the shorter of the reported distance from the domestic supplier to the factory or the distance from the nearest seaport to the factory where appropriate. This adjustment is in accordance with the

Court of Appeals for the Federal Circuit's decision in *Sigma Corp.* v. *United States*, 117 F. 3d 1401 (Fed. Cir. 1997).

For this preliminary determination, in accordance with past practice, we used data from the Indian Import Statistics in order to calculate surrogate values for the mandatory respondents' material inputs. In selecting the best available information for valuing factors of production in accordance with section 773(c)(1) of the Act, the Department's practice is to select, to the extent practicable, surrogate values which are non-export average values, most contemporaneous with the POI, product-specific, and tax-exclusive. The record shows that data in the Indian Import Statistics represents import data, is contemporaneous with the POI, is product-specific, and is tax-exclusive. *See Manganese Metal From the People's Republic of China; Final Results and Partial Rescission of Antidumping Duty Administrative Review*, 63 FR 12441, 12442 (March 13, 1998). Additionally, there is no record evidence which indicates that any of the factors being valued are of low value compared to other items in the basket categories; thus, our use of these statistics does not result in a distortion in favor of higher values. Further, the Indian Import Statistics contain values at both ends of the spectrum (*i.e.*, high value and low value), indicating further that the Indian Import values are not distorted when taken as an average, as we are doing in this case. Therefore, we determined that the Indian Import Statistics provide the best available information for valuing the factors of production. Consequently, we valued raw material inputs for each mandatory respondent using the weighted-average unit import values derived from the World Trade Atlas® online ("Indian Import Statistics"), published by the DGCI&S, Ministry of Commerce of India, which were reported in rupees and are contemporaneous with POI. *See Factor-Valuation Memorandum.* Where we could not obtain publicly available information contemporaneous to the POI with which to value factors, we adjusted the surrogate values using, where appropriate, the Indian Wholesale Price Index ("WPI") or the Indian Producer Price Index ("PPI") as published in the *International Financial Statistics* of the International Monetary Fund.

Furthermore, with regard to both the Indian import-based surrogate values and the market-economy input values, we have disregarded prices that we have reason to believe or suspect may be subsidized. We have reason to believe or suspect that prices of inputs from Indonesia, South Korea, and Thailand may have been subsidized. We have found in other proceedings that these countries maintain broadly available, non-industry-specific export subsidies and, therefore, it is reasonable to infer that all exports to all markets from these countries are subsidized. *See Amended Final Determination of Sales at Less Than Fair Value: Automotive Replacement Glass Windshields From the People's Republic of China*, 67 FR 11670 (March 15, 2002). We are also directed by the legislative history not to conduct a formal investigation to ensure that such prices are not subsidized. *See* H.R. Rep. 100–576 at 590 (1988). Rather, Congress directed the Department to base its decision on information that is available to it at the time it makes its determination. Therefore, we have not used prices from these countries either in calculating the Indian import-based surrogate values or in calculating market-economy input values. In instances where a market-economy input was obtained solely from suppliers located in these countries, we used Indian import-based surrogate values to value the input. *See Final Determination of Sales at Less Than Fair Value: Certain Automotive Replacement Glass Windshields From The People's Republic of China*, 67 FR 6482 (February 12, 2002), and accompanying Issues and Decision Memorandum at Comment 1.

We used the Indian Import Statistics to value the following raw material inputs, energy, by-products, and packing materials that RSM and Tianjin used to produce the subject merchandise during the POI: Ferrosilicon, dolomite, No.2 flux, fluorite powder, sulfur powder, primary magnesium, magnesium scrap, zinc, AlBe5, AlBe1, manganese powder, magnesium, aluminum-magnesium alloy, sulfuric acid manganese chip, magnesium chloride, potassium chloride, barium chloride, aluminum, sulfur dioxide, nitrogen, argon, coal, bituminous coal, anthracite, liquified petroleum gas ("LPG"), propane, steel strap, LDPE sheet, printing ink, printing ink solvent, particle board, pallet, little steel sheet, steel band, and plastic bags. For a detailed description of all surrogate values used for respondents, *see Factor-Valuation Memorandum.*

To value electricity, we used data from the International Energy Agency ("IEA") *Key World Energy Statistics* (2003 edition), submitted by the Petitioners in Exhibit 5 of their August 19, 2004, submission. Because the value was not contemporaneous with the POI, we adjusted the rate for inflation. *See Factor-Valuation Memorandum.*

To value heavy oil and diesel fuel, we used data from IEA's *Key World Energy Statistics* (2003 edition) which was submitted by Petitioners in their August 19, 2004, submission. Because the value was not contemporaneous with the POI, we adjusted the rate for inflation. *See Factor-Valuation Memorandum.*

For direct, indirect, and packing labor, consistent with 19 CFR 351.408(c)(3), we used the PRC regression-based wage rate as reported on Import Administration's home page, Import Library, Expected Wages of Selected NME Countries, revised in September 2003, *http://ia.ita.doc.gov/wages/01wages/01wages.html.* The source of these wage-rate data on the Import Administration's Web site is the Yearbook of Labour Statistics 2002, ILO (Geneva: 2002), Chapter 5B: Wages in Manufacturing. Because this regression-based wage rate does not separate the labor rates into different skill levels or types of labor, we have applied the same wage rate to all skill levels and types of labor reported by the respondent.

The respondents also reported packing inputs. We used Indian Import Statistics data from the period July 2003 to December 2003 to value these inputs. *See Factor-Valuation Memorandum.*

RSM reported magnesium alloy slag as by-product of the production process. We used Indian Import Statistics data from the period July 2003 to December 2003 to value this by-product. *See Factor-Valuation Memorandum.*

We used Indian transport information in order to value the transportation of raw materials. To calculate domestic inland freight for trucking services, we selected freight values from *Chemical Weekly.* Some inputs were transported by market-economy transportation firms and paid for in a market-economy currency. Where this was the case, we added the actual market-economy transportation expense to the valuation of the factor of production.

We used Indian rail freight information in order to value the transportation of raw materials. To value the rail freight, we used two price quotes from November 1999 for steel shipments within India. Because the value was not contemporaneous with the POI, we adjusted the rate for inflation. *See Factor-Valuation Memorandum.*

To value factory overhead, selling, general, and administrative expenses, and profit, we used the audited financial statements for the fiscal year ending March 31, 2003, from the following aluminum producers in India: National Aluminium Company Limited;

Indian Aluminium Company; Limited, Bharat Aluminium Company Limited; the Madras Aluminium Company Limited; and HINDALCO Industries Limited. *See Factor-Valuation Memorandum* for a full discussion of the calculation of these ratios from these financial statements.

Currency Conversion

We made currency conversions into U.S. dollars, in accordance with section 773A(a) of the Act, based on the exchange rates in effect on the dates of the U.S. sales as certified by the Federal Reserve Bank.

Verification

As provided in section 782(I)(1) of the Act, we intend to verify the information upon which we will rely in making our final determination.

Preliminary Determination

The weighted-average dumping margins are as follows:

MAGNESIUM METAL FROM THE PRC

Manufacturer/exporter	Weighted-average margin (percent)
Tianjin	177.62
RSM	128.11
Jiangsu Metals	117.41
Guangling	140.09
China-Wide Rate	177.62

Disclosure

We will disclose the calculations performed within five days of the date of publication of this notice to parties in this proceeding in accordance with 19 CFR 351.224(b).

Suspension of Liquidation

In accordance with section 733(d) of the Act, we will instruct U.S. Customs and Border Protection ("CBP") to suspend liquidation of all entries of subject merchandise, entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. We will instruct CBP to require a cash deposit or the posting of a bond equal to the weighted-average amount by which the normal value exceeds U.S. price, as indicated above. The suspension of liquidation will remain in effect until further notice.

International Trade Commission Notification

In accordance with section 733(f) of the Act, we have notified the ITC of our preliminary affirmative determination of sales at less than fair value. Because we have postponed the deadline for our final determination to 135 days from the date of publication of this preliminary determination, section 735(b)(2) of the Act requires the ITC to make its final determination as to whether domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports of wooden bedroom furniture, or sales (or the likelihood of sales) for importation, of the subject merchandise within 45 days of our final determination.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Import Administration no later than seven days after the date of the final verification report is issued in this proceeding and rebuttal briefs limited to issues raised in case briefs no later than five days after the deadline date for case briefs. A list of authorities used and an executive summary of issues should accompany any briefs submitted to the Department. This summary should be limited to five pages total, including footnotes.

In accordance with section 774 of the Act, we will hold a public hearing, if requested, to afford interested parties an opportunity to comment on arguments raised in case or rebuttal briefs. If a request for a hearing is made, we intend to hold the hearing three days after the deadline of submission of rebuttal briefs at the U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230, at a time and location to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Import Administration, U.S. Department of Commerce, Room 1870, within 30 days after the date of publication of this notice. *See* 19 CFR 351.310(c). Requests should contain the party's name, address, and telephone number, the number of participants, and a list of the issues to be discussed. At the hearing, each party may make an affirmative presentation only on issues raised in that party's case brief and may make rebuttal presentations only on arguments included in that party's rebuttal brief.

We will make our final determination no later than 135 days after the date of publication of this preliminary determination, pursuant to section 735(a)(2) of the Act.

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act.

Dated: September 24, 2004.

James J. Jochum,

Assistant Secretary for Import Administration.

[FR Doc. E4–2478 Filed 10–1–04; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–821–819]

Notice of Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination: Magnesium Metal From the Russian Federation

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: In response to a petition filed by U.S. Magnesium LLC (U.S. Magnesium), United Steelworkers of America, Local 8319, Glass, Molders, Pottery, Plastics and Allied Workers International, Local 374 (collectively, the Petitioners), the U.S. Department of Commerce (the Department) initiated and is conducting an investigation of sales of magnesium metal from the Russian Federation for the period January 1, 2003, through December 31, 2003. *See Notice of Initiation of Antidumping Duty Investigations: Magnesium Metal From the People's Republic of China and the Russian Federation*, 69 FR 15293 (March 25, 2004) (*Initiation Notice*). The Department preliminarily determines that magnesium metal from the Russian Federation is being or is likely to be sold in the United States at less than fair value (LTFV), as provided in Section 733 of the Tariff Act of 1930, as amended (the Act). The estimated margins of sales at LTFV are listed in the "Suspension of Liquidation" section of this notice. Interested parties are invited to comment on this preliminary determination.

EFFECTIVE DATE: October 4, 2004.

FOR FURTHER INFORMATION CONTACT: Joshua Reitze or Sebastian Wright at (202) 482–0666 or (202) 482–5254, respectively; Office of AD/CVD Operations VI, Import Administration, Room 1870, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Preliminary Determination

Case History

This investigation was initiated on March 18, 2004. *See Initiation Notice.* Since the initiation of the investigation, the following events have occurred.

On March 26, 2004, the Department issued a letter providing interested parties an opportunity to comment on a proposed set of model-match criteria. We received comments in response to this letter from the Petitioners and JSC Avisma Magnesium-Titanium Works and VSMPO-Tirus, U.S. (Avisma) on April 1, 2004. Based on these submissions, we determined the appropriate model-match characteristics and included them in the antidumping questionnaire issued to Avisma and Solikamsk Magnesium Works (SMW), Respondents in this investigation, on April 24, 2004.

On March 31, 2004, the Department set aside a period for all interested parties to raise issues regarding the scope of this investigation. On April 16, 2004, the following companies submitted timely comments: Reade Manufacturing Company, Magnesium Elektron North America, Inc., and Hart Metals, Inc. (collectively, Reade) and Avisma. On April 26, 2004, the Department received rebuttal comments from the Petitioners, and additional comments from Northwest Alloys, Inc. (Northwest) and Alcoa, Inc. (Alcoa). On June 25, June 28, and July 9, 2004, we received additional comments on the scope of this investigation from Petitioners, Alcoa, Reade, and Avisma, in response to questions that we issued to all interested parties on June 9, 2004.

On May 17, 2004, the United States International Trade Commission (ITC) preliminarily determined that there is a reasonable indication that imports of the products subject to this investigation are materially injuring an industry in the United States producing the domestic like products. *See Magnesium From China and Russia,* 69 FR 29329 (May 21, 2004) (*ITC Preliminary Determination*).

On June 28, 2004, the Petitioners requested that the Department extend the preliminary determination in this investigation from August 5, 2004, to September 24, 2004. *See Notice of Postponement of Preliminary Determinations in Antidumping Duty Investigations of Magnesium Metal From the People's Republic of China and the Russian Federation,* 69 FR 43561 (July 21, 2004) (*Postponement of Preliminary Determinations*). Because there were no compelling reasons to deny the request, we postponed the preliminary determination to September 24, 2004, under section 733(c)(1) of the Act.

In their petition, the Petitioners alleged that Russian energy costs were distorted by excessive involvement by the Russian government in the energy sector, and requested that the Department make adjustments to energy costs to account for the effects of this involvement. In the *Initiation Notice,* the Department stated its intent to investigate the Russian government's involvement in the energy sector, and to consider whether an adjustment was appropriate. On July 30, 2004, the Petitioners submitted additional information to support their claim that Russian government involvement resulted in gas and electricity prices that do not reflect "economic reality," stating their argument that the Department has the legal authority to disregard or adjust the energy costs reported by Respondents to account for this distortion, and suggesting options for correcting the effects of this distortion. On September 1 and 3, 2004, Avisma submitted arguments to rebut the Petitioners' claims. On September 15, 2004, SMW submitted comments which endorsed the legal analysis of Avisma's September 1 and 3, 2004, comments.

Postponement of Final Determination and Extension of Provisional Measures

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise. Section 351.210(e)(2) of the Department's regulations requires that exporters requesting postponement of the final determination must also request an extension of the provisional measures referred to in section 733(d) of the Act from a four-month period until not more than six months. On September 14 and September 21, 2004, we received requests to postpone the final determination from SMW and Avisma, respectively. Both requests consented to the extension of provisional measures from four months to no longer than six months. Since this preliminary determination is affirmative, the requests for postponement are made by exporters that account for a significant proportion of exports of the subject merchandise, and since there is no compelling reason to deny the Respondents' requests, we have extended the deadline for issuance of the final determination until the 135th day after the date of publication of this preliminary determination in the **Federal Register** and have extended provisional measures to no longer than six months.

Selection of Respondents

Section 777A(c)(1) of the Act directs the Department to calculate individual dumping margins for each known exporter and producer of the subject merchandise. Where it is not practicable to examine all known producers/exporters of subject merchandise, section 777A(c)(2) of the Act permits the Department to investigate either: (1) A sample of exporters, producers, or types of products that is statistically valid, based on the information available at the time of selection; or (2) exporters and producers accounting for the largest volume of the subject merchandise that can reasonably be examined. In the petition, the Petitioners identified two potential producers and exporters of magnesium metal in the Russian Federation: Avisma and SMW. This was confirmed by the Department's analysis of data collected by U.S. Customs and Border Protection (CBP), which was placed on the record on June 17, 2004.

On May 21, 2004, the Department received an e-mail message from another Russian producer of magnesium. In a subsequent e-mail message, the producer informed the Department that it had sold a small amount of subject merchandise to the United States during the period of investigation (POI). It also informed the Department that it is unrelated to the other Respondents. The sales amount reported by this producer is extremely small in comparison to the import statistics on the ITC Web site. As discussed in the memorandum for selection of Respondents, the Department found that it was not practical to examine all known exporters and producers of the subject merchandise. *See Antidumping Duty Investigation of Magnesium Metal From the Russian Federation; Selection of Mandatory Respondents,* June 29, 2004 (*Respondent Selection Memo*). Furthermore, the Department found that the two Respondents named in the initiation account for almost all exports of subject merchandise to the United States. Id. Accordingly, because Avisma and SMW account for the largest volume of the subject merchandise that can be reasonably examined, the Department has calculated individual dumping margins for those two companies. *See* section 777A(c)(2)(B) of the Act.

Period of Investigation

The period of investigation (POI) is January 1, 2003, through December 31, 2003. This period corresponds to the four most recent fiscal quarters prior to the month of filing of the petition (*i.e.*, March 2004) involving imports from a market economy, and is in accordance with the Department's regulations. *See* . 19 CFR 351.204(b)(1).

Scope of Investigation

For the purpose of this investigation, the product covered is magnesium metal (also referred to as magnesium). The products covered by this investigation are primary and secondary pure and alloy magnesium metal, regardless of chemistry, raw material source, form, shape, or size. Magnesium is a metal or alloy containing by weight primarily the element magnesium. Primary magnesium is produced by decomposing raw materials into magnesium metal. Secondary magnesium is produced by recycling magnesium-based scrap into magnesium metal. The magnesium covered by this investigation includes blends of primary and secondary magnesium.

The subject merchandise includes the following pure and alloy magnesium metal products made from primary and/or secondary magnesium, including, without limitation, magnesium cast into ingots, slabs, rounds, billets, and other shapes, and magnesium ground, chipped, crushed, or machined into raspings, granules, turnings, chips, powder, briquettes, and other shapes: (1) Products that contain at least 99.95 percent magnesium, by weight (generally referred to as "ultra-pure" magnesium); (2) products that contain less than 99.95 percent but not less than 99.8 percent magnesium, by weight (generally referred to as "pure" magnesium); and (3) chemical combinations of magnesium and other material(s) in which the magnesium content is 50 percent or greater, but less that 99.8 percent, by weight, whether or not conforming to an "ASTM Specification for Magnesium Alloy."

The scope of this investigation excludes: (1) Magnesium that is in liquid or molten form; and (2) mixtures containing 90 percent or less magnesium in granular or powder form by weight and one or more of certain non-magnesium granular materials to make magnesium-based reagent mixtures, including lime, calcium metal, calcium silicon, calcium carbide, calcium carbonate, carbon, slag coagulants, fluorspar, nephaline syenite, feldspar, alumina (Al203), calcium aluminate, soda ash, hydrocarbons, graphite, coke, silicon, rare earth metals/mischmetal, cryolite, silica/fly ash, magnesium oxide, periclase, ferroalloys, dolomite lime, and colemanite.[1]

The merchandise subject to this investigation is classifiable under items 8104.11.00, 8104.19.00, 8104.30.00, and 8104.90.00 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS items are provided for convenience and customs purposes, the written description of the merchandise under investigation is dispositive.

Scope Issues

On March 31, 2004, the Department set aside a period for all interested parties to raise issues regarding the scope of this investigation. As discussed above, we received comments from Reade, Northwest, Alcoa, and Avisma, as well as rebuttal comments from Petitioners. These comments are summarized in the Department's September 24, 2004 memorandum *Product Coverage in Magnesium Metal From the Russian Federation* (*Product Coverage Memorandum*). In their comments, parties raised two issues: (1) Whether alloy and pure magnesium should be treated as two separate like products; and (2) whether ultra high purity (UHP) magnesium should be excluded from the scope of this investigation. Based on our analysis of the evidence on the record, we preliminarily determine that UHP magnesium is within the scope of the investigation. We also preliminarily determine that pure magnesium and alloy magnesium constitute a single like product. For a detailed discussion of our decision, *see Product Coverage Memorandum*.

Fair Value Comparisons

To determine whether sales of magnesium metal were made in the United States at LTFV, we compared the constructed export price (CEP) to the normal value (NV), as described in the "Constructed Export Price" and "Normal Value" sections below. In accordance with section 777A(d)(1)(A)(i) of the Act, we calculated weighted-average CEPs. We then compared these to weighted-average home market prices in Russia.

Date of Sale

Avisma reported invoice date as the date of sale for both the home and U.S. markets. Avisma issues invoices at the time of shipment, which, in the home market, may come after payment. For contract sales, the invoice establishes the price and quantity of the sale, as well as the parameters by which price and quantity may change under the contract. Invoices also set the price and quantity for spot sales. Because the material terms of sale are established when the invoice is issued, and because of our presumption that invoice date is the date of sale, as stated in section 351.401(i) of our regulations, we are using invoice date as the date of sale for all Avisma transactions in both markets.

For both the home and U.S. markets, SMW reported contract date as the date of sale. The contract date is the date when the material terms of sale (*i.e.*, price and quantity) are first established with the customer, but, as with Avisma's contracts, these values are allowed to change under the terms of the contract. In such cases where the price or quantity of a contract were amended, SMW reported the date of the amendment as the date of sale. SMW reported all sales with contracts that were initiated or amended during or prior to the POI and with invoices issued during the POI.

Because the material terms of SMW's contracts are susceptible to amendment, and in fact are amended, we are using invoice date as the date of sale for this preliminary determination for both the home and U.S. markets. As noted above, the Department's regulations presume that invoice date is the date of sale. *See* 19 CFR 351.401(i) ("In identifying the date of sale of the subject merchandise or foreign like product, the Secretary normally will use the date of invoice"). Therefore, we preliminarily determine that invoice date is the proper date of sale for both markets.

Constructed Export Price

For U.S. price, we used CEP, as defined in section 772(b) of the Act. Section 772(b) of the Act defines CEP as the price at which the subject merchandise is first sold in the United States before or after the date of importation by or for the account of the producer or exporter of such merchandise or by a seller affiliated with the producer or exporter, to a purchaser not affiliated with the

[1] This second exclusion for magnesium-based reagent mixtures is based on the exclusion for reagent mixtures in the 2000–2001 investigations of magnesium from China, Israel, and Russia. *See Final Determination of Sales at Less Than Fair Value: Pure Magnesium in Granular Form From the People's Republic of China*, 66 FR 49345 (September 27, 2001); *Final Determination of Sales at Less Than Fair Value: Pure Magnesium From Israel*, 66 FR 49349 (September 27, 2001); *Final Determination of Sales at Not Less Than Fair Value: Pure Magnesium From the Russian Federation*, 66 FR 49347 (September 27, 2001). These mixtures are not magnesium alloys, because they are not chemically combined in liquid form and cast into the same ingot.

producer or exporter, as adjusted under subsections 772(c) and (d) of the Act.

In its questionnaire responses, Avisma identified all of its sales to the United States as CEP sales. All of Avisma's sales are properly classified as CEP sales because they were made for the account of Avisma, by Avisma's U.S. affiliate, VSMPO-Tirus, U.S., Inc. (Tirus US), to unaffiliated purchasers in the United States. U.S. sales to the first unaffiliated party were made in the United States, by the U.S. affiliate, thus satisfying the Department's requirements for treating sales as CEP sales. Avisma and Tirus US are affiliated through common ownership. *See* Section 771(33)(F) of the Act.

In accordance with Section 772(c)(2) of the Act, for Avisma's CEP sales we made deductions from price for movement expenses and discounts, and additions for billing adjustments, where appropriate. More specifically, after reviewing the terms of delivery for Avisma's CEP sales to the United States, we deducted early payment discounts, added billing adjustments, and deducted foreign inland freight from plant to port, international freight and insurance, U.S. customs duties, U.S. brokerage and handling, and U.S. inland freight. *See Analysis Memorandum for Magnesium Metal from the Russian Federation: JSC AVISMA Titanium-Magnesium Works and VSMPO-Tirus, U.S., Inc.* (*Avisma Analysis Memorandum*).

Section 772(d)(1) of the Act provides for additional adjustments to calculate CEP. Accordingly, we deducted direct selling expenses and indirect selling expenses related to commercial activity in the United States. Pursuant to section 772(d)(3) of the Act, we made an adjustment for CEP profit.

SMW also identified all of its U.S. sales as CEP sales in its questionnaire responses. During the POI, all sales of SMW's subject merchandise to the United States were made through its U.S. affiliates, Solimin and Cometals. We find that Cometals is affiliated with SMW by virtue of an agency agreement, in which Cometals acts as a North American distributor of pure and alloy magnesium products. *See* Section 771(33) of the Act; *See also Notice of Final Determination of Sales at Less Than Fair Value: Engineered Process Gas Turbo-Compressor Systems, Whether Assembled or Unassembled, and Whether Complete or Incomplete, from Japan*, 62 FR 24394, 24403 (May 5, 1997). For a complete discussion of the basis for finding SMW and Cometals affiliated, *see Analysis Memorandum for Magnesium Metal from the Russian Federation: Solikamsk Magnesium Works* (*SMW Analysis Memorandum*). We also find that Solimin is affiliated with SMW under section 771(33)(G) of the Act because it is wholly owned by SMW. All of SMW's sales are properly classified as CEP sales because they were made for the account of SMW, by SMW's U.S. affiliates, Solimin and Cometals, to unaffiliated purchasers in the United States. U.S. sales to the first unaffiliated party were made in the United States, by the U.S. affiliates, thus satisfying the Department's requirements for characterizing sales as CEP sales.

In accordance with section 772(c)(2) of the Act, for SMW's CEP sales, we made deductions from price for movement expenses and billing adjustments, where appropriate. More specifically, after reviewing the terms of delivery for SMW's CEP sales, we deducted foreign inland freight from plant to port; foreign brokerage, handling, and port charges; international freight and insurance; U.S. brokerage, handling, and port charges; U.S. warehousing; U.S. and foreign customs duties; and U.S. inland freight. *See SMW Analysis Memorandum.*

In accordance with section 772(d)(1) of the Act, we deducted direct selling expenses and indirect selling expenses related to commercial activity in the United States. Pursuant to section 772(d)(3) of the Act, we made an adjustment for CEP profit.

Normal Value

A. Selection of Comparison Markets

Section 773(a)(1) of the Act directs the Department to calculate NV based on the price at which the foreign like product is sold in the home market, provided that the merchandise is sold in sufficient quantities (or value, if quantity is inappropriate), and that there is no particular market situation that prevents a proper comparison with the EP or CEP. Under the statute, the Department will normally consider quantity (or value) insufficient if it is less than five percent of the aggregate quantity (or value) of sales of the subject merchandise to the United States. *See* Section 773(a)(1)(C) of the Act. We found that both Avisma and SMW had a viable home market for magnesium metal. As such, Avisma and SMW submitted home market sales data for the calculation of NV. In deriving NV, we made adjustments as detailed in the section below on "Calculation of Normal Value Based on Home Market Prices" section.

B. Affiliated Party Transactions and Arm's-Length Test

We used sales to affiliated customers in the home market only where we determined such sales were made at arm's-length prices (*i.e.*, at prices comparable to the prices at which the Respondent sold identical merchandise to unaffiliated customers). To test whether the sales to affiliates were made at arm's-length prices, we compared the unit prices of sales to affiliated and unaffiliated customers net of all movement charges, direct selling expenses, discounts and packing. In accordance with the Department's practice, if the prices charged to an affiliated party were, on average, between 98 and 102 percent of the prices charged to unaffiliated parties for merchandise identical or most similar to that sold to the affiliated party, we consider the sales to be at arm's-length prices. *See* 19 CFR 351.403(c). For the sole affiliated reseller that failed the arm's-length test, we based NV on its sales to unaffiliated parties (*i.e.*, downstream sales). The remaining affiliated parties that did not pass the arm's-length test were consumers, and, therefore, there were no downstream sales on which to base NV. Sales to these affiliated consumers were excluded from our NV calculations. *See 19 CFR 351.403(d); see also Antidumping Proceedings: Affiliated Party Sales in the Ordinary Course of Trade*, 67 FR 69186 (November 15, 2002).

C. Cost of Production Analysis

On June 29, 2004, Petitioners alleged that Avisma and SMW made sales in the home market at less than the COP. On July 15, 2004, Petitioners amended this allegation and revised their methodology. Based on these allegations, and in accordance with section 773(b)(2)(A)(i) of the Act, we found reasonable grounds to believe or suspect that magnesium sales were made in Russia at prices below the cost of production (COP). *See Initiation of Sales Below Cost Investigation: Avisma* (July 22, 2004) (*Avisma Cost Initiation Memorandum*) and *Initiation of Sales Below Cost Investigation: Solikamsk Magnesium Works* (July 30, 2004) (*SMW Cost Initiation Memorandum*). As a result, the Department is conducting an investigation to determine whether Avisma and SMW made home market sales of magnesium at prices below their respective COPs during the POI within the meaning of section 773(b) of the Act.

1. Calculation of Cost of Production

In accordance with section 773(b)(3) of the Act, we calculated a weighted-average COP based on the sum of the cost of materials and fabrication for the foreign like product, plus amounts for the home market selling, general, and administrative (SG&A) expenses, including interest expenses and packing expenses. We relied on the COP data submitted by Avisma and SMW in their cost questionnaire responses, with the following changes.

We adjusted Avisma's financial expense ratio to include the total net foreign exchange gains and losses from Avisma's 2003 audited financial statements. *See Memorandum to Neal M. Halper, Director, Office of Accounting, from Robert B. Greger, Senior Accountant, Cost of Production and Constructed Value Calculation Adjustments for the Preliminary Determination for Magnesium Metal from the Russian Federation*, (September 24, 2004). For SMW, we revised the reported general and administrative (G&A) expense ratio to include certain administrative costs recorded as part of the cost of goods sold in the company's financial statements. We then excluded these costs from the cost of goods sold denominator that we used to calculate the G&A expense ratio. We also revised SMW's reported financial expense ratio to exclude certain administrative costs from the cost of goods sold denominator that we used to calculate the end ratio. *See Memorandum to Neal M. Halper, Director, Office of Accounting, from Ernest Z. Gzyrian, Senior Accountant, Cost of Production and Constructed Value Calculation Adjustments for the Preliminary Determination for Magnesium Metal from the Russian Federation—Solikamsk Magnesium Works*, (September 24, 2004).

As noted above under "Case History," Petitioners have alleged that Russian energy costs are distorted by excessive government involvement, and have requested that the Department make adjustments to Respondents' reported energy costs to account for the effects of this involvement. In their various submissions (identified in the "Case History" section above). Petitioners argue such adjustments are allowed under section 773(f) of the Act, which states:

> Costs shall normally be calculated based on the records of the exporter or producer of the merchandise, if such records are kept in accordance with the generally accepted accounting principles of the exporting country (or the producing country, where appropriate) and reasonably reflect the costs associated with the production and sale of the merchandise.

Petitioners argue the use of the word "normally" in section 773(f) of the Act gives the Department the discretion to disregard reported costs in certain circumstances. According to Petitioners, energy is a cost "associated with" the production and sale of magnesium. Petitioners argue that non-market forces pervade the Russian energy sector, and that Russian energy prices do not reflect the true cost of energy production. In support of their position, Petitioners submitted documents from various organizations examining the Russian energy sector, and based on their analysis of these documents, they proposed options for the requested adjustment. Petitioners also noted that the Department's 2002 memorandum granting Russia market economy status, and the suspension agreement signed in 2002 in the antidumping investigation of cut-to-length carbon steel plate from Russia, alluded to the fact that prices in the Russian energy sector would merit particular scrutiny in future antidumping proceedings. In Petitioners' view, therefore, there is a sufficient legal and factual basis to reject Respondents' reported energy costs.

Respondents, on the other hand, argue that the Department has no authority to disregard their reported energy costs. Respondents note that, in a case involving a market economy, the Department is required to use the companies' reported energy costs unless one of the exceptions specified in the statute exists. Respondents argue that the statute focuses on the costs to the respondent, not the costs of an unaffiliated energy supplier, and there is no statutory authority to disregard a company's costs due to alleged government action. Rather, Respondents argue, there is a long line of precedent from both the Department and the courts holding that a company's reported costs may not be adjusted due to the receipt of government subsidies.

We believe that the legal arguments raised by both Petitioners and Respondents have merit, but we do not reach this legal issue in this preliminary determination. For the reasons discussed below, we have preliminarily concluded that the factual record of this investigation, to date, does not lead us to conclude that the Department should disregard Respondents' reported energy costs at this time.

We have carefully reviewed Petitioners' allegations regarding energy prices in Russia, as well as all relevant facts and information on the record, particularly since the Department has, in other contexts, expressed concerns about Russian energy pricing and pricing policies. Because, in the production of magnesium, gas costs are less important than electricity costs, our discussion focuses on electricity costs.[2] While the evidence that Petitioners have placed on the record indicates that Russian energy reforms remain incomplete, particularly on the structural side, the evidence and arguments advanced to date do not sufficiently support Petitioners' allegation that Russian electricity prices are highly distorted from a full cost-recovery standpoint.

The analysis submitted by Petitioners to support their allegation that there is a significant price distortion compares retail-level cost (of sales off the low-voltage grid) to electricity prices Respondents paid, which, as reported by Respondents in their questionnaire responses, reflect sales off the high-voltage grid, *i.e.*, at the wholesale level. Therefore, this does not appear to be an apples-to-apples comparison. Petitioners also argue that any measure of cost recovery must take into account the costs of replacing the electricity transmission and distribution grid. While the Department continues to evaluate these arguments, we have several concerns. For example, it is unclear how the higher distribution costs that are associated with sales off a low-voltage grid should or could be evaluated in a wholesale price-cost analysis. Furthermore, the matter of estimating capital costs is problematic, in part, because of assumptions about future conditions that can underlie some estimates.

Finally, Petitioners argue that a meaningful measure of cost recovery for the electricity sector must include a price for gas used to make electricity that itself reflects full cost recovery. With respect to this argument, we have identified a number of issues that require further consideration. For example, one would need to assess the role of other non-gas based electricity supply sources in determining whether a significant distortion exists and the extent to which it is appropriate to employ estimates of future prices in calculating any adjustment to electricity prices. In addition, assuming, *arguendo*, that the Department were to reach the issue of whether it has the legal authority to disregard reported costs of production of the subject merchandise, this still leaves open the question of the

[2] For a comparison of the relative importance of each input in overall magnesium production costs, *see SMW Analysis Memorandum* and *Avisma Analysis Memorandum*.

boundaries of any such authority to examine the cost of inputs into the inputs used in producing the subject merchandise.

Given these questions and reservations, the Department considers that it is appropriate to use Respondents' reported energy costs for purposes of the preliminary determination. We will, however, continue examining this issue in preparation for our final determination. We encourage the parties to submit additional information and arguments on this issue, inviting them in particular to comment on the concerns that we have outlined above. We also will be verifying Respondents' questionnaire responses including the information about their energy purchases that we have relied upon in this preliminary analysis. In order to allow proper review by the Department and all interested parties, we request that any additional arguments and factual information concerning this issue be filed as early as possible during the remainder of the proceeding. With respect to factual information, the following deadlines will apply. Any new, revised or updated factual information concerning Respondents' actual energy costs and all aspects of their energy usage and their relationships (if any) with energy suppliers must be submitted no later than the deadlines specified in any future questionnaires issued by the Department and in accordance with 19 CFR 351.301(c)(2)(ii), since such information is part of the questionnaire responses which must be verified. Any new factual information and arguments pertaining to the broader issue of whether electricity prices in Russia are or are not significantly distorted and whether an adjustment to such prices is or is not warranted must be submitted no later than November 8, 2004, and rebuttals of any such factual information and rebuttal comments no later than November 18, 2004, in accordance with 19 CFR 351.301(c)(1) and (c)(2)(ii). If the Department finds that an adjustment may be warranted after further review, we will issue for comment a memorandum outlining our preliminary analysis of why such an adjustment is warranted and the type of adjustment we are proposing, in order to ensure that all aspects of such an adjustment are carefully considered in time for the final determination.

2. Test of Home Market Sales Prices

We compared the weighted-average COP for Avisma and SMW to their home market sales prices of the foreign like product, as required under section 773(b) of the Act, to determine whether these sales had been made at prices below the COP within an extended period of time (*i.e.*, a period of one year) in substantial quantities, and whether such prices were sufficient to permit the recovery of all costs within a reasonable period of time. On a model-specific basis, we compared the COP to the home market prices, less any applicable movement charges, discounts, rebates, and direct and indirect selling expenses.

3. Results of the COP Test

We disregarded below-cost sales where (1) 20 percent or more of either Respondent's sales of a given product during the POI were made at prices below the COP, and thus such sales were made within an extended period of time in substantial quantities in accordance with sections 773(b)(2)(B) and (C) of the Act, and (2) based on comparisons of price to weighted-average COPs for the POI, we determined that the below-cost sales of the product were at prices which would not permit recovery of all costs within a reasonable time period, in accordance with section 773(b)(2)(D) of the Act. We found that both Avisma and SMW made sales below cost and we disregarded such sales where appropriate.

D. Calculation of Normal Value Based on Home Market Prices

Where appropriate, we determined NV for Avisma and SMW based on home market prices. However, both Respondents reported a significant number of "barter" sales in the home market. As this is the first investigation of Russian exporters conducted since the Department determined Russia to be a market economy,[3] within the context of the Act, the Department has not previously been presented with the issue of examining barter sales in the Russian market.

We have examined barter sales in the Argentinian and Japanese markets in two cases decided prior to the effective date of the amendments made by the Uruguay Round Agreements Act (URAA). In *Notice of Preliminary Determination of Sales at Less Than Fair Value: Certain Cold-Rolled Carbon Steel Flat Products From Argentina*, 58 FR 7066 (Feb. 4, 1993), we disregarded barter sales as being outside the ordinary course of trade. In *Final Determination of Sales at Less Than Fair Value: Certain All-Terrain Vehicles From Japan*, 54 FR 4864, 4865 (Jan. 31, 1989), we found barter trade to be small and insignificant, and disregarded it.

In *Gray Portland Cement and Clinker From Mexico: Final Results of Antidumping Duty Administrative Review*, 68 FR 54203 (Sept. 16, 2003) (*Cement From Mexico*), a case subsequent to the passage of the URAA, the Department encountered an exchange of cement between a Mexican producer and an unaffiliated U.S. customer. The Respondent in that case argued that this "swap" of cement should not be considered a U.S. sale. Relying on information confirmed at verification, the Department concluded that this "swap" of cement with an unaffiliated customer constituted a U.S. sale. We stated that "{w}e verified the appropriateness of {the reported price} and found no discrepancies. At verification, CEMEX explained that this amount reflects a price established between CEMEX and its unaffiliated customer for actual sales made between the parties in the past." *See Cement From Mexico* and accompanying Issues and Decision Memorandum, at comment 9. Thus, we noted the importance of verification, especially concerning the "appropriateness" of the reported price.

Therefore, the Department will need to examine this issue in greater detail. Questions we will need to examine further concerning these sales include, but are not limited to: the alignment of barter prices with non-barter prices charged for similar goods sold; the linkage of the price charged with the goods received, including any internal and external procedures for ensuring reasonable compensation is received in exchange for magnesium; and how these sales are recorded in Respondents' books and records. Of particular concern in this case, is the apparent discrepancy between prices charged on average for products sold on a barter basis compared to prices charged for the identical or most similar products when sold on a cash basis. While the Department has issued questionnaires concerning these sales in general, given the novelty of this issue for the Russian market, noted above, we do not currently have enough information concerning these sales on the record, and therefore have concluded that we should disregard the barter sales in our calculations for this preliminary determination.

For all remaining sales, we deducted home market movement expenses, pursuant to section 773(a)(6)(A) of the Act. We made circumstances of sale (COS) adjustments for Avisma's and SMW's transactions by deducting direct selling expenses incurred for home

[3] *See Memorandum for Faryar Shirzad from Albert Hsu, Inquiry into the Status of the Russian Federation as a Non-Market Economy Country Under the U.S. Antidumping Law*, dated June 6, 2002, effective April 1, 2002.

market sales (credit expense). We also made adjustments for any differences in packing, pursuant to section 773(a)(6)(B)(ii) of the Act. *See Avisma Analysis Memorandum* and *SMW Analysis Memorandum.*

E. Calculation of Normal Value Based on Constructed Value

Section 773(a)(4) of the Act provides that, where NV cannot be based on comparison-market sales, NV may be based on constructed value (CV). Accordingly, for sales of magnesium for which we could not determine the NV based on comparison-market sales, either because there were no useable sales of a comparable product or all sales of the comparable products failed the COP test, we based NV on CV.

Section 773(e) of the Act provides that CV shall be based on the sum of the cost of materials and fabrication for the imported merchandise, plus amounts for SG&A expenses, profit, and U.S. packing costs. We calculated the cost of materials and fabrication based on the methodology described in the "Cost of Production Analysis" section, above. We based SG&A and profit on the actual amounts incurred and realized in connection with the production and sale of the foreign like product in the ordinary course of trade for consumption in the comparison market, in accordance with section 773(e)(2)(A) of the Act.

We made adjustments to CV for differences in COS in accordance with section 773(a)(8) of the Act and 19 CFR 351.410. For comparisons to CEP, we made COS adjustments by deducting from CV direct selling expenses incurred on home-market sales.

F. Level of Trade/Constructed Export Price Offset

In accordance with section 773(a)(1)(B)(i) of the Act, to the extent practicable, we determine NV based on sales in the comparison market at the same LOT as U.S. sales. *See* 19 CFR 351.412. The NV LOT is the level of the starting-price sale in the comparison market or, when NV is based on CV, the level of the sales from which we derive SG&A and profit. For EP, the U.S. LOT is also the level of the starting-price sale, which is usually from exporter to importer. For CEP, it is the level of the constructed sale from the exporter to the importer.

To determine whether NV sales are at a different LOT than EP or CEP sales, we examine stages in the marketing process and selling functions along the chain of distribution between the producer and the unaffiliated customer in the home market. If the comparison-market sales are at a different LOT, and the difference affects price comparability, as manifested in a pattern of consistent price differences between the sales on which NV is based and comparison-market sales at the LOT of the export transaction, we make an LOT adjustment under section 773(a)(7)(A) of the Act. Finally, for CEP sales, if the NV level is more remote from the factory than the CEP level and there is no basis for determining whether the difference in the levels between NV and CEP affects price comparability, we adjust NV under section 773(a)(7)(B) of the Act (the CEP offset provision). *See Notice of Final Determination of Sales at Less than Fair Value: Certain Cut-to-Length Carbon Steel Plate From South Africa*, 62 FR 61731 (November 19, 1997). For CEP sales, we consider only the selling activities reflected in the price after the deduction of expenses and CEP profit under section 772(d) of the Act. See *Micron Technology Inc.* v. *United States*, 243 F.3d 1301, 1314–1315 (Fed. Cir. 2001).

In the current investigation, SMW claimed that sales in the home market and the United States market were made at different LOTs, but did not claim a LOT adjustment. Based on the selling functions performed, we preliminarily determine that SMW did not sell at different LOTs in the home and U.S. markets. After examining the selling functions for the one LOT reported in the United States, and the two claimed LOTs reported in the home market, we determine that these sale are, in fact, all made at one LOT. While SMW claimed that there were some differences between these various distribution channels, which it claimed to constitute separate LOTs, we have preliminarily determined that some of these differences do not constitute differences in selling functions. Differences between other functions, *e.g.*, provisions of warranty or types of packing, are already accounted for through other aspects of the Department's calculations, such as the deduction of direct selling expenses from CEP and NV. Moreover, the Department finds that the differences in selling functions are not significant differences. Since much of our analysis involves business proprietary information, a full discussion of the bases for our preliminary determination is set forth in the *SMW Analysis Memorandum.*

In conducting this analysis, we examined the U.S. LOT after excluding the selling functions performed by SMW's U.S. affiliates (*i.e.*, after excluding those selling functions associated with the expenses deducted under 772(d)(1)). Because we have determined that the U.S. LOT is the same LOT as that in the home market, we have preliminarily determined that the NV LOT is not more remote from the factory than the CEP LOT, and that, therefore, a CEP offset is not warranted under section 773(a)(7)(B) of the Act.

Avisma reported one LOT in the home market and one LOT in the United States. It did not claim a LOT adjustment. After examining the selling functions performed in the home market and the United States (excluding those functions performed by the U.S. affiliate) we have preliminarily determined that the LOT for home market and U.S. sales is the same. *See Avisma Analysis Memorandum.* We have concluded that there are no significant differences between the selling functions performed in these two markets by Avisma. We note that, as with SMW, some of the reported differences do not appear to relate to selling functions, but to other functions. Also as with SMW, because U.S. and home market sales are at the same LOT, a CEP offset is not appropriate.

Currency Conversions

We made currency conversions into U.S. dollars in accordance with section 773A of the Act based on exchange rates in effect on the dates of the U.S. sales, as obtained from the Federal Reserve Bank (the Department's preferred source for exchange rates).

Verification

In accordance with section 782(i) of the Act, we will verify the questionnaire responses of Avisma and SMW before making our final determination.

Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, we are directing CBP to suspend liquidation of all entries of magnesium from Russia that are entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. We are also instructing CBP to require a cash deposit or the posting of a bond equal to the weighted-average dumping margins as indicated in the chart below. These instructions suspending liquidation will remain in effect until further notice. The weighted-average dumping margins are as follows:

Producer/exporter	Weighted-average margin (percentage)
Avisma	10.62
SMW	21.49
All Others	12.36

Disclosure

In accordance with 19 CFR 351.224(b), the Department will disclose to interested parties the calculations performed in this preliminary determination within five days of the date of public announcement.

Public Comment

Interested parties are invited to comment on the preliminary determination. Interested parties may submit case briefs on the later of 50 days after the date of publication of this notice or ten days after the issuance of the verification reports. *See* 19 CFR 351.309(c)(1)(I). Rebuttal briefs, the content of which is limited to the issues raised in the case briefs, must be filed within five days after the deadline for the submission of case briefs. *See* 19 CFR 351.309(d). A list of authorities used, a table of contents, and an executive summary of issues should accompany any briefs submitted to the Department. Executive summaries should be limited to five pages total, including footnotes.

In accordance with section 774 of the Act, we will hold a public hearing, if requested, to afford interested parties an opportunity to comment on arguments raised in case or rebuttal briefs. If a request for a hearing is made, we will tentatively hold the hearing two days after the deadline for submission of rebuttal briefs at the U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230, at a time and in a room to be determined. Parties should confirm by telephone the date, time, and location of the hearing 48 hours before the scheduled date.

Interested parties who wish to request a hearing, or to participate in a hearing if one is requested, must submit a written request to the Assistant Secretary for Import Administration, U.S. Department of Commerce, Room 1870, within 30 days of the date of publication of this notice. Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. At the hearing, oral presentations will be limited to issues raised in the briefs. *See* 19 CFR 351.310(c). The Department will make its final determination no later than 135 days after the date of the Department's preliminary determination. *See* 19 CFR 351.210(b)(1).

International Trade Commission Notification

In accordance with section 733(f) of the Act, we have notified the ITC of the Department's preliminary affirmative determination. If the final determination in this proceeding is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination whether imports of magnesium metal from the Russian Federation are materially injuring, or threatening material injury to, the U.S. industry.

This determination is issued and published pursuant to sections 733(f) and 777(i)(1) of the Act.

Dated: September 24, 2004.

James J. Jochum,

Assistant Secretary for Import Administration.

[FR Doc. E4–2479 Filed 10–1–04; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–583–841]

Initiation of Anti Dumping Duty Investigation: Polyvinyl Alcohol From Taiwan

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: October 4, 2004.

FOR FURTHER INFORMATION CONTACT: Susan Lehman or Richard Rimlinger, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–0180 or (202) 482–4477, respectively.

SUPPLEMENTARY INFORMATION:

The Petition

On September 7, 2004, the Department of Commerce (the Department) received a petition on imports of polyvinyl alcohol (PVA) from Taiwan filed in proper form by Celanese Chemicals Ltd. (the petitioner). On September 9, 2004, and September 15, 2004, the Department issued supplemental questionnaires requesting additional information and clarification of certain areas of the petition. The Department also requested additional information in September 17, 2004, and September 24, 2004, conference telephone calls with the petitioner. *See* Memorandum from Catherine Cartsos through Mark Ross to the File dated September 20, 2004, and Memorandum from Susan Lehman through Mark Ross to the File dated September 27, 2004. The petitioner filed supplements to the petition on September 13, 2004, September 21, 2004, and September 27, 2004.

On September 23, 2004, E.I. DuPont de Nemours & Co. (DuPont), a domestic producer of PVA, upon the request of the Department, filed a statement detailing DuPont's total production of PVA for the calendar year 2003. On September 24, 2004, DuPont submitted two challenges to the petition. On September 27, 2004, Solutia Inc. (Solutia), a domestic producer of PVA, submitted a document informing the Department that it "neither supports nor opposes the antidumping duty petition" on PVA from Taiwan.

In accordance with section 732(b) of the Tariff Act of 1930, as amended (the Act), the petitioner alleges that imports of PVA from Taiwan are being, or are likely to be, sold in the United States at less than fair value within the meaning of section 731 of the Act and that such imports are materially injuring and threaten to injure an industry in the United States.

The Department finds that the petitioner filed this petition on behalf of the domestic industry because it is an interested party as defined in section 771(9)(c) of the Act and the petitioner has demonstrated sufficient industry support with respect to the investigation that the petitioner is requesting the Department to initiate (*see* "Determination of Industry Support for the Petition" below).

Scope of Investigation

The merchandise covered by this investigation is PVA. This product consists of all PVA hydrolyzed in excess of 80 percent, whether or not mixed or diluted with commercial levels of defoamer or boric acid. PVA in fiber form is not included in the scope of this investigation. The merchandise under investigation is currently classifiable under subheading 3905.30.00 of the *Harmonized Tariff Schedule of the United States* ("HTSUS"). Although the HTSUS subheading is provided for convenience and customs purposes, the written description of the merchandise under investigation is dispositive.

During our review of the petition, we discussed the scope with the petitioner to ensure that it is an accurate reflection of the products for which the domestic industry is seeking relief. Moreover, as discussed in the preamble to the regulations (*Antidumping Duties, Countervailing Duties, Final Rule*, 62 FR 27296, 27323)(May 19, 1997), we are setting aside a period for interested parties to raise issues regarding product coverage. The Department encourages all interested parties to submit such comments within 20 calendar days of

publication of this notice. Comments should be addressed to Import Administration's Central Records Unit at Room 1870, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230. The period of scope consultations is intended to provide the Department with ample opportunity to consider all comments and consult with parties prior to the issuance of the preliminary determination.

Determination of Industry Support for the Petition

Section 732(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 732(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (1) At least 25 percent of the total production of the domestic like product; and (2) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition.

Section 771(4)(A) of the Act defines the "industry" as the producers as a whole of a domestic like product. Thus, to determine whether the petition has the requisite industry support, the statute directs the Department to look to producers and workers who produce the domestic like product. The International Trade Commission (ITC), which is responsible for determining whether "the domestic industry" has been injured, must also determine what constitutes a domestic like product in order to define the industry. While the Department and the ITC must apply the same statutory definition regarding the domestic like product they do so for different purposes and pursuant to separate and distinct authority. *See* section 771(10) of the Act. In addition, the Department's determination is subject to limitations of time and information. Although this may result in different definitions of the domestic like product, such differences do not render the decision of either agency contrary to law.[1]

Section 771(10) of the Act defines the domestic like product as "a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this subtitle." Thus, the reference point from which the domestic like product analysis begins is "the article subject to an investigation," *i.e.*, the class or kind of merchandise to be investigated, which normally will be the scope as defined in the petition.

With regard to the definition of domestic like product, the petitioner does not offer a definition of domestic like product distinct from the scope of the investigation. Based on our analysis of the information presented by the petitioner, we have determined that there is a single domestic like product, PVA, which is defined in the "Scope of Investigation" section above, and we have analyzed industry support in terms of the domestic like product.

On September 24, 2004, the Department received opposition to the petition from DuPont, a producer of the domestic like product. Also, on September 27, 2004, the Department received a submission from Solutia, a producer of the domestic like product, expressing that it takes neither an affirmative nor a negative position with regard to this proceeding. However, the Department confirmed the necessary industry support based on the actual 2003 production figures which each domestic producer provided (*i.e.*, the petitioner represents over 50 percent of total production of the domestic like product). *See* Attachment II of the Initiation Checklist, dated September 27, 2004 (Initiation Checklist), on file in the Central Records Unit, Room B–099 of the Department of Commerce. The domestic producer who supports the petition accounts for at least 25 percent of the total production of the domestic like product, and the requirements of section 732(c)(4)(A)(i) are met. Further, the domestic producer who supports the petition accounts for more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for or opposition to the petition. Thus, the requirements of section 732(c)(4)(A)(ii) are also met.

On September 24, 2004, the same producer of the domestic like product that filed an opposition to the petition (DuPont) filed a submission in which it urged the Department to reject the petition "because the petitioner has engaged in improper conduct" with respect to the establishment of industry support. Because the petitioner represents over 50 percent of total U.S. production, notwithstanding the allegations contained in DuPont's September 24, 2004, submission, it is not appropriate to reject the petition.

Accordingly, the Department determines that the petition was filed on behalf of the domestic industry within the meaning of section 732(b)(1) of the Act.

Period of Investigation

The anticipated period of investigation is July 1, 2003, through June 30, 2004.

Export Price and Normal Value

The following is a description of the allegation of sales at less than fair value upon which the Department based its decision to initiate this investigation. The sources of data for the deductions and adjustments relating to U.S. price and normal value (NV) are discussed in greater detail in the Initiation Checklist. Should the need arise to use any of this information as facts available under section 776 of the Act, we may reexamine the information and revise the margin calculation, if appropriate.

The petition identified one producer of PVA in Taiwan. *See* Volume I of the September 7, 2004, petition at page 25. The petitioner based export price (EP) on Taiwan export statistics, U.S. price quotes from two U.S. distributors engaged in the sale of Taiwan-origin PVA, and U.S. import statistics. We have not used the Taiwanese EP statistics because it is our practice to use U.S. import statistics used in the petition when there is a close correlation between the relevant HTS number and the subject merchandise. We found no compelling evidence to suggest that we should use the Taiwanese information over U.S. information. We have not used the U.S. price quotes because the prices were not as reasonably reliable as average per-unit values derived from U.S. import statistics. The price quotes were estimated prices based on rejected sales offers made by the petitioner. Therefore, we used the average unit prices based on U.S. import statistics that the petitioner provided in Exhibit 2 of its September 21, 2004, submission.

The petitioner calculated EP by deducting an amount for foreign inland freight from factory to port. We reviewed the information provided regarding EP and have determined that it represents information reasonably available to the petitioner and have reviewed it for adequacy and accuracy. See Initiation Checklist.

To calculate NV, the petitioner obtained contemporaneous home-market prices for PVA sold in Taiwan from a Web site sponsored by the Taiwan Institute of Chemical Industry. The petitioner made an adjustment to home-market price by deducting amounts for inland freight and imputed credit expense. The petitioner compared home-market prices to its own cost of production (COP), adjusted for known cost differences between Taiwan and

[1] *See USEC, Inc.* v. *United States*, 132 F. Supp. 2d 1, 8 (CIT 2001), citing *Algoma Steel Corp.* v. *United States*, 688 F. Supp. 639, 642–44 (CIT 1988).

the United States, to support a sales-below-cost allegation.

The Statement of Administrative Action (SAA), accompanying the URAA, states that an allegation of sales below COP need not be specific to individual exporters or producers. See SAA, H.R. Doc. No. 103–316 at 833 (1994). The SAA states that "Commerce will consider allegations of below-cost sales in the aggregate for a foreign country, just as Commerce currently considers allegations of sales at less than fair value on a country-wide basis for purposes of initiating an antidumping investigation." *Id.*

Further, the SAA provides that the "new section 773(b)(2)(A) retains the current requirement that Commerce have 'reasonable grounds to believe or suspect' that below cost sales have occurred before initiating such an investigation. 'Reasonable grounds' * * * exist when an interested party provides specific factual information on costs and prices, observed or constructed, indicating that sales in the foreign market in question are at below-cost prices." *Id.*

Pursuant to section 773(b)(3) of the Act, COP consists of the COM and SG&A (including financial expenses). The petitioner calculated COP based on its own experience as a U.S. producer during 2003, adjusted for known differences between costs incurred to manufacture PVA in the United States and in Taiwan. With the exception of labor, the publicly available data the petitioner used was contemporaneous with the prospective POI. *See* Initiation Checklist.

Based upon a comparison of the home-market prices of the foreign like product to the calculated COP of the product, we find reasonable grounds to believe or suspect that sales of the foreign like product were made below the COP, within the meaning of section 773(b)(2)(A)(i) of the Act. Accordingly, the Department is initiating a country-wide cost investigation.

As such, pursuant to sections 773(a)(4) and 773(e) of the Act, the petitioner calculated NV based on constructed value (CV). Consistent with section 773(e)(2)(B)(iii) of the Act, the petitioner included in CV an amount for profit. For profit, the petitioner relied upon amounts reported in Chang Chun Petrochemical Ltd.'s (CCP's), the potential respondent's, 2003 financial statements.

We adjusted the petitioner's calculated margin because the petitioner subtracted inland freight expenses from the CV and we do not normally deduct such expenses from CV. Therefore, we added the inland freight expense of 0.30 New Taiwan dollars per kilogram to the CV calculated by the petitioner and then converted the recalculated CV to a U.S. dollars per pound figure using the same methodology as the petitioner used. This results in a CV of US$ 0.8418 per pound and a U.S. price that is US$ 0.2398 per pound lower than CV. We reviewed the NV and CV information provided and have determined that it represents information reasonably available to the petitioner and have reviewed it for adequacy and accuracy.

Based on a comparison of EP derived from U.S. average unit values (AUVs) to adjusted CV, the dumping margin is 39.83 percent for PVA from Taiwan.

As indicated above, the petitioner also provided information demonstrating reasonable grounds to believe or suspect that sales of PVA in the home market were made at prices below the COP, within the meaning of section 773(b) of the Act, and requested that the Department conduct a country-wide sales-below-cost investigation.

Fair-Value Comparison

Based on the data provided by the petitioner, there is reason to believe that imports of PVA from Taiwan are being, or are likely to be, sold in the United States at less than fair value.

Allegations and Evidence of Material Injury and Causation

The petitioner alleges that the U.S. industry producing the domestic like product is being materially injured and is threatened with material injury by reason of the imports of the subject merchandise sold at less than normal value. The petitioner contends that the industry's injured condition is evidenced by the volume of lost sales, declining profitability, reductions in employment, and stagnant capacity utilization. Furthermore, the petitioner contends that injury and threat of injury is evidenced by negative effects on its revenue, market share, and growth.

These allegations are supported by relevant evidence including import data, lost sales, and pricing information. The Department assessed the allegations and supporting evidence regarding material injury and causation and determined that these allegations are supported by accurate and adequate evidence and meet the statutory requirements for initiation. *See* Initiation Checklist.

Initiation of Antidumping Investigation

Based upon the examination of the petition on PVA from Taiwan, and other information reasonably available to the Department, we find that the petition meets the requirements of section 732 of the Act. Therefore, we are initiating an antidumping duty investigation to determine whether imports of PVA from Taiwan are being, or are likely to be, sold in the United States at less than fair value. Unless postponed, we will make our preliminary determination no later than 140 days after the date of this initiation.

Distribution of Copies of the Petition

In accordance with section 732(b)(3)(A) of the Act, a copy of the public version of the petition has been provided to the representatives of the government of Taiwan. We will attempt to provide a copy of the public version of the petition to the producer named in the petition.

International Trade Commission Notification

We have notified the ITC of our initiation, as required by section 732(d) of the Act.

Preliminary Determination by the International Trade Commission

The ITC will preliminarily determine, no later than October 22, 2004, whether there is a reasonable indication that imports of PVA from Taiwan are causing material injury, or threatening to cause material injury, to a U.S. industry. A negative ITC determination will result in the investigation being terminated; otherwise, this investigation will proceed according to statutory and regulatory time limits.

This notice is issued and published pursuant to section 777(i) of the Act.

Dated: September 27, 2004.

James J. Jochum,

Assistant Secretary for Import Administration.

[FR Doc. E4–2476 Filed 10–1–04; 8:45 am]

BILLING CODE 3510–DS–P

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Adjustment of Import Limits for Certain Cotton, Wool Man-Made Fiber, Silk Blend and Other Vegetable Fiber Textile Products Produced or Manufactured in Hong Kong

September 28, 2004.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner, Bureau of Customs and Border Protection adjusting limits.

EFFECTIVE DATE: October 4, 2004.

FOR FURTHER INFORMATION CONTACT: Naomi Freeman, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port, call (202) 927–5850, or refer to the Bureau of Customs and Border Protection website at http://www.cbp.gov. For information on embargoes and quota re-openings, refer to the Office of Textiles and Apparel website at http://otexa.ita.doc.gov.

SUPPLEMENTARY INFORMATION:

Authority: Section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854); Executive Order 11651 of March 3, 1972, as amended.

The current limits for certain categories are being adjusted for swing and special shift.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 69 FR 4926, published on February 2, 2004). Also see 68 FR 59917, published on October 20, 2003.

D. Michael Hutchinson,

Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

September 28, 2004.

Commissioner,
Bureau of Customs and Border Protection, Washington, DC 20229.

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on October 14, 2003, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton, wool, man-made fiber, silk blend and other vegetable fiber textiles and textile products, produced or manufactured in Hong Kong and exported during the twelve-month period which began on January 1, 2004 and extends through December 31, 2004.

Effective on October 4, 2004, you are directed to adjust the limits for the following categories, as provided for under the Uruguay Round Agreement on Textiles and Clothing:

Category	Adjusted twelve-month limit [1]
Group II	
237, 239pt. [2], 331pt. [3] 332–348, 351, 352, 359(1) [4], 359(2) [5], 359pt. [6], 433–438, 440–448, 459pt. [7], 631pt. [8] 633–648, 651, 652, 659(1) [9], 659(2) [10], 659pt. [11], and 443/444/643/644(1), as a group.	945,555,286 square meters equivalent.
Sublevels in Group II	
647	688,867 dozen.
648	1,217,104 dozen of which not more than 1,217,104 dozen shall be in Category 648–W [12].
Within Group II subgroup	
342	658,059 dozen.
351	1,271,964 dozen.
642	306,457 dozen.
651	410,382 dozen.
Group III–only 852	1,854,891 square meters equivalent.

[1] The limits have not been adjusted to account for any imports exported after December 31, 2003.

[2] Category 239pt.: only HTS number 6209.20.5040 (diapers).

[3] Category 331pt.: all HTS numbers except 6116.10.1720, 6116.10.4810, 6116.10.5510, 6116.10.7510, 6116.92.6410, 6116.92.6420, 6116.92.6430, 6116.92.6440, 6116.92.7450, 6116.92.7460, 6116.92.7470, 6116.92.8800, 6116.92.9400 and 6116.99.9510.

[4] Category 359(1): only HTS numbers 6103.42.2025, 6103.49.8034, 6104.62.1020, 6104.69.8010, 6114.20.0048, 6114.20.0052, 6203.42.2010, 6203.42.2090, 6204.62.2010, 6211.32.0010, 6211.32.0025 and 6211.42.0010.

[5] Category 359(2): only HTS numbers 6103.19.2030, 6103.19.9030, 6104.12.0040, 6104.19.8040, 6110.20.1022, 6110.20.1024, 6110.20.2030, 6110.20.2035, 6110.90.9044, 6110.90.9046, 6201.92.2010, 6202.92.2020, 6203.19.1030, 6203.19.9030, 6204.12.0040, 6204.19.8040, 6211.32.0070 and 6211.42.0070.

[6] Category 359pt.: all HTS numbers except 6115.19.8010, 6117.10.6010, 6117.20.9010, 6203.22.1000, 6204.22.1000, 6212.90.0010, 6214.90.0010, 6406.99.1550, 6505.90.1525, 6505.90.1540, 6505.90.2060, 6505.90.2545 and HTS numbers in 359(1) and 359(2).

[7] Category 459pt.: all HTS numbers except 6115.19.8020, 6117.10.1000, 6117.10.2010, 6117.20.9020, 6212.90.0020, 6214.20.0000, 6405.20.6030, 6405.20.6060, 6405.20.6090, 6406.99.1505, 6406.99.1560.

[8] Category 631pt.: all HTS numbers except 6116.10.1730, 6116.10.4820, 6116.10.5520, 6116.10.7520, 6116.93.8800, 6116.93.9400, 6116.99.4800, 6116.99.5400 and 6116.99.9530.

[9] Category 659(1): only HTS numbers 6103.23.0055, 6103.43.2020, 6103.43.2025, 6103.49.2000, 6103.49.8038, 6104.63.1020, 6104.63.1030, 6104.69.1000, 6104.69.8014, 6114.30.3044, 6114.30.3054, 6203.43.2010, 6203.43.2090, 6203.49.1010, 6203.49.1090, 6204.63.1510, 6204.69.1010, 6210.10.9010, 6211.33.0010, 6211.33.0017 and 6211.43.0010.

[10] Category 659(2): only HTS numbers 6112.31.0010, 6112.31.0020, 6112.41.0010, 6112.41.0020, 6112.41.0030, 6112.41.0040, 6211.11.1010, 6211.11.1020, 6211.12.1010 and 6211.12.1020.

[11] Category 659pt.: all HTS numbers except 6115.11.0010, 6115.12.2000, 6117.10.2030, 6117.20.9030, 6212.90.0030, 6214.30.0000, 6214.40.0000, 6406.99.1510, 6406.99.1540 and HTS numbers in 659(1) and 659(2).

[12] Category 648–W: only HTS numbers 6204.23.0040, 6204.23.0045, 6204.29.2020, 6204.29.2025, 6204.29.4038, 6204.63.2000, 6204.63.3000, 6204.63.3510, 6204.63.3530, 6204.63.3532, 6204.63.3540, 6204.69.2510, 6204.69.2530, 6204.69.2540, 6204.69.2560, 6204.69.6030, 6204.69.9030, 6210.50.5035, 6211.20.1555, 6211.20.6820, 6211.43.0040 and 6217.90.9060.

The Committee for the Implementation of Textile Agreements has determined that these actions fall 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. E4–2475 Filed 10–1–04; 8:45 am]

BILLING CODE 3510–DR–S

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Adjustment of Import Limits for Certain Cotton, Wool and Man-Made Fiber Textiles and Textile Products Produced or Manufactured in Indonesia

September 29, 2004.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner, Bureau of Customs and Border Protection adjusting limits.

EFFECTIVE DATE: October 4, 2004.

FOR FURTHER INFORMATION CONTACT: Ross Arnold, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 344–2650. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port, call (202) 927–5850, or refer to the Bureau of Customs and Border Protection website at http://www.cbp.gov. For information on embargoes and quota re-openings, refer to the Office of Textiles and Apparel website at http://otexa.ita.doc.gov.

SUPPLEMENTARY INFORMATION:

Authority: Section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854); Executive Order 11651 of March 3, 1972, as amended.

The current limits for certain categories are being adjusted for swing.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 69 FR 4926, published on February 2, 2004). Also see 68 FR 65254, published on November 19, 2003.

D. Michael Hutchinson,

Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

September 29, 2004.

Commissioner,
Bureau of Customs and Border Protection, Washington, DC 20229.

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on November 13, 2003, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton, wool, man-made fiber, silk blend and other vegetable fiber textiles and textile products, produced or manufactured in Indonesia and exported during the twelve-month period which began on January 1, 2004 and extends through December 31, 2004.

Effective on October 4, 2004, you are directed to adjust the limits for the categories listed below, as provided for under the Uruguay Round Agreement on Textiles and Clothing:

Category	Twelve-month restraint limit [1]
Levels in Group I	
314–O [2]	108,441,116 square meters.
445/446	73,112 dozen.
619/620	18,687,153 square meters.
643	670,628 numbers.
645/646	1,586,209 dozen.
Subgroup in Group II	
400, 410, 414, 434, 435, 436, 438, 440, 442, 444, 459pt. and 469pt., as a group	3,850,936 square meters equivalent.
In Group II subgroup	
435	60,459 dozen.

[1] The limits have not been adjusted to account for any imports exported after December 31, 2003.

[2] Category 314–O: all HTS numbers except 5209.51.6015.

The Committee for the Implementation of Textile Agreements has determined that these actions fall 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. E4–2466 Filed 10–1–04; 8:45 am]

BILLING CODE 3510–DR–S

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 04–33]

36(b)(1) Arms Sales Notification

AGENCY: Department of Defense, Defense Security Cooperation Agency.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated 21 July 1996.

FOR FURTHER INFORMATION CONTACT: Ms. J. Hurd, DSCA/OPS–ADMIN, (703) 604–6575.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 04–33 with attached transmittal, policy justification, and Sensitivity of Technology.

Dated: September 27, 2004.

L. M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–M

DEFENSE SECURITY COOPERATION AGENCY

WASHINGTON, DC 20301-2800

In reply refer to:
I-04/009601

The Honorable J. Dennis Hastert
Speaker of the House of Representatives
Washington, D.C. 20515-6501

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 04-33, concerning the Department of the Navy's proposed Letter(s) of Offer and Acceptance to the Netherlands for defense articles and services estimated to cost $70 million. Soon after this letter is delivered to your office, we plan to notify the news media.

Sincerely,

JEFFREY B. KOHLER
LIEUTENANT GENERAL, USAF
DIRECTOR

Enclosures:
1. Transmittal No. 04-33
2. Policy Justification
3. Sensitivity of Technology

Same ltr to: House Committee on International Relations
Senate Committee on Foreign Relations
House Committee on Armed Services
Senate Committee on Armed Services
House Committee on Appropriations
Senate Committee on Appropriations

Transmittal No. 04-33

Notice of Proposed Issuance of Letter of Offer
Pursuant to Section 36(b)(1)
of the Arms Export Control Act, as amended

(i) **Prospective Purchaser: Netherlands**

(ii) **Total Estimated Value:**

Major Defense Equipment*	$66 million
Other	$ 4 million
TOTAL	$70 million

(iii) **Description and Quantity or Quantities of Articles or Services under Consideration for Purchase: 55 SM-2 Block IIIA STANDARD missiles, 55 MK 13 MOD 0 canisters, containers, spare and repair parts, supply support, personnel training and training equipment, publications and technical data, U.S. Government and contractor technical assistance and other related elements of logistics support.**

(iv) **Military Department: Navy (AFY)**

(v) **Prior Related Cases, if any:**
FMS case AFU - $19 million - 21Aug02
FMS case AFN - $23 million - 29Nov99
FMS case AEY - $20 million - 28Sep90
FMS case AEM - $26 million - 30Oct85

(vi) **Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid: none**

(vii) **Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold: See Annex attached**

(viii) **Date Report Delivered to Congress:**

*** as defined in Section 47(6) of the Arms Export Control Act.**

POLICY JUSTIFICATION

Netherlands – SM-2 Block IIIA STANDARD Missiles

The Government of the Netherlands has requested a possible sale of 55 SM-2 Block IIIA STANDARD missiles, 55 MK 13 MOD 0 canisters, containers, spare and repair parts, supply support, personnel training and training equipment, publications and technical data, U.S. Government and contractor technical assistance and other related elements of logistics support. The estimated cost is $70 million.

The proposed sale will contribute to the foreign policy and national security objectives of the United States by helping to improve the military capabilities of the Netherlands, a NATO ally, and furthering standardization and interoperability.

The proposed sale will provide the Netherlands continued NATO anti-aircraft defense capabilities for its Navy. The evolution of the anti-aircraft warfare threat in littoral nations mandates this defense capability. The Netherlands Navy intends to use the SM-2 missiles on its destroyer class surface ships for self-defense against air and cruise missile threats in the Netherlands and the NATO theater. The Netherlands, which already has STANDARD missiles in its inventory, will have no difficulty absorbing these additional missiles.

The proposed sale of this equipment and support will not affect the basic military balance in the region.

The prime contractor will be Raytheon Systems Company of Tucson, Arizona. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will not require the assignment of any additional U.S. Government or contractor representatives to the Netherlands.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 04-33

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex
Item No. vii

(vii) Sensitivity of Technology:

1. The SM-2 Block IIIA STANDARD missile is a U.S. Navy surface-launched guided missile and is classified Confidential. It is operationally deployed on cruisers, destroyers, and frigates for use against air and surface threats (aircraft, missiles, and ships). The guidance system employs a continuous-wave or interrupted continuous wave radar link for homing to the target. Steering and roll commands from the adaptive auto pilot system provide flight stability via four aft-mounted control surfaces. Propulsion is provided by a solid propellant, dual thrust rocket motor, which is an integral part of the missile airframe. The target-detecting device is a complex fuze with dual radar systems to optimize warhead lethality against a spectrum of target sizes and speeds. The telemeter unit transmits missile performance data to ground stations to be analyzed for accuracy of missile/target scenario. Certain operation frequencies and performance characteristics are classified Secret.

2. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures or equivalent systems which might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

3. A determination has been made that the Netherlands can provide substantially the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

[FR Doc. 04–22175 Filed 10–1–04; 8:45 am]
BILLING CODE 5001–06–C

DEPARTMENT OF DEFENSE

Office of the Secretary

TRICARE; Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); Fiscal Year 2005 Diagnosis Related Group (DRG) Updates

AGENCY: Office of the Secretary, DoD.
ACTION: Notice of DRG revised rates.

SUMMARY: This notice describes the changes made to the TRICARE DRG-based payment system in order to conform to changes made to the Medicare Prospective Payment System (PPS). It also provides the updated fixed loss cost outlier threshold, cost-to-charge ratios and the Internet address for accessing the updated adjusted standardized amount and DRG relative weights to be used for FY 2005 under the TRICARE DRG-based payment system.

EFFECTIVE DATES: The rates, weights and Medicare PPS changes which affect the TRICARE DRG-based payment system contained in this notice are effective for admissions occurring on or after October 1, 2004.

ADDRESSES: TRICARE Management Activity (TMA), Medical Benefits and Reimbursement Systems, 16401 East Centretech Parkway, Aurora, CA 80011–9066.

FOR FURTHER INFORMATION CONTACT: Marty Maxey, Medical Benefits and Reimbursement Systems, TMA, telephone (303) 676–3627. Questions regarding payment of specific claims under the TRICARE DRG-based payment system should be addressed to the appropriate contractor.

SUPPLEMENTARY INFORMATION: The final rule published on September 1, 1987 (52 FR 32992) set forth in basic procedures used under the CHAMPUS DRG-based payment system. This was subsequently amended by final rules published August 31, 1988 (53 FR 33461), October 21, 1988 (53 FR 41331), December 16, 1988 (53 FR 50515), May 30, 1990 (55 FR 21863), October 22, 1990 (55 FR 42560), and September 10, 1998 (63 FR 48439). An explicit tenet of these final rules, and one based on the statute authorizing the use of DRGs by TRICARE, is that the TRICARE DRG-

based payment system is modeled on the Medicare PPS, and that, whenever practicable, the TRICARE system will follow the same rules that apply to the Medicare PPS. The Centers for Medicare and Medicaid Services (CMS) publishes these changes annually in the **Federal Register** and discusses in detail the impact of the changes.

In addition, this notice updates the rates and weights in accordance with our previous final rules. The actual changes we are making, along with a description of their relationship to the Medicare PPS, are detailed below.

I. Medicare PPS Changes Which Affect the TRICARE DRG-Based Payment System

Following is a discussion of the changes CMS has made to the Medicare PPS that affect the TRICARE DRG-based payment system.

A. DRG Classifications

Under both the Medicare PPS and the TRICARE DRG-based payment system, cases are classified into the appropriate DRG by a Grouper program. The Grouper classifies each case into a DRG on the basis of the diagnosis and procedure codes and demographic information (that is, sex, age, and discharge status). The Grouper used for the TRICARE DRG-based payment system is the same as the current Medicare Grouper with two modifications. The TRICARE system has replaced Medicare DRG 435 with two age-based DRGs (900 and 901), and has implemented thirty-four (34) neonatal DRGs in place of Medicare DRGS 385 through 390. For admission occurring on or after October 1, 2001, DRG 435 has been replaced by DRG 523. The TRICARE system has replaced DRG 523 with the two age-based DRGs (900 and 901). For admissions occurring on or after October 1, 1995, the CHAMPUS grouper hierarchy logic was changed so the age split (age <29 days) and assignments to MDC 15 occur before assignment of the PreMDC DRGs. This resulted in all neonate tracheostomies and organ transplants to be grouped to MDC 15 and not to DRGs 480–483 or 495. For admissions occurring on or after October 1, 1998, the CHAMPUS grouper hierarchy logic was changed to move DRG 103 to the PreMDC DRGs and to assign patients to PREMDC DRGs 480, 103 and 495 before assignment to MDC 15 DRGs and the neonatal DRGs. For admissions occurring on or after October 1, 2001, DRGs 512 and 513 were added to the PREMDC DRGs, between DRGs 480 and 103 in the TRICARE grouper hierarchy logic. For admissions occurring on or after October 1, 2004, DRG 483 was deleted and replaced with DRGs 541 and 542, splitting the assignment of cases on the basis of the performance of a major operating room procedure. The description for DRG480 was changed to "Liver Transplant and/or Intestinal Transplant", and the description for DRG 103 was changed to "Heart/Heart Lung Transplant or Implant of Heart Assist System".

For FY 2005, CMS will implement classification changes, including surgical hierarchy changes. The TRICARE Grouper will incorporate all changes made to the Medicare Grouper, with the exception of the changes made to MDC 11, DRG 315 to accommodate the congressional mandate to cover the pancreatic inlet cell transplantation clinical trial for Medicare patients.

B. Wage Index and Medicare Geographic Classification Review Board Guidelines

TRICARE will continue to use the same wage index amounts used for the Medicare PPS. In addition, TRICARE will duplicate all changes with regard to the wage index for specific hospitals that are redesignated by the Medicare Geographic Classification Review Board.

C. Out-Commuting Wage Index Adjustment

TRICARE is adopting the out commuting wage index adjustment used in the Medicare PPS due to the passage of the Medicare Modernization Act of 2003 (MMA) P.L. 108–173.

D. Updated Labor Market Areas

TRICARE is adopting the new labor market areas used in the Medicare PPS.

E. Equalization of Large Urban and Other Area Adjusted Standardized Amounts (ASAs)

TRICARE is adopting CMS' permanent equalization of the ASA rate for large urban and other areas due to the passage of the MMA of 2003. Under TRICARE, children's hospitals are reimbursed under the TRICARE DRG-based payment system and are entitled to receive the children's hospital differential. The differential amount is based on large urban and other areas. With the elimination of the other area ASA rate for hospitals subject to the TRICARE DRG-based payment, TRICARE is also eliminating the other area children's hospital differential rate and adopting the large urban differential rate for all children's hospitals.

F. Revision of the Labor-Related Share of the Wage Index

TRICARE is adopting CMS' percentage of labor related share of the standardized amount. For wage index values greater than 1.0, the labor related portion of the ASA shall equal 71.1 percent. For wage index values less than or equal to 1.0 the labor related portion of the ASA shall equal 62 percent.

G. Hospital Market Basket.

TRICARE will update the adjusted standardized amounts according to the final updated hospital market basket used for the Medicare PPS for all hospitals subject to the TRICARE DRG-based payment system according to CMS's August 11, 2004, final rule.

H. Outlier Payments

Since TRICARE does not include capital payments in our DRG-based payments, we will use the fixed loss cost outlier threshold calculated by CMS for paying cost outliers in the absence of capital prospective payments. For FY 2005, the fixed loss cost outlier threshold is based on the sum of the applicable DRG-based payment rate plus any amounts payable for IDME plus a fixed dollar amount. Thus, for FY 2005, in order for a case to qualify for cost outlier payments, the costs must exceed the TRICARE DRG based payment rate (wage adjusted) for the DRG plus the IDME payment plus $23,762 (wage adjusted). The marginal cost factor for cost outliers continues to be 80 percent.

I. National Operating Standard Cost as a Share of Total Costs

The FY 2005 TRICARE National Operating Standard Cost as a Share of Total Costs used in calculating the cost outlier threshold is 0.921.

J. Indirect Medical Education (IDME) Adjustment

Passage of the MMA of 2003 modified the formula multipliers to be used in the calculation of the indirect medical education IDME adjustment factor. Since the IDME formula used by TRICARE does not include disproportionate share hospitals (DSHs), the variables in the formula are different than Medicare's, however; the percentage reduction that will be applied to Medicare's, formula will also be applied to the TRICARE IDME formula. The new multiplier for the IDME adjustment factor for TRICARE for FY 2005 is 1.07.

K. Expansion of the Post Acute Care Transfer Policy

For FY 2005 TRICARE is adopting CMS' expanding post acute care transfer policy according to CMS' final rule published August 11, 2004.

II. Cost to Charge Ratio

For FY 2005, the cost-to-charge ratio used for the TRICARE DRG-based payment system will be 0.4438, which is increased to 0.4508 to account for bad debts. This shall be used to calculate the adjusted standardized amounts and to calculate cost outlier payments, except for children's hospitals. For children's hospital cost outliers, the cost-to charge ratio used is 0.4887.

III. Updated Rates and Weights

The updated rates and weights are accessible through the Internet at *http://www.tricare.osd.mil* under the sequential headings TRICARE Provider Information, Rates and Reimbursements, and DRB Information. Table 1 provides the ASA rates and Table 2 provides the DRG weights to be used under the TRICARE DRG-based payment system during FY 2005 and which is a result of the changes described above. The implementing regulations for the TRICARE/CHAMPUS DRG-based payment system are in 32 CFR Part 199.

Dated: September 28, 2004.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 04–22169 Filed 10–1–04; 8:45 am]

BILLING CODE 5001–04–M

DEPARTMENT OF DEFENSE

Office of the Secretary

President's Information Technology Advisory Committee (PITAC)

ACTION: Notice of meeting.

SUMMARY: PITAC's Subcommittee on Cyber Security will provide a status update of its activities and present its draft findings and recommendations. PITAC will discuss the Subcommittee's presentation and provide guidance for use in the completion of the report. In addition, an update of the activities of PITAC's Subcommittee on Computational Science will be presented and discussed. Each of the sessions for the two Subcommittees will conclude with a public comment period. A small fraction of the meeting time will be allocated for other PITAC updates at the discretion of the co-hairs and designated Federal officer.

DATES: Wednesday, October 20, 2004, 10 a.m. to 3 p.m.

ADDRESSES: National Science Foundation, Stafford II Building—Room 555, 4201 Wilson Boulevard, Arlington, Virginia 22230.

SUPPLEMENTARY INFORMATION: Members of the public are invited to attend this meeting in-person at the National Science Foundation. Remote participation by teleconference and the Internet (through the Webex application) will also bed supported. Detailed information about this meeting, including the agenda and details concerning registration for in-person or remote participation, will be posted at PITAC's Web site (*http"// www.nitrd.gov/pitac*) no later than October 6th. This information may also be obtained by calling 703–292–4873

FOR FURTHER INFORMATION CONTACT: Alan Inouye at the National Coordination Office for Information Technology Research and Development at 703–292–4873 or by email at *inouye@nitrd.gov*.

Dated: September 28, 2004.

L. M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 04–22173 Filed 10–01–04; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Science Board

AGENCY: Department of Defense.

ACTION: Notice of Advisory Committee Meetings.

SUMMARY: The Defense Science Board Task Force on Missile Defense, Phase IV (Information Policy) will meet in closed session on October 15, 2004 and December 9–10, 2004, at the Institute for Defense Analyses, 1801 N. Beauregard Street, Alexandria, VA. The Task Force will assess: the scope of the modeling and simulation effort; the appropriateness of the level of fidelity of classes of simulations; the impact of communications in the end-to-end models; the approaches to ensuring the validity of simulations for all uses, including exercises and wargaming done for training and operations concept development; and additional opportunities for modeling and simulation contribution to Ballistic Missile Defense Systems development and evaluation.

The mission of the Defense Science Board is to advise the Secretary of Defense and the Under Secretary of Defense for Acquisition, Technology & Logistics on scientific and technical matters as they affect the perceived needs of the Department of Defense. At this meeting, the Defense Science Board Task Force will address the above mentioned issues in a system of systems context with particular emphasis on battle management systems, command and control systems, and the global sensor system. The Task Force will provide advice on the state of modeling and simulation for use in assessing overall performance of segments of the Ballistic Missile Defense Systems; e.g., ground-based midcourse intercept system, space-based interceptor system.

In accordance with Section 10(d) of the Federal Advisory Committee Act, Pub. L. 92–463, as amended (5 U.S.C. App. II), it has been determined that this Defense Science Board Task Force meeting concerns matters listed in 5 U.S.C. 552b(c)(1) and that, accordingly, the meeting will be closed to the public.

Dated: September 28, 2004.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 04–22171 Filed 10–1–04; 8:45 am]

BILLING CODE 5001–08–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Science Board

AGENCY: Department of Defense.

ACTION: Notice of Advisory Committee Meeting.

SUMMARY: The Defense Science Board Task Force on Mobility will meet in closed session on October 14–15, 2004; November 17–18, 2004; and December 14–15, 2004, in Arlington, VA. This task Force will identify the acquisition issues in improving our strategic mobility capabilities.

The mission of the Defense Science Board is to advise the Secretary of Defense and the Under Secretary of Defense for Acquisition, Technology & Logistics on scientific and technical matters as they affect the perceived needs of the Department of Defense. At this meeting, the Defense Science Board Task Force will review: The part transport plays in our present-day military capability—the technical strengths and weaknesses the operational opportunities and constraints; the possible advantage of better alignment of current assets with those in production and those to be delivered in the very near future; how

basing and deployment strategies—CONUS-basing, prepositioning (ashore or afloat), and seabasing—drive our mobility effectiveness; the possible advantages available from new transport technologies and systems whose expected IOC dates are either short term (~12 years) or, separately, the long term (~25 years).

In accordance with Section 10(d) of the Federal Advisory Committee Act, Pub. L. 92–463, as amended (5 U.S.C. App. II), it has been determined that this Defense Science Board Task Force meeting concerns matters listed in 5 U.S.C. 552b(c)(1) and that, accordingly, the meeting will be closed to the public.

Dated: September 27, 2004

L. M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 04–22172 Filed 10–1–04; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Office of the Secretary of Defense

Defense Threat Reduction Agency (DTRA); Membership of the DTRA Performance Review Board (PRB)

AGENCY: Department of Defense, Defense Threat Reduction Agency.

ACTION: Notice of PRB membership.

SUMMARY: This notice announces the appointment of DTRA's PRB membership. The publication of the PRB membership is required by 5 U.S.C. 4314(c)(4). The PRB shall provide fair and impartial review of Senior Executive Service performance appraisals and make recommendations regarding performance ratings and performance awards to the Acting Director, Defense Threat Reduction Agency.

EFFECTIVE DATE: The effective date of service for the appointees of the DTRA PRB is on or about October 1, 2004.

FOR FURTHER INFORMATION CONTACT: Tana Farrell, Operations Office, Business Directorate, (703) 767–5759, Defense Threat Reduction Agency, 8725 John J. Kingman Road, Stop 6201, Ft. Belvoir, VA 22060–6201.

SUPPLEMENTARY INFORMATION: In accordance with 5 U.S.C. 4314(c)(4), the officials appointed to serve as members of the DTRA PRB are set forth below:

PRB Chair: Mr. Myron K. Kunka.
Member: Dr. Arthur T. Hopkins.
Member: Mr. Michael K. Evenson.

The following DTRA officials will serve as alternate members of the DTRA PRB, as appropriate.

Mr. Douglas Bruder
Dr. Mark Byers
Ms. Shari Durand
Mr. Douglas Englund
Mr. Kevin Flanagan
Dr. Charles Gallaway
Dr. Joe Golden
Mr. Richard Gullickson
Dr. Don Linger
Ms. Joan Ma Pierre

Dated: September 28, 2004

L. M. Bynum,

Alternate OSO Federal Register Liaison Officer, Department of Defense.

[FR Doc. 04–22174 Filed 10–1–04; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Office of Secretary

Revised Non-Foreign Overseas Per Diem Rates

AGENCY: DoD, Per Diem, Travel and Transportation Allowance Committee.

ACTION: Notice of Revised Non-Foreign Overseas Per Diem Rates.

SUMMARY: The Per Diem, Travel and Transportation Allowance Committee is publishing Civilian Personnel Per Diem bulletin Number 236. This bulletin lists revisions in the per diem rates prescribed for U.S. Government employees for official travel in Alaska, Hawaii, Puerto Rico, the Northern Mariana Islands and Possessions of the United States. AEA changes announced in Bulletin Number 194 remain in effect. Bulletin Number 236 is being published in the **Federal Register** to assure that travelers are paid per diem at the most current rates.

EFFECTIVE DATE: October 1, 2004.

SUPPLEMENTARY INFORMATION: This document gives notice of revisions in per diem rates prescribed by the Per Diem Travel and Transportation Allowance Committee for non-foreign areas outside the continental United States. It supersedes Civilian Personnel Per Diem Bulletin Number 235. Distribution of Civilian Personnel Per Diem Bulletins by mail was discontinued. Per Diem Bulletins published periodically in the **Federal Register** now constitute the only notification of revisions in per diem rates to agencies and establishments outside the Department of Defense. For more information or questions about per diem rates, please contact your local travel office. The text of the Bulletin follows:

Dated: September 28, 2004.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, DoD.

BILLING CODE 5001–06–M

Maximum Per Diem Rates for official travel in Alaska, Hawaii, the Commonwealths of Puerto Rico and the Northern Mariana Islands and Possessions of the United States by Federal Government civilian employees.

LOCALITY	MAXIMUM LODGING AMOUNT (A) +	M&IE RATE (B) =	MAXIMUM PER DIEM RATE (C)	EFFECTIVE DATE
THE ONLY CHANGE IN CIVILIAN BULLETIN 236 IS UPDATE TO THE RATES FOR BETTLES, ALASKA.				
ALASKA				
ADAK	120	79	199	07/01/2003
ANCHORAGE [INCL NAV RES]				
05/01 - 09/15	170	89	259	06/01/2004
09/16 - 04/30	95	81	176	06/01/2004
BARROW	159	95	254	05/01/2002
BETHEL	119	77	196	06/01/2004
BETTLES	135	62	197	10/01/2004
CLEAR AB	80	55	135	09/01/2001
COLD BAY	90	73	163	05/01/2002
COLDFOOT	135	71	206	10/01/1999
COPPER CENTER				
05/16 - 09/15	109	63	172	07/01/2003
09/16 - 05/15	99	63	162	07/01/2003
CORDOVA	110	75	185	06/01/2004
CRAIG	100	68	168	06/01/2004
DEADHORSE	95	67	162	05/01/2002
DELTA JUNCTION	89	75	164	06/01/2004
DENALI NATIONAL PARK				
06/01 - 08/31	114	65	179	06/01/2004
09/01 - 05/31	80	61	141	06/01/2004
DILLINGHAM	114	69	183	06/01/2004
DUTCH HARBOR-UNALASKA	119	72	191	06/01/2004
EARECKSON AIR STATION	80	55	135	09/01/2001
EIELSON AFB				
05/01 - 09/15	159	88	247	06/01/2004
09/16 - 04/30	75	79	154	06/01/2004
ELMENDORF AFB				
05/01 - 09/15	170	89	259	06/01/2004
09/16 - 04/30	95	81	176	06/01/2004
FAIRBANKS				
05/01 - 09/15	159	88	247	06/01/2004
09/16 - 04/30	75	79	154	06/01/2004
FOOTLOOSE	175	18	193	06/01/2002
FT. GREELY	89	75	164	06/01/2004
FT. RICHARDSON				
05/01 - 09/15	170	89	259	06/01/2004
09/16 - 04/30	95	81	176	06/01/2004
FT. WAINWRIGHT				
05/01 - 09/15	159	88	247	06/01/2004
09/16 - 04/30	75	79	154	06/01/2004
GLENNALLEN				
05/01 - 09/30	137	75	212	06/01/2004
10/01 - 04/30	89	70	159	06/01/2004
HEALY				
06/01 - 08/31	114	65	179	06/01/2004
09/01 - 05/31	80	61	141	06/01/2004

Maximum Per Diem Rates for official travel in Alaska, Hawaii, the Commonwealths of Puerto Rico and the Northern Mariana Islands and Possessions of the United States by Federal Government civilian employees.

LOCALITY	MAXIMUM LODGING AMOUNT (A) +	M&IE RATE (B) =	MAXIMUM PER DIEM RATE (C)	EFFECTIVE DATE
HOMER				
05/15 - 09/15	145	77	222	06/01/2004
09/16 - 05/14	99	72	171	06/01/2004
JUNEAU	120	84	204	06/01/2004
KAKTOVIK	165	86	251	05/01/2002
KAVIK CAMP	150	69	219	05/01/2002
KENAI-SOLDOTNA				
04/01 - 10/31	110	83	193	04/01/2003
11/01 - 03/31	69	75	144	04/01/2003
KENNICOTT	179	83	262	06/01/2004
KETCHIKAN				
05/01 - 09/30	113	80	193	06/01/2004
10/01 - 04/30	98	78	176	06/01/2004
KING SALMON				
05/01 - 10/01	225	91	316	05/01/2002
10/02 - 04/30	125	81	206	05/01/2002
KLAWOCK	100	68	168	06/01/2004
KODIAK	99	81	180	06/01/2004
KOTZEBUE				
05/01 - 08/31	141	86	227	06/01/2004
09/01 - 04/30	125	85	210	06/01/2004
KULIS AGS				
05/01 - 09/15	170	89	259	06/01/2004
09/16 - 04/30	95	81	176	06/01/2004
MCCARTHY	179	83	262	06/01/2004
METLAKATLA				
05/30 - 10/01	98	48	146	05/01/2002
10/02 - 05/29	78	47	125	05/01/2002
MURPHY DOME				
05/01 - 09/15	159	88	247	06/01/2004
09/16 - 04/30	75	79	154	06/01/2004
NOME	120	89	209	06/01/2004
NUIQSUT	180	53	233	05/01/2002
PETERSBURG	90	64	154	06/01/2004
POINT HOPE	130	70	200	03/01/1999
POINT LAY	105	67	172	03/01/1999
PORT ALSWORTH	135	88	223	05/01/2002
PRUDHOE BAY	95	67	162	05/01/2002
SEWARD				
05/01 - 09/30	145	82	227	06/01/2004
10/01 - 04/30	89	72	161	06/01/2004
SITKA-MT. EDGECUMBE				
05/01 - 09/30	119	74	193	06/01/2004
10/01 - 04/30	99	72	171	06/01/2004
SKAGWAY				
05/01 - 09/30	113	80	193	06/01/2004
10/01 - 04/30	98	78	176	06/01/2004
SPRUCE CAPE	99	81	180	06/01/2004
ST. GEORGE	129	55	184	06/01/2004
TALKEETNA	100	89	189	07/01/2002

Maximum Per Diem Rates for official travel in Alaska, Hawaii, the Commonwealths of Puerto Rico and the Northern Mariana Islands and Possessions of the United States by Federal Government civilian employees.

LOCALITY	MAXIMUM LODGING AMOUNT (A) +	M&IE RATE (B) =	MAXIMUM PER DIEM RATE (C)	EFFECTIVE DATE
TANANA	120	89	209	06/01/2004
TOGIAK	100	39	139	07/01/2002
TOK				
05/01 - 09/30	90	66	156	06/01/2004
10/01 - 04/30	60	63	123	06/01/2004
UMIAT	150	98	248	04/01/2003
UNALAKLEET	79	80	159	04/01/2003
VALDEZ				
05/01 - 10/01	129	77	206	06/01/2004
10/02 - 04/30	79	72	151	06/01/2004
WASILLA				
05/01 - 09/30	134	82	216	06/01/2004
10/01 - 04/30	80	77	157	06/01/2004
WRANGELL				
05/01 - 09/30	113	80	193	06/01/2004
10/01 - 04/30	98	78	176	06/01/2004
YAKUTAT	110	68	178	03/01/1999
[OTHER]	80	55	135	09/01/2001
AMERICAN SAMOA				
AMERICAN SAMOA	135	67	202	06/01/2004
GUAM				
GUAM (INCL ALL MIL INSTAL)	135	89	224	09/01/2004
HAWAII				
CAMP H M SMITH	129	91	220	06/01/2004
EASTPAC NAVAL COMP TELE AREA	129	91	220	06/01/2004
FT. DERUSSEY	129	91	220	06/01/2004
FT. SHAFTER	129	91	220	06/01/2004
HICKAM AFB	129	91	220	06/01/2004
HONOLULU (INCL NAV & MC RES CTR)	129	91	220	06/01/2004
ISLE OF HAWAII: HILO	100	80	180	06/01/2003
ISLE OF HAWAII: OTHER	150	79	229	06/01/2003
ISLE OF KAUAI	158	93	251	06/01/2004
ISLE OF MAUI	159	95	254	06/01/2004
ISLE OF OAHU	129	91	220	06/01/2004
KEKAHA PACIFIC MISSILE RANGE FAC	158	93	251	06/01/2004
KILAUEA MILITARY CAMP	100	80	180	06/01/2003
LANAI	400	148	548	06/01/2004
LUALUALEI NAVAL MAGAZINE	129	91	220	06/01/2004
MCB HAWAII	129	91	220	06/01/2004
MOLOKAI	93	91	184	06/01/2004
NAS BARBERS POINT	129	91	220	06/01/2004
PEARL HARBOR [INCL ALL MILITARY]	129	91	220	06/01/2004
SCHOFIELD BARRACKS	129	91	220	06/01/2004
WHEELER ARMY AIRFIELD	129	91	220	06/01/2004
[OTHER]	72	61	133	01/01/2000
JOHNSTON ATOLL				
JOHNSTON ATOLL	0	14	14	05/01/2002
MIDWAY ISLANDS				
MIDWAY ISLANDS [INCL ALL MILITAR	150	47	197	02/01/2000
NORTHERN MARIANA ISLANDS				

Maximum Per Diem Rates for official travel in Alaska, Hawaii, the Commonwealths of Puerto Rico and the Northern Mariana Islands and Possessions of the United States by Federal Government civilian employees.

LOCALITY	MAXIMUM LODGING AMOUNT (A) +	M&IE RATE (B) =	MAXIMUM PER DIEM RATE (C)	EFFECTIVE DATE
ROTA	129	90	219	09/01/2004
SAIPAN	121	92	213	09/01/2004
TINIAN	85	70	155	09/01/2004
[OTHER]	55	72	127	04/01/2000
PUERTO RICO				
BAYAMON				
04/11 - 12/23	155	71	226	01/01/2000
12/24 - 04/10	195	75	270	01/01/2000
CAROLINA				
04/11 - 12/23	155	71	226	01/01/2000
12/24 - 04/10	195	75	270	01/01/2000
FAJARDO [INCL CEIBA & LUQUILLO]	82	54	136	01/01/2000
FT. BUCHANAN [INCL GSA SVC CTR,				
04/11 - 12/23	155	71	226	01/01/2000
12/24 - 04/10	195	75	270	01/01/2000
HUMACAO	82	54	136	01/01/2000
LUIS MUNOZ MARIN IAP AGS				
04/11 - 12/23	155	71	226	01/01/2000
12/24 - 04/10	195	75	270	01/01/2000
MAYAGUEZ	85	59	144	01/01/2000
PONCE	96	69	165	01/01/2000
ROOSEVELT RDS & NAV STA	82	54	136	01/01/2000
SABANA SECA [INCL ALL MILITARY]				
04/11 - 12/23	155	71	226	01/01/2000
12/24 - 04/10	195	75	270	01/01/2000
SAN JUAN & NAV RES STA				
04/11 - 12/23	155	71	226	01/01/2000
12/24 - 04/10	195	75	270	01/01/2000
[OTHER]	62	57	119	01/01/2000
VIRGIN ISLANDS (U.S.)				
ST. CROIX				
04/15 - 12/14	98	83	181	08/01/2003
12/15 - 04/14	135	87	222	08/01/2003
ST. JOHN				
04/15 - 12/14	110	91	201	08/01/2003
12/15 - 04/14	185	98	283	08/01/2003
ST. THOMAS				
04/15 - 12/14	163	95	258	08/01/2003
12/15 - 04/14	220	99	319	08/01/2003
WAKE ISLAND				
WAKE ISLAND	60	32	92	09/01/1998

[FR Doc. 04–22170 Filed 10–1–04; 8:45 am]
BILLING CODE 5001–06–C

FEDERAL ENERGY REGULATORY COMMISSION

Sunshine Act; Meeting

September 8, 2004.

The following notice of meeting is published pursuant to section 3(a) of the Government in the Sunshine Act (Pub. L. 94–409), 5 U.S.C. 552b:

AGENCY HOLDING MEETING: Federal Energy Regulatory Commission, DOE.

DATE AND TIME: September 15, 2004, 10 a.m.

PLACE: Room 2C, 888 First Street, NE., Washington, DC 20426.

STATUS: Open.

MATTERS TO BE CONSIDERED: Agenda.

*Note—Items listed on the Agenda may be deleted without further notice.

CONTACT PERSON FOR MORE INFORMATION: Magalie R. Salas, Secretary, Telephone (202) 502–8400. For a recording listing items stricken from or added to the meeting, call (202) 502–8627.

This is a list of matters to be considered by the commission. It does not include a listing of all papers relevant to the items on the Agenda;

however, all public documents may be examined in the Reference and Information Center.

868th Meeting—September 15, 2004—Regular Meeting, 10 A.M.

Administrative Agenda

A–1.
DOCKET# AD02–1, 000, AGENCY ADMINISTRATIVE MATTERS
A–2.
DOCKET# AD02–7, 000, CUSTOMER MATTERS, RELIABILITY, SECURITY AND MARKET OPERATIONS
A–3.
DOCKET# AD04–11, 000, STAFF REPORT ON NATURAL GAS STORAGE
A–4.
DOCKET# AD04–12, 000, COST RANGES FOR THE DEVELOPMENT AND OPERATION OF A "DAY ONE" RTO

Markets, Tariffs and Rates—Electric

E–1.
DOCKET# ER02–1656, 017, CALIFORNIA INDEPENDENT SYSTEM OPERATOR CORPORATION
OTHER#S ER02–1656, 018, CALIFORNIA INDEPENDENT SYSTEM OPERATOR CORPORATION
OTHER#S ER02–1656, 019, CALIFORNIA INDEPENDENT SYSTEM OPERATOR CORPORATION
E–2.
DOCKET# ER04–925, 001, MERRILL LYNCH COMMODITIES, INC.
E–3.
DOCKET# ER04–691, 000, MIDWEST INDEPENDENT TRANSMISSION SYSTEM OPERATOR, INC.
OTHER#S ER04–106, 002, MIDWEST INDEPENDENT TRANSMISSION SYSTEM OPERATOR, INC.
OTHER#S ER04–104, 000, PUBLIC UTILITIES WITH GRANDFATHERED AGREEMENTS IN THE MIDWEST ISO REGION
E–4.
DOCKET# ER04–829, 000, PJM INTERCONNECTION, LLC AND VIRGINIA ELECTRIC AND POWER COMPANY
OTHER#S ER04–829, 001, PJM INTERCONNECTION, LLC AND VIRGINIA ELECTRIC AND POWER COMPANY
E–5.
DOCKET# ER04–834, 000, VIRGINIA ELECTRIC AND POWER COMPANY
E–6.
DOCKET# RM04–12, 000, FINANCIAL REPORT AND COST ACCOUNTING, OVERSIGHT AND RECOVERY PRACTICES FOR REGIONAL TRANSMISSION ORGANIZATIONS AND INDEPENDENT SYSTEM OPERATORS
E–7.
OMITTED
E–8.
OMITTED
E–9.
OMITTED
E–10.
DOCKET# RT04–1, 001, SOUTHWEST POWER POOL, INC.
OTHER#S ER04–48, 001, SOUTHWEST POWER POOL, INC.
E–11.
DOCKET# ER04–1077, 000, PJM INTERCONNECTION, LLC
E–12.
DOCKET# ER04–1033, 000, WABASH VALLEY POWER ASSOCIATION, INC.
OTHER#S ER04–789, 000, WABASH VALLEY POWER ASSOCIATION, INC.
OTHER#S ER04–802, 000, WABASH VALLEY POWER ASSOCIATION, INC.
E–13.
DOCKET# ER04–1034, 000, FLORIDA POWER & LIGHT COMPANY
E–14.
OMITTED
E–15.
DOCKET# ER04–1055, 000, RIVERSIDE ENERGY CENTER, LLC
E–16.
DOCKET# ER04–1059, 000, ROCKGEN ENERGY, LLC
E–17.
DOCKET# ER04–886, 000, ENTERGY SERVICES, INC.
E–18.
DOCKET# ER04–1064, 000, NEW ENGLAND POWER POOL
E–19.
DOCKET# ER04–1091, 000, ILLINOIS POWER COMPANY
E–20.
OMITTED
E–21.
OMITTED
E–22.
DOCKET# ER00–1, 004, CROSS-SOUND CABLE COMPANY,LLC
E–23.
DOCKET# ER02–2595, 000, MIDWEST INDEPENDENT TRANSMISSION SYSTEM OPERATOR, INC.
OTHER#S ER02–2595, 003, MIDWEST INDEPENDENT TRANSMISSION SYSTEM OPERATOR, INC.
E–24
DOCKET# ER03–599, 000, ENTERGY SERVICES, INC.
OTHER#S ER03–599, 001, ENTERGY SERVICES, INC.
OTHER#S ER03–599, 002, ENTERGY SERVICES, INC.
OTHER#S ER03–599, 003, ENTERGY SERVICES, INC.
E–25.
DOCKET# NJ04–4, 000, ORLANDO UTILITIES COMMISSION
E–26.
DOCKET# ER03–647, 004, NEW YORK INDEPENDENT SYSTEM OPERATOR, INC.
E–27.
OMITTED
E–28.
DOCKET# ER98–997, 003, CALIFORNIA INDEPENDENT SYSTEM OPERATOR CORPORATION
OTHER#S ER98–1309, 002, CALIFORNIA INDEPENDENT SYSTEM OPERATOR CORPORATION
OTHER#S ER02–2297, 002, CALIFORNIA INDEPENDENT SYSTEM OPERATOR CORPORATION
OTHER#S ER02–2298, 002, CALIFORNIA INDEPENDENT SYSTEM OPERATOR CORPORATION
E–29.
DOCKET# RT04–1, 004, SOUTHWEST POWER POOL, INC.
OTHER#S ER04–48, 004, SOUTHWEST POWER POOL, INC.
E–30.
DOCKET# QF95–328, 006, ECOELéCTRICA, L.P.
E–31.
OMITTED
E–32.
OMITTED
E–33.
DOCKET# TS04–261, 000, ALCOA POWER GENERATING INC.
OTHER#S TS04–255, 000, CROSS SOUND CABLE COMPANY, LLC
OTHER#S TS04–242, 000, DAUGHIN ISLAND GATHERING PARTNERS
OTHER#S TS04–6, 000, DISTRIGAS OF MASSACHUSETTS LLC
OTHER#S TS04–236, 000, DISTRIGAS OF MASSACHUSETTS LLC
OTHER#S TS04–267, 000, EL PASO CORPORATION
OTHER#S TS04–150, 000, GRANITE STATE GAS TRANSMISSION CO.
OTHER#S TS04–262, 000, HIGH ISLAND OFFSHORE SYSTEM, LLC
OTHER#S TS04–249, 000, KINDER MORGAN PIPELINES
OTHER#S TS04–271, 000, KINDER MORGAN PIPELINES
OTHER#S TS04–272, 000, KINDER MORGAN PIPELINES

OTHER#S OA04–1, 000, LINCOLN ELECTRIC SYSTEM
OTHER#S TS04–209, 000, MIDWESTERN GAS TRANSMISSION CO.
OTHER#S TS04–208, 000, NORTHERN BORDER PIPELINE COMPANY
OTHER#S TS04–248, 000, NATIONAL FUEL GAS SUPPLY CORPORATION
OTHER#S TS04–3, 000, NORTHWESTERN ENERGY
OTHER#S TS04–3, 001, NORTHWESTERN ENERGY
OTHER#S TS04–252, 000, OHIO VALLEY ELECTRIC CORPORATION AND INDIANA-KENTUCKY ELECTRIC CORPORATION
OTHER#S TS04–184, 000, PANTHER INTERSTATE PIPELINE ENERGY, LLC
OTHER#S TS04–263, 000, PETAL GAS STORAGE, L.L.C.
OTHER#S TS04–231, 000, QUESTAR PIPELINE COMPANY, OVERTHRUST PIPELINE COMPANY, AND QUESTAR SOUTHERN TRAILS PIPELINE COMPANY
OTHER#S TS04–71, 000, PPL ELECTRIC UTILITIES
OTHER#S TS04–152, 000, SALTVILLE GAS STORAGE COMPANY LLC
OTHER#S TS04–273, 000, SHELL OFFSHORE INC. AND SHELL GULF OF MEXICO
OTHER#S TS04–274, 000, SHELL GAS TRANSMISSION, LLC
OTHER#S TS04–222, 000, SOUTHWEST GAS TRANSMISSION COMPANY
OTHER#S TS04–253, 000, TEXAS GAS TRANSMISSION LLC
OTHER#S TS04–212, 000, VIKING GAS TRANSMISSION CO.
OTHER#S TS04–260, 000, WILLISTON BASIN INTERSTATE PIPELINE CO.

E–34.
OMITTED

E–35.
DOCKET# EL04–90, 000, NEVADA POWER COMPANY

E–36.
OMITTED

E–37.
DOCKET# ER01–2536, 005, NEW YORK INDEPENDENT SYSTEM OPERATOR, INC.

E–38.
DOCKET# EL04–71, 000, EMPIRE DISTRICT ELECTRIC COMPANY

E–39.
DOCKET# PL04–5, 000, POLICY STATEMENT ON MATTERS RELATED TO BULK POWER SYSTEM RELIABILITY

E–40.
OMITTED

E–41.
OMITTED

E–42.
DOCKET# EL99–14, 000, *SOUTHWESTERN ELECTRIC COOPERATIVE, INC.* V. *SOYLAND POWER COOPERATIVE, INC.*
OTHERS# EL99–14, 005, SOUTHWESTERN ELECTRIC COOPERATIVE, INC. V. *SOYLAND POWER COOPERATIVE, INC.*

E–43.
DOCKET# ERO3–1247, 003, NORTHEAST UTILITIES SERVICE COMPANY

E–44.
DOCKET# ER03–31, 005, UNITED ILLUMINATING COMPANY

E–45.
DOCKET# ER03–549, 000, SOUTHERN CALIFORNIA EDISON COMPANY
OTHER#S ER03–549, 001, SOUTHERN CALIFORNIA EDISON COMPANY
OTHER#S ERO3–549, 002, SOUTHERN CALIFORNIA EDISON COMPANY

E–46.
DOCKET# ER04–109, 000, PACIFIC GAS AND ELECTRIC COMPANY
DOCKET# EL04–37, 000, PACIFIC GAS AND ELECTRIC COMPANY

E–47.
DOCKET# ER04–55, 000, MAINE YANKEE ATOMIC POWER COMPANY

E–48.
DOCKET# ER04–653, 002, PJM INTERCONNECTION, LLC

E–49.
DOCKET# EC02–113, 001, CINERGY SERVICES, INC., ON BEHALF OF PSI ENERGY, INC., CINCAP MADISON, LLC AND CINCAP VII, LLC

E–50.
DOCKET# EL03–219, 001, CENTRAL IOWA POWER COOPERATIVE, CLARKE ELECTRIC COOPERATIVE, INC., CONSUMERS ENERGY COOPERATIVE, EAST-CENTRAL IOWA RURAL ELECTRIC COOPERATIVE, EASTERN IOWA LIGHT & POWER COOPERATIVE, FARMERS ELECTRIC COOPERATIVE, INC., GUTHRIE COUNTY RURAL ELECTRIC COOPERATIVE ASSOCIATION, MAQUOKETA VALLEY ELECTRIC COOPERATIVE, MIDLAND POWER COOPERATIVE, PELLA COOPERATIVE ELECTRIC ASSOCIATION, RIDETA ELECTRIC COOPERATIVE INC., SOUTH IOWA MUNICIPAL ELECTRIC COOPERATIVE ASSOCIATION, SOUTHWEST IOWA SERVICE COOPERATIVE, AND T.I.P. RURAL ELECTRIC COOPERATIVE

E–51.
OMITTED

E–52.
DOCKET# EL03–53, 001, *GREGORY SWECKER* V. *MIDLAND POWER COOPERATIVE*

E–53.
DOCKET# EL04–51, 001, *INTERGEN SERVICES, INC. ON BEHALF OF COTTONWOOD ENERGY COMPANY, LP* V. *ENTERGY SERVICES, INC. AND ENTERGY GULF STATES, INC.*

E–54.
OMITTED

E–55.
DOCKET# ER01–2998, 004, PACIFIC GAS AND ELECTRIC COMPANY
OTHER#S ER02–358, 004, *PACIFIC GAS AND ELECTRIC COMPANY*
OTHERS#S EL02–64, 004, *NORTHERN CALIFORNIA POWER AGENCY* V. *PACIFIC GAS AND ELECTRIC COMPANY AND THE CALIFORNIA INDEPENDENT SYSTEM OPERATOR CORPORATION*

E–56.
DOCKET# ER01–890, 006, BOSTON EDISON COMPANY
OTHER#S ER01–890, 007, BOSTON EDISON COMPANY
OTHER#S ER02–1465, 003, BOSTON EDISON COMPANY
OTHER#S ER02–1465, 004, BOSTON EDISON COMPANY

E–57.
DOCKET# ER02–1333, 001, PJM INTERCONNECTION, LLC

E–58.
DOCKET# ER02–2463, 002, ISO NEW ENGLAND, INC.
OTHER#S ERO2–2463, 003, ISO NEW ENGLAND, INC.

E–59.
DOCKET# ER02–851, 004, SOUTHERN COMPANY SERVICES, INC.
OTHER#S ER02–851, 012, SOUTHERN COMPANY SERVICES, INC.

E–60.
DOCKET# ER04–335, 003, NEW ENGLAND POWER POOL

E–61.
DOCKET# ER04–337, 004, PACIFIC GAS AND ELECTRIC COMPANY

E–62.
DOCKET# ER04–449, 001, AMERICAN ELECTRIC POWER SERVICE CORPORATION
OTHER#S ER04–499, 002, AMERICAN ELECTRIC POWER SERVICE CORPORATION

E–63.
DOCKET# ER04–608, 001, PJM INTERCONNECTION, LLC
E–64.
DOCKET# ER04–714, 001, FLORIDA POWER & LIGHT COMPANY—NEW ENGLAND DIVISION
OTHER#S ER04–157, 006, BANGOR HYDRO-ELECTRIC COMPANY, CENTRAL MAINE POWER COMPANY, NSTAR ELECTRIC & GAS CORPORATION, NEW ENGLAND POWER COMPANY, NORTHEAST UTILITIES SERVICE COMPANY, THE UNITED ILLUMINATING COMPANY, AND VERMONT ELECTRIC POWER COMPANY
E–65.
DOCKET# ER04–742, 001, PJM INTERCONNECTION, LLC
E–66.
DOCKET# QF86–681, 006, ORMESA LLC
E–67.
DOCKET# EL03–152, 000, DUKE ENERGY TRADING AND MARKETING COMPANY
E–68.
DOCKET# ER96–2495, 020, AEP POWER MARKETING, INC.
OTHER#S ER97–4143, 008, AEP SERVICE CORPORATION
OTHER#S ER97–1238, 015, CSW POWER MARKETING, INC.
OTHER#S ER98–2075, 014, CSW ENERGY SERVICES, INC.
OTHER#S ER98–542, 010, CENTRAL AND SOUTH WEST SERVICES, INC.
OTHER#S EL04–131, 000, CENTRAL AND SOUTH WEST SERVICES, INC.
E–69.
DOCKET# ER99–2326, 006, PACIFIC GAS AND ELECTRIC COMPANY
OTHER#S ER99–68, 006, PACIFIC GAS AND ELECTRIC COMPANY
E–70.
DOCKET# EL03–159, 000, MODESTO IRRIGATION DISTRICT
E–71.
DOCKET# ER97–4166, 015, SOUTHERN COMPANY ENERGY MARKETING, INC.
OTHER#S EL04–124, 000, SOUTHERN COMPANY ENERGY MARKETING, INC.
E–72.
DOCKET# ER91–569, 023, ENTERGY SERVICES, INC.
OTHER#S EL04–123, 000, ENTERGY SERVICES, INC.
E–73.
DOCKET# ER04–132, 000, WOLVERINE POWER SUPPLY COOPERATIVE INC
OTHER#S EL04–38, 000, WOLVERINE POWER SUPPLY COOPERATIVE INC.
E–74.
DOCKET# EL02–123, 003, BOSTON EDISON COMPANY
OTHER#S EL02–123, 004, BOSTON EDISON COMPANY
E–75.
DOCKET# ER01–989, 002, GREEN MOUNTAIN POWER CORPORATION
OTHER#S ER01–989, 003, GREEN MOUNTAIN POWER CORPORATION
E–76.
DOCKET# ER04–435, 002, SOUTHERN CALIFORNIA EDISON COMPANY
OTHER#S ER04–435, 004, SOUTHERN CALIFORNIA EDISON COMPANY

Markets, Tariffs and Rates—Gas

G–1.
DOCKET# RP98–18, 015, IROQUOIS GAS TRANSMISSION SYSTEM, L.P.
G–2.
DOCKET# PR04–12, 000, NATIONAL FUEL GAS DISTRIBUTION CORPORATION
G–3.
DOCKET# RP04–269, 000, BLACK MARLIN PIPELINE COMPANY
OTHER#S RP04–269, 001, BLACK MARLIN PIPELINE COMPANY
G–4.
DOCKET# RP02–361, 028, GULFSTREAM NATURAL GAS SYSTEM, L.L.C.
G–5.
DOCKET# RP03–398, 009, NORTHERN NATURAL GAS COMPANY
G–6.
DOCKET# RP04–168, 003, GREAT LAKES GAS TRANSMISSION LIMITED PARTNERSHIP
G–7.
OMITTED
G–8.
OMITTED
G–9.
DOCKET# RP04–217, 000, *CALPINE ENERGY SERVICES, LP* V. *GAS TRANSMISSION NORTHWEST CORPORATION*
G–10.
DOCKET# RP04–281, 001, NORTHERN NATURAL GAS COMPANY

Energy Projects—Hydro

H–1.
OMITTED
H–2.
DOCKET# P–2000, 053, NEW YORK POWER AUTHORITY
OTHER#S EL03–224, 003, *MASSACHUSETTS MUNICIPAL WHOLESALE ELECTRIC COMPANY* V. *NEW YORK POWER AUTHORITY*
H–3.
DOCKET# P–1971, 090, IDAHO POWER COMPANY
H–4.
DOCKET# P–2612, 015, FPL ENERGY MAINE HYDRO LLC
H–5.
DOCKET# P–77, 121, PACIFIC GAS AND ELECTRIC COMPANY
H–6.
DOCKET# P–2232, 449, DUKE ENERGY CORPORATION

Energy Projects—Certificates

C–1.
DOCKET# CP04–346, 000, CENTERPOINT ENERGY—MISSISSIPPI
C–2.
DOCKET# CP04–64, 000, TRUNKLINE GAS COMPANY, LLC
OTHER#S CP04–60, 004, TRUCKLINE GAS COMPANY, LLC
C–3.
DOCKET# CP04–55, 000, NORTHWEST PIPELINE CORPORATION AND TERASEN SUMAS, INC.
OTHER#S CP04–56, 000, TERASEN SUMAS, INC.
C–4.
OMITTED
C–5.
DOCKET# CP03–75, 001, FREEPORT LNG DEVELOPMENT, L.P.
C–6.
DOCKET# CP02–396, 008, GREENBRIER PIPELINE COMPANY, L.L.C.
C–7.
DOCKET# CP04–121, 001, EL PASO NATURAL GAS COMPANY

The Capitol Connection offers the opportunity for remote listening and viewing of the meeting. It is available for a fee, live over the Internet, via C–Band Satellite. Persons interested in receiving the broadcast, or who need information on making arrangements should contact David Reininger or Julia Morelli at the Capitol Connection (703–993–3100) as soon as possible or visit the Capitol Connection website at *http://www.capitolconnection.gmu.edu* and click on "FERC".

Magalie R. Salas,
Secretary.
[FR Doc. 04–22385 Filed 9–30–04; 8:45 am]
BILLING CODE 6717–01–M

ENVIRONMENTAL PROTECTION AGENCY

[OECA–2004–0027; FRL–7823–3]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; Evaluation of PrintSTEP (Renewal); EPA ICR Number 1941.03, OMB Control Number 2020–0023

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. This ICR is scheduled to expire on October 31, 2004. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB. This ICR describes the nature of the information collection and its estimated burden and cost.

DATES: Additional comments may be submitted on or before November 3, 2004.

ADDRESSES: Submit your comments, referencing docket ID number OECA–2004–0027, to: (1) EPA online using EDOCKET (our preferred method), by e-mail to *docket.oeca@epa.gov*, or by mail to: EPA Docket Center, Environmental Protection Agency, Enforcement and Compliance Docket and Information Center, Mail Code: 2201T, 1200 Pennsylvania Ave., NW., Washington, DC 20460; and (2) OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Maureen Lydon, Office of Compliance, Mail Code 2221A, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 564–4046; fax number: (202) 564–0027; e-mail address: *lydon.maureen@epa.gov*.

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On May 13, 2004 (69 FR 26598), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments.

EPA has established a public docket for this ICR under Docket ID No. OECA–2004–0027, which is available for public viewing at the Enforcement and Compliance Docket and Information Center in the EPA Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center 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 Reading Room is (202) 566–1744, and the telephone number for the Enforcement and Compliance Docket and Information Center is (202) 566–1752. An electronic version of the public docket is available through EPA Dockets (EDOCKET) at *http://www.epa.gov/edocket*. Use EDOCKET to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search," then key in the docket ID number identified above.

Any comments related to this ICR should be submitted to EPA and OMB within 30 days of this notice. EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EDOCKET as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose public disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EDOCKET. The entire printed comment, including the copyrighted material, will be available in the public docket. Although identified as an item in the official docket, information claimed as CBI, or whose disclosure is otherwise restricted by statute, is not included in the official public docket, and will not be available for public viewing in EDOCKET. For further information about the electronic docket, *see* EPA's **Federal Register** notice describing the electronic docket at 67 FR 38102 (May 31, 2002), or go to *http://www.epa.gov/edocket*.

Title: Evaluation of PrintSTEP (Renewal).

Abstract: Information will be collected for the evaluation of the PrintSTEP pilot program in New Hampshire and St. Louis, Missouri. PrintSTEP stands for "Printers Simplified Total Environmental Partnership" and is the first simplified program for managing the various environmental regulatory requirements for printers. PrintSTEP's two-year pilot has four features: operational flexibility, incentives for and assistance with pollution prevention activities, regulatory simplification, and public participation. The evaluation will determine the extent to which the goals of the pilot program are met. These goals are: enhanced environmental protection; increased use of pollution prevention practices; simplified regulatory process for printers; improved efficiency of administration of state agencies; enhanced public involvement; participants realize benefits and are motivated to participate in PrintSTEP; and cost effectiveness for all stakeholders. The evaluation encompasses a baseline survey, mid-point review, and end-of-pilot survey. The baseline survey and mid-point review will have been completed by the time the current ICR expires. So, the proposed ICR is necessary for the end-of-pilot survey of the 56 printers voluntarily participating in the pilot. There are also 2 state agencies implementing the pilot which will assist the participating printers, provide supplementary data to EPA and answer some end-of-pilot survey questions directed towards the states. The lessons learned from the pilot will be shared with states interested in establishing PrintSTEP-like programs and may be translated into a guide for developing, implementing and evaluating pilot programs.

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 40 CFR are listed in 40 CFR part 9 and are identified on the form and/or instrument, if applicable.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 2.5 hours per response. Burden means the 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.

Respondents/Affected Entities: The affected entities are the 56 printing facilities which are participating in the PrintSTEP pilot in New Hampshire and St. Louis, Missouri, as well as the 2 State agencies implementing the pilots.

Estimated Number of Respondents: 58.

Frequency of Response: One-time response at the end of the pilot (including response to telephone survey and submission of written information).

Estimated Total Annual Hour Burden: 143 hours.

Estimated Total Annual Cost: $5,000, includes $0 annual capital/startup and $O&M costs.

Changes in the Estimates: There is a decrease of 1,857 hours in the total estimated burden currently identified in the OMB Inventory of Approved ICR Burdens. Originally, the evaluation approach was going to include the use of a control group of printers. It was determined that this approach was not feasible. The decrease in hours is the result of not using a control group, as well as knowing the final number of printers who will be subject to the evaluation.

Dated: September 22, 2004.

Oscar Morales,

Director, Collection Strategies Division.

[FR Doc. 04–22255 Filed 10–1–04; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7824–1]

Notice of a Public Meeting for an Expert Panel Workshop on Lead Service Line Replacement

AGENCY: Environmental Protection Agency.

ACTION: Notice of public meeting.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is convening an expert panel workshop to discuss issues associated with the Lead and Copper Rule (LCR). This workshop will examine and discuss potential issues associated with lead service line replacement including full and partial replacement programs, techniques, testing, sampling protocols, identification of lead service lines, and managing inventory.

DATES: The workshop on Lead Service Line Replacement will be held on Tuesday, October 26, 2004, from 8 a.m. to 5 p.m., Eastern time (ET) and Wednesday, October 27, 2004, from 8 a.m. to 1 p.m., ET.

ADDRESSES: The workshop will be held at the Atlanta Airport Marriott, 4711 Best Road College Park, GA 30337 USA.

FOR FURTHER INFORMATION CONTACT: To attend this workshop as an observer, please contact Donna Strahm at 503–223–3033 between 11 a.m. and 7 p.m. (ET), or by e-mail: *donna.strahm@hdrinc.com*. For administrative meeting information, call Brian Murphy, HDR/ Economic and Engineering Services, Inc., at 503–223–3033, or by e-mail *brian.murphy@hdrinc.com*. For technical information, contact Kylee Dewis, Office of Water, Office of Ground Water and Drinking Water, U.S. EPA, 1200 Pennsylvania Ave., NW., Mail Code 4607M, Washington, DC 20460, at 202–564–2072, or by e-mail at *dewis.kylee@epa.gov*.

SUPPLEMENTARY INFORMATION: Members of the public may attend as observers at the workshop and provide comments during 30-minute periods each on Tuesday and Wednesday. Individual comments should be limited to no more than 5 minutes. There is no charge for attending this workshop as an observer, but seats are limited, so register as soon as possible. Any person needing special accommodations at any of these meetings, including wheelchair access, should make this known at the time of registration.

Dated: September 28, 2004.

Cynthia C. Dougherty,

Director, Office of Ground Water and Drinking Water.

[FR Doc. 04–22238 Filed 10–1–04; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0345; FRL–7683–6]

Pesticide Program Dialogue Committee and Endangered Species Workshop; Notice of Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA's Pesticide Program Dialogue Committee (PPDC) will hold a public meeting on October 21 and 22, 2004. An agenda is being developed and will be posted on EPA's website by October 7. Agenda topics will include a report from PPDC's Registration Review Work Group; a preview of the pesticide program's budget; the Pesticide Safety Education Program; endangered species; brief updates on human testing, anticipated residue policy, termiticide bait draft Pesticide Registration Notice, and activity-based re-entry intervals (REI's). There will also be brief reports from the Committee's other Work Groups, the PRIA (Pesticide Registration Improvement Act) Process Improvements Work Group and the Consumer Pesticide Label Improvement Work Group, as well as a presentation on tribal pesticide program issues. On October 20, the day preceding the PPDC meeting, there will be an Endangered Species Workshop which is also open to the public. The Workshop will involve discussion of a case study using a specific pesticide to demonstrate how the Agency conducts screening level and species-specific assessments following the Technical Overview document which can be found at: *http://www.epa.gov/espp/consultation/ecorisk-overview.pdf*.

DATES: The PPDC meeting will be held on Thursday, October 21, 2004, from 9 a.m. to 5:15 p.m. and on Friday, October 22, 2004, from 9 a.m. to 12:45 p.m.

The Endangered Species Workshop will be held on Wednesday, October 20, 2004, from 9 a.m. to 5 p.m.

ADDRESSES: Both the PPDC meeting and Workshop will be held at the Radisson Hotel Old Town, 901 N Fairfax St., Alexandria, VA 22314. The hotel telephone number is (703) 683–6000. The Radisson is 12 blocks from the Braddock Road Metro station (on the blue and yellow lines) and two miles from Ronald Reagan National Airport, with courtesy transportation available from the airport and its Metro station.

FOR FURTHER INFORMATION CONTACT: Margie Fehrenbach, Office of Pesticide Programs, Mail code 7501C, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–4775; fax number: (703) 308–4776; e-mail address: *Fehrenbach.Margie@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of particular interest to persons who work in agricultural settings or persons who are concerned about implementation of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); the Federal Food, Drug, and Cosmetic Act (FFDCA); and the amendments to both of these major pesticide laws by the Food Quality Protection Act (FQPA) of 1996. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this

action. Potentially affected entities may include but are not limited to: Agricultural workers and farmers; pesticide industry and trade associations; environmental, consumer, and farmworker groups; pesticide users and growers; pest consultants; State, local, and Tribal governments; academia; public health organizations; food processors; and the public. 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 Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP–2004–0345. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing 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.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at *http://www.epa.gov/fedrgstr/.*

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select "search," then key in the appropriate docket ID number.

II. Background

EPA's Office of Pesticide Programs is entrusted with responsibility to help ensure the safety of the American food supply, the education and protection from unreasonable risk of those who apply or are exposed to pesticides occupationally or through use of products, and general protection of the environment and special ecosystems from potential risks posed by pesticides.

PPDC was established under the Federal Advisory Committee Act (FACA), Public Law 92–463, in September 1995, for a 2–year term and has been renewed every 2 years since that time. PPDC provides advice and recommendations to the Office of Pesticide Programs on a broad range of pesticide regulatory, policy, and program implementation issues that are associated with evaluating and reducing risks from use of pesticides. The following sectors are represented on the PPDC: Pesticide industry and trade associations; environmental/public interest and consumer groups; farm worker organizations; pesticide user, grower, and commodity groups; Federal and State/local/Tribal governments; the general public; academia; and public health organizations.

Copies of the PPDC Charter are filed with appropriate committees of Congress and the Library of Congress and are available upon request.

List of Subjects

Environmental protection, Agricultural workers, Agriculture, Chemicals, Foods, Pesticides, Pests, Public health, Risk assessment, Tolerance reassessment.

Dated: September 27, 2004.

James Jones,

Director, Office of Pesticide Programs.

[FR Doc. 04–22236 Filed 10–1–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPPT–2004–0115; FRL–7682–9]

Forum on State and Tribal Toxics Action; Notice of Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is announcing the meeting of the Forum on State and Tribal Toxics Action (FOSTTA) to collaborate on environmental protection and pollution prevention issues. Representatives and invited guests of the Chemical Information and Management Project, the Pollution Prevention Project, and the Tribal Affairs Project (TAP), components of FOSTTA, will be meeting October 18-19, 2004. The meeting is being held to provide participants an opportunity to have in-depth discussions on the environment and human health issues. This notice announces the location and times for the meeting and sets forth some tentative agenda topics. EPA invites all interested parties to attend the public meeting.

DATES: The three projects will meet on Monday, October 18, 2004, from 9:45 a.m. to 5:00 p.m., and on Tuesday, October 19, 2004, from 8 a.m. to noon. A plenary session is being planned for the participants on the Integrated Toxics Management Project on Monday, October 18, 2004, from 8 a.m. to 9:30 a.m.

Requests to participate in the meeting, identified by docket identification (ID) number OPPT–2004–0115, must be received on or before October 14, 2004.

ADDRESSES: The meeting will be held at the Phoenix Park Hotel, 520 North Capitol Street, NW., Washington, DC.

Requests to participate in the meeting may be submitted to the technical person listed under **FOR FURTHER INFORMATION CONTACT.**

FOR FURTHER INFORMATION CONTACT: *For general information contact*: Colby Lintner, Regulatory Coordinator, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 554–1404; e-mail address: *TSCA-Hotline@epa.gov.*

For technical information contact: Darlene Harrod, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 564–8814; e-mail address: *harrod.darlene@epa.gov.*

Margaret Sealey, Environmental Council of the States, 444 North Capitol Street, NW., Suite 445, Washington, DC 20001; telephone number: (202) 624–3661; fax number: (202) 624–3662; e-mail address: *msealey@sso.org.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are interested in FOSTTA and hearing about the perspectives of the states and tribes on EPA programs and information exchange regarding important issues related to human health and environmental exposure to toxic chemicals. Potentially affected entities may include, but are not limited to:

- States and federally recognized tribes
- State, federal, and local environmental and public health organizations

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. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket ID number OPPT–2004–0115. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the EPA Docket Center, Rm. B102-Reading Room, EPA West, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The EPA Docket Center Reading Room telephone number is (202) 566–1744 and the telephone number for the OPPT Docket, which is located in the EPA Docket Center, is (202) 566–0280.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at *http://www.epa.gov/fedrgstr/.*

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select "search," then key in the appropriate docket ID number.

II. Background

The Toxic Substances Control Act, 15 U.S.C. 2609, section 10(g), authorizes EPA and other federal agencies to establish and coordinate a system for exchange among federal, state, and local authorities of research and development results respecting toxic chemical substances and mixtures, including a system to facilitate and promote the development of standard data format and analysis and consistent testing procedures. Through FOSTTA, the Chemical Information and Management Project (CIMP) focuses on EPA's chemical program and works to develop a more coordinated effort involving federal, state, and tribal agencies. The Pollution Prevention (P2) Project promotes the prevention ethic across society, helping companies incorporate P2 approaches and techniques and integrating P2 into mainstream environmental activities at both the federal level and among the states and tribes. The TAP concentrates on chemical and pollution prevention issues that are most relevant to the tribes, including lead control and abatement, tribal traditional/subsistence lifeways, and hazard communications and outreach. FOSTTA's vision is to focus on major policy-level issues of importance to states and tribes, recruit more senior state and tribal leaders, increase outreach to all 50 states and some 560 federally recognized tribes, and vigorously seek ways to engage the states and tribes in ongoing substantive discussions on complex and oftentimes controversial environmental issues.

In January 2002, the Environmental Council of the States (ECOS), in cooperation with the National Tribal Environmental Council (NTEC), was awarded the new FOSTTA cooperative agreement. ECOS, NTEC, and EPA's Office of Pollution Prevention and Toxics (OPPT) are co-sponsoring the meetings. As part of a cooperative agreement, ECOS facilitates ongoing efforts of the state and tribal leaders and OPPT to increase understanding and improve collaboration on toxic chemicals and pollution prevention issues, and to continue a dialogue on how federal environmental programs can best be implemented among the states, tribes, and EPA.

III. How Can I Request to Participate in this Meeting?

You may submit a request to participate in this meeting to the technical person listed under **FOR FURTHER INFORMATION CONTACT.** Do not submit any information in your request that is considered CBI. Requests to participate in the meeting, identified by docket ID number OPPT–2004–0115, must be received on or before October 14.

IV. The Meeting

In the interest of time and efficiency, the meetings are structured to provide maximum opportunity for state, tribal, and EPA participants to discuss items on the predetermined agenda. At the discretion of the chair, an effort will be made to accommodate participation by observers attending the proceedings. The FOSTTA representatives and EPA will collaborate on environmental protection and pollution prevention issues. The tentative agenda items identified by the states and the tribes follow:

1. High Production Volume (HPV) Challenge Program database demonstration
2. Moving the HPV outreach plan from strategy to implementation
3. Multimedia Pollution Prevention Forum (M2P2) presentation
4. Performance Partnership Grants (PPG) guidance for FY 2005
5. TAP working plan
6. Tribal college Interagency Personnel Agreement (IPA) proposal

List of Subjects

Environmental protection, Pollution prevention, Chemical information and management.

Dated: September 24, 2004.

Barbara A. Cunningham,

Director, Environmental Assistance Division, Office of Pollution Prevention and Toxics.

[FR Doc. 04–22237 Filed 10–1–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7823–5]

Papers Addressing Scientific Issues in the Risk Assessment of Metals

AGENCY: Environmental Protection Agency.

ACTION: Notice of availability.

SUMMARY: The Environmental Protection Agency (EPA) today announces the availability of five scientific papers on metals risk assessment. The papers include: (1) Issue Paper on the Environmental Chemistry of Metals; (2) Issue Paper on Metal Exposure Assessment; (3) Issue Paper on the Ecological Effects of Metals; (4) Issue Paper on the Human Health Effects of Metals; and (5) Issue Paper on the Bioavailability and Bioaccumulation of

Metals. Development of these papers was led by Eastern Research Group Inc., a contractor to EPA. These papers will inform EPA's continuing discussion of practices and methods for the risk assessment of metals.

DATES: The scientific papers will be available on or about October 4, 2004.

ADDRESSES: The issue papers are available primarily via the Internet on the Risk Assessment Forum's Web page *http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=86119*. A limited number of paper copies will be available from the EPA's National Service Center for Environmental Publications (NSCEP), P.O. Box 42419, Cincinnati, OH 45242; telephone: 1–800–490–9198 or 513–489–8190; facsimile: 513–489–8695. Please provide your name and mailing address and the title and EPA number of the requested publication, "Papers Addressing Scientific Issues in the Risk Assessment of Metals" (EPA/630/R–04/118).

FOR FURTHER INFORMATION CONTACT: For technical information, contact Dr. William P. Wood, Executive Director, Risk Assessment Forum, National Center for Environmental Assessment, Office of Research and Development; telephone: (202) 564–3361; facsimile: (202) 565–0062; or e-mail: *risk.forum@epa.gov@epa.gov*.

SUPPLEMENTARY INFORMATION: EPA has recognized the need for consistent application of methods and data to metals risk assessment in consideration of the unique properties of metals. Early in 2002, the Agency's Science Policy Council initiated the development a framework to assess the risks of metals to humans and the environment. An Agency Action Plan was developed and reviewed by EPA's Science Advisory Board (SAB) in September 2002. The SAB emphasized the importance of focusing on the unique properties of metals as they relate to environmental chemistry, bioavailability, bioaccumulation, exposure, and toxicity. The SAB also emphasized the importance of engaging the outside community so as to contribute to the knowledge base the Agency would draw from in developing guidance on the risk assessment of metals.

To inform the consideration of metals properties, and to engage the external scientific community, the Agency commissioned external experts to lead the development of a series of issue papers. (Some individual EPA experts contributed specific discussions on topic(s) for which he or she has scientific expertise or knowledge of current Agency practice.) A public comment period was held on the draft papers from September 22 through November 7, 2003, wherein comments were collected utilizing the Agency's on-line commenting system (E–Docket). Additionally, comment was received via a public meeting held October 28, 2003, in Washington, DC (comments remain available for viewing at *www.epa.gov/edocket*, Docket Number OAR–2003–0192.) Comments were requested on technical issues including the level of detail in the papers, the chemical, biological and physical processes addressed or omitted, models and approaches that might reduce uncertainty, and other considerations that would improve the utility of the papers to the development of the framework. To finalize the papers, authors were directed to EPA's E–Docket to review and consider public comments received. The final papers reflect the authors responses to scientific comments received during the public comment period. Therefore, the views expressed are those of the authors and do not necessarily reflect the views or policies of the EPA and should not be construed as implying EPA consent or endorsement.

Having engaged the external community to broaden our knowledge base, the Agency is working to develop a framework for metals risk assessment. The framework will be provided for public comment, and SAB review.

Dated: September 27, 2004.

Peter W. Preuss,

Director, National Center for Environmental Assessment.

[FR Doc. 04–22254 Filed 10–1–04; 8:45 am]

BILLING CODE 6560–50–P

EXECUTIVE OFFICE OF THE PRESIDENT

Office of Administration; Notice of Meeting of the Commission on the Intelligence Capabilities of the United States Regarding Weapons of Mass Destruction

ACTION: Notice.

SUMMARY: The Commission on the Intelligence Capabilities of the United States Regarding Weapons of Mass Destruction ("Commission") will meet in closed session on Wednesday, October 20, 2004, and Thursday, October 21, 2004, in its offices in Arlington, Virginia.

Executive Order 13328 established the Commission for the purpose of assessing whether the Intelligence Community is sufficiently authorized, organized, equipped, trained, and resourced to identify and warn in a timely manner of, and to support the United States Government's efforts to respond to, the development of Weapons of Mass Destruction, related means of delivery, and other related threats of the 21st Century. This meeting will consist of briefings and discussions involving classified matters of national security, including classified briefings from representatives of agencies within the Intelligence Community; Commission discussions based upon the content of classified intelligence documents the Commission has received from agencies within the Intelligence Community; and presentations concerning the United States' intelligence capabilities that are based upon classified information. While the Commission does not concede that it is subject to the requirements of the Federal Advisory Committee Act (FACA), 5 United States Code Appendix 2, it has been determined that the October 20–21 meeting would fall within the scope of exceptions (c)(1) and (c)(9)(B) of the Sunshine Act, 5 United States Code, Sections 552b(c)(1) & (c)(9)(B), and thus could be closed to the public if FACA did apply to the Commission.

DATES: Wednesday, October 20, 2004 (9 a.m. to 5 p.m.) and Thursday, October 21, 2004 (9 a.m. to 1 p.m.).

ADDRESSES: Members of the public who wish to submit a written statement to the Commission are invited to do so by facsimile at (703) 414–1203, or by mail at the following address: Commission on the Intelligence Capabilities of the United States Regarding Weapons of Mass Destruction, Washington, DC 20503. Comments also may be sent to the Commission by e-mail at *comments@wmd.gov*.

FOR FURTHER INFORMATION CONTACT: Brett C. Gerry, Associate General Counsel, Commission on the Intelligence Capabilities of the United States Regarding Weapons of Mass Destruction, by facsimile, or by telephone at (703) 414–1200.

Victor E. Bernson, Jr.

Executive Office of the President, Office of Administration, General Counsel.

[FR Doc. 04–22218 Filed 10–1–04; 8:45 am]

BILLING CODE 3130–W4–P

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection(s) Requirement Submitted to OMB for Emergency Review and Approval

September 28, 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 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 (PRA) 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 comments should be submitted on or before November 3, 2004. 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 contacts listed below as soon as possible.

ADDRESSES: Direct all comments to Kristy L. LaLonde, Office of Management and Budget (OMB), Room 10236 NEOB, Washington, DC 20503, (202) 395–3087 or via the Internet at *Kristy_L._LaLonde@omb.eop.gov*, and Les Smith, Federal Communications Commission, Room 1–A804, 445 12th Street, SW., Washington, DC 20554 or via Internet to *Leslie.Smith@fcc.gov*.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collections contact Les Smith at (202) 418–0217 or via Internet at *Leslie.Smith@fcc.gov*.

SUPPLEMENTARY INFORMATION: The Commission has requested approval of these two information collections under the emergency processing provisions of the PRA by September 28, 2004.

OMB Control Number: 3060–0027.

Title: Application for Construction Permit for Commercial Broadcast Station, FCC Form 301.

Form Number: FCC 301.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities; Not-for-profit institutions.

Number of Respondents: 3,247.

Estimated Hours per Response: 2 to 4 hours.

Frequency of Response: On occasion requirements; Third party disclosure.

Total Annual Burden: 8,380 hours.

Total Annual Cost: $44,630,924.00.

Privacy Impact Assessment: No impact(s).

Needs and Uses: FCC Form 301 is used to apply for authority to construct a new commercial AM, FM, or TV broadcast station, or to make changes in existing facilities of such a station. In addition, FM licensees or permittees may request, by application on FCC Form 301, upgrades on adjacent and co-channels, modifications to adjacent channels of the same class and downgrades to adjacent channels without first submitting a petition for rulemaking. All applicants using this one-step process must demonstrate that a suitable site exists which would comply with allotment standards with respect to minimum distance separation and city-grade coverage and which would be suitable for tower construction. To receive authorization for commencement of Digital Television ("DTV") operation, commercial broadcast licensees must file FCC Form 301 for a construction permit. This application may be filed anytime after receiving the initial DTV allotment but must be filed before mid-point in a particular applicant's required construction period. The Commission will consider these applications as minor changes in facilities. Applications will not have to supply full legal or financial qualification information.

On June 24, 2004, the U. S. Court of Appeals for the Third Circuit (the "Court") issued an Opinion and Judgment ("*Remand Order*") in which it upheld certain aspects of the new Commission's ownership rules adopted on June 2, 2003 (See 18 FCC Rcd 13620 (2003)), specifically those dealing with local radio ownership, while requiring further explanation for all other aspects of the new rules. The Court stated that its prior stay of all the new rules would remain in effect pending the outcome of the remand proceeding. The Commission filed a petition for rehearing requesting that the Court lift the stay partially—*i.e.*, with respect to the radio ownership rules which the Court's *Remand Order* upheld. In the *Rehearing Order*, the Court granted the petition, thus partially lifting the stay. As a result of the *Rehearing Order*, the new radio ownership rules took effect September 3, 2004.

OMB Control Number: 3060–0031.

Title: Application for Consent to Assignment of Broadcast Station Construction Permit or License, FCC Form 314.

Form Number: FCC 314.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities and Not-for-profit institutions.

Number of Respondents: 2,225.

Estimated Hours per Response: 1—2 hours.

Frequency of Response: On occasion reporting requirement, Third party disclosure.

Total Annual Burden: 3,990 hours.

Total Annual Cost: $16,017,631.25.

Privacy Impact Assessment: No impact(s).

Needs and Uses: FCC Form 314 and applicable exhibits/explanations are required to be filed when applying for consent for assignment of an AM, FM, or TV broadcast station construction permit or license. In addition, the applicant must notify the Commission when an approved assignment of a broadcast station construction permit or license has been consummated.

This collection also includes the third party disclosure requirement of 47 CFR 73.3580. This section requires local public notice in a newspaper of general circulation of the filing of all applications for assignment of license/permit. This notice must be completed within 30 days of the tendering of the application. This notice must be published at least twice a week for two consecutive weeks in a three-week period. A copy of this notice must be placed in the public inspection file along with the application. Additionally, an applicant for assignment of license must broadcast the same notice over the station at least once daily on four days in the second week immediately following the tendering for filing of the application.

On June 24, 2004, the U.S. Court of Appeals for the Third Circuit (the "Court") issued an Opinion and Judgment ("*Remand Order*") in which it upheld certain aspects of the new Commission's ownership rules adopted on June 2, 2003 (*See* 18 FCC Rcd 13620 (2003)), specifically those dealing with local radio ownership, while requiring further explanation for all other aspects of the new rules. The Court stated that its prior stay of all the new rules would remain in effect pending the outcome of the remand proceeding. The Commission filed a petition for rehearing requesting that the Court lift the stay partially—*i.e.*, with respect to the radio ownership rules which the Court's *Remand Order* upheld. In the *Rehearing Order*, the Court granted the petition, thus partially lifting the stay.

As a result of the *Rehearing Order*, the new radio ownership rules took effect September 3, 2004.

OMB Control Number: 3060–0032.

Title: Application for Consent to Transfer Control of Entity Holding Broadcast Station Construction Permit or License, FCC Form 315.

Form Number: FCC 315.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities and Not-for-profit institutions.

Number of Respondents: 2,225.

Estimated Time per Response: 1-2 hours.

Frequency of Response: On occasion reporting requirement; Third party disclosure.

Total Annual Burden: 3,990 hours.

Total Annual Cost: $16,017,631.25.

Privacy Impact Assessment: No impact(s).

Needs and Uses: FCC Form 315 and applicable exhibits/explanations are required to be filed when applying for transfer of control of a corporation holding an AM, FM, or TV broadcast station construction permit or license. In addition, the applicant must notify the Commission when an approved transfer of control of a broadcast station construction permit or license has been consummated.

This collection also includes the third party disclosure requirement of 47 CFR 73.3580. This section requires local public notice in a newspaper of general circulation of the filing of all applications for transfer of control of license/permit. This notice must be completed within 30 days of the tendering of the application. This notice must be published at least twice a week for two consecutive weeks in a three-week period. A copy of this notice must be placed in the public inspection file along with the application. Additionally, an applicant for transfer of control of license must broadcast the same notice over the station at least once daily on four days in the second week immediately following the tendering for filing of the application.

On June 24, 2004, the U. S. Court of Appeals for the Third Circuit (the "Court") issued an Opinion and Judgment ("*Remand Order*") in which it upheld certain aspects of the new Commission's ownership rules adopted on June 2, 2003 (*See* 18 FCC Rcd 13620 (2003)), specifically those dealing with local radio ownership, while requiring further explanation for all other aspects of the new rules. The Court stated that its prior stay of all the new rules would remain in effect pending the outcome of the remand proceeding. The Commission filed a petition for rehearing requesting that the Court lift the stay partially—*i.e.*, with respect to the radio ownership rules which the Court's *Remand Order* upheld. In the *Rehearing Order*, the Court granted the petition, thus partially lifting the stay. As a result of the *Rehearing Order*, the new radio ownership rules took effect September 3, 2004.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 04–22227 Filed 10–1–04; 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 October 28, 2004.

A. Federal Reserve Bank of Philadelphia (Michael E. Collins, Senior Vice President) 100 North 6th Street, Philadelphia, Pennsylvania 19105–1521:

1. Fulton Financial Corporation, Lancaster, Pennsylvania; to merge with First Washington Financial Corp., Windsor, New Jersey, and thereby indirectly acquire First Washington State Bank, Windsor, New Jersey.

B. Federal Reserve Bank of Atlanta (Sue Costello, Vice President) 1000 Peachtree Street, N.E., Atlanta, Georgia 30303:

1. Synovus Financial Corp., Columbus, Georgia; to acquire 100 percent of the voting shares of Cohutta Banking Company of Tennessee, Chattanooga, Tennessee, a *de novo* bank.

Board of Governors of the Federal Reserve System, September 28, 2004.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 04–22178 Filed 10–1–04; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Notice of Proposals to Engage in Permissible Nonbanking Activities or to Acquire Companies that are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y (12 CFR Part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act. 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 the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than October 18, 2004.

A. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166–2034:

1. Cass Information Systems, Inc., Bridgeton, Missouri; to acquire substantially all of the assets of NTransit, Inc., and NTransit, LLC, Wellington, Kansas, and thereby engage in data processing and management consulting activities, pursuant to sections 225.28(b)(9)(i)(A)(2) and (b)(14)(i) of Regulation Y.

Board of Governors of the Federal Reserve System, September 28, 2004.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 04–22177 Filed 10–1–04; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Federal Open Market Committee; Domestic Policy Directive of August 10, 2004

In accordance with § 271.25 of its rules regarding availability of information (12 CFR part 271), there is set forth below the domestic policy directive issued by the Federal Open Market Committee at its meeting held on August 10, 2004.[1]

The Federal Open Market Committee seeks monetary and financial conditions that will foster price stability and promote sustainable growth in output. To further its long–run objectives, the Committee in the immediate future seeks conditions in reserve markets consistent with increasing the federal funds rate to an average of around 1-1/2 percent.

By order of the Federal Open Market Committee, September 27, 2004.

Vincent R. Reinhart,

Secretary, Federal Open Market Committee.

[FR Doc. 04–22208 Field 10–1–04; 8:45 am]

BILLING CODE 6210–01–S

[1] Copies of the Minutes of the Federal Open Market Committee meeting on August 10, 2004, which includes the domestic policy directive issued at the meeting, are available upon request to the Board of Governors of the Federal Reserve System, Washington, D.C. 20551. The minutes are published in the Federal Reserve Bulletin and in the Board's annual report.

GENERAL SERVICES ADMINISTRATION

Office of the Chief Acquisition Officer; Industry Day to Provide Information to Vendors on FAI/DAU Training Plans and Requirements

AGENCY: Office of the Chief Acquisition Officer, GSA.

ACTION: Notice of Industry Day.

SUMMARY: The Federal Acquisition Institute (FAI) intends to hold an Industry Day for interested vendors to provide information related to FAI's initiatives and activities under the Acquisition Workforce Training Fund (AWTF). FAI will describe our plans and requirements for training related services. DAU will present information on recent contracting curriculum changes.

DATES: Industry Day is scheduled for October 13, 2004, from 10:00 a.m. to 12:00 noon at the following location: SRA's Fair Lakes North-C Presentation Center, 4350 Fair Lakes Court (Receptionist, 2nd Floor), Fairfax, Virginia 22033.

Interested parties may register by e-mail at Jamie.ready@gsa.gov, or telephone (202) 219-3454.

FOR FURTHER INFORMATION CONTACT: Ms. Jamie Ready, Federal Acquisition Institute, General Services Administration, via telephone at (202) 703-219-3454; e-mail at Jamie.ready@gsa.gov; or fax at (202) 501-3341.

SUPPLEMENTARY INFORMATION: FAI works in partnership with the Defense Acquisition University (DAU). DAU provides mandatory, assignment-specific, and continuing education courses for military and civilian acquisition personnel within the Department of Defense. As part of Industry Day, DAU will present information on recent contracting curriculum changes.

Who should attend? Training developers, vendors with Commercial-Off-The-Shelf (COTS) training products, and vendors with capabilities related to the full instructional system design (ISD) methodologies, and acquisition experts.

FAI's mission is to foster and promote the development of a professional acquisition workforce into effective business leaders. Section 1412 of the National Defense Authorization Act for Fiscal Year 2004 (H.R. 1588) authorized an Acquisition Workforce Training Fund (AWTF) "to ensure that the Federal acquisition workforce adapts to fundamental changes in the nature of Federal Government acquisition of property and services associated with the changing roles of the Federal Government; and acquires new skills and a new perspective to enable it to contribute effectively in the changing environment of the 21st century." FAI will use the fund to develop training resources needed to enable federal acquisition professionals to transition to a service oriented and technology driven federal market.

FAI coordinates with the Office of Federal Procurement Policy (OFPP), the FAI Board of Directors and the Chief Acquisition Officers (CAO) Council, and DAU to identify training needs and set priorities for use of the fund. OFPP provides guidance on Administration initiatives and new issues in acquisition.

Dated: September 29, 2004

Gloria Sochon,

Program Manager, Federal Acquisition Institute, Office of the Chief Information Officer

[FR Doc. 04–22242 Filed 10–1–04; 8:45 am]

BILLING CODE 6820–EP–S

OFFICE OF GOVERNMENT ETHICS

Updated OGE Senior Executive Service Performance Review Board

AGENCY: Office of Government Ethics (OGE).

ACTION: Notice.

SUMMARY: Notice is hereby given of the appointment of members of the updated OGE Senior Executive Service (SES) Performance Review Board.

EFFECTIVE DATE: October 4, 2004.

FOR FURTHER INFORMATION CONTACT: Daniel D. Dunning, Deputy Director for Administration and Information Management, Office of Government Ethics, Suite 500, 1201 New York Avenue, NW., Washington, DC 20005–3917; Telephone: (202) 482–9300; TDD: (202) 208–9293; FAX: (202) 482–9237.

SUPPLEMENTARY INFORMATION: 5 U.S.C. 4314(c) requires each agency to establish, in accordance with regulations prescribed by the Office of Personnel Management at 5 CFR part 430, subpart C and § 430.310 thereof in particular, one or more Senior Executive Service performance review boards. As a small executive branch agency, OGE has just one board. In order to ensure an adequate level of staffing and to avoid a constant series of recusals, the designated members of OGE's SES Performance Review Board are being drawn, as in the past, largely from the ranks of other agencies. The board shall

review and evaluate the initial appraisal of each OGE senior executive's performance by his or her supervisor, along with any recommendations in each instance to the appointing authority relative to the performance of the senior executive. This notice updates the membership of OGE's SES Performance Review Board as it was last published at 68 FR 60392 (October 22, 2003).

Approved: September 28, 2004.

Marilyn L. Glynn,

Acting Director, Office of Government Ethics.

The following have been selected as regular members of the SES Performance Review Board of the Office of Government Ethics:

John J. Covaleski [Chair], Deputy Director for Agency Programs, Office of Government Ethics;

Stuart D. Rick [Alternate Chair], Deputy General Counsel, Office of Government Ethics;

Joseph E. Gangloff, Senior Counsel, Office of International Affairs, Department of Justice;

Rosalind A. Knapp, Deputy General Counsel, Department of Transportation;

Steven Y. Winnick, Deputy General Counsel, Department of Education.

[FR Doc. 04–22209 Filed 10–1–04; 8:45 am]

BILLING CODE 6345–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Program To Promote Diabetes Education Strategies in Minority Communities: The National Diabetes Education Program

Announcement Type: New.

Funding Opportunity Number: RFA 05014.

Catalog of Federal Domestic Assistance Number: 93.945.

Key Dates

Letter of Intent (LOI) Deadline: October 14, 2004.

Application Deadline: November 18, 2004.

Executive Summary

Diabetes is a serious and costly public health problem in the United States. In November 2003, the number of Americans with diabetes rose to an all time high with an estimated 18.2 million people. Diabetes continues to be the sixth leading cause of death in the United States. An estimated 13 million Americans have been diagnosed with diabetes and about 5.2 million additional Americans have the disease but have not been diagnosed. Diabetes disproportionately affects some ethnic populations such as American Indians/Alaskan Natives, blacks or African Americans, Hispanics or Latinos, Asian Americans, Native Hawaiians and other Pacific Islanders. The Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) joined forces in 1995 to develop the National Diabetes Education Program (NDEP). The NDEP is a collaborative effort based on a partnership of public and private organizations that are concerned about the health status of their constituents. The NDEP is designed to improve treatment and outcomes for people with diabetes, to promote early diagnosis and to prevent the onset of diabetes. The NDEP aims to change the way diabetes is treated by working through its Partnership Network to increase awareness via media campaigns, create tools for community interventions, and promote health systems change for better diabetes management and prevention. It is through this commitment that the NDEP focuses on working with national and regional organizations that demonstrate the ability to reach populations disproportionately affected by diabetes. These organizations are critical partners of the NDEP, and it is through them and other partners that partnerships are formed to extend the reach of NDEP and its impact on reducing the burden of diabetes among racial and ethnic minority populations.

I. Funding Opportunity Description

Authority: This program is authorized under Sections 301(a) and 317(k)(2) of the Public Health Service (PHS) Act, [42 U.S.C. 241(a) and 247b(k)(2)] as amended. Applicable program regulations are found in 45 CFR part 74.

Purpose

The purpose of this program announcement is to support the National Diabetes Education Program (NDEP) activities that strengthen the capacity of national and regional organizations to reduce the disproportionate burden of diabetes among high-risk populations (*e.g.*, American Indians/Alaskan Natives, blacks or African Americans, Hispanics or Latinos, Asian Americans, Native Hawaiians and other Pacific Islanders). This announcement is consistent with CDC's Government Performance and Results Act (GPRA) performance plan. This program addresses the "Healthy People 2010" focus areas of Diabetes, Heart Disease and Stroke, Nutrition and Overweight, Physical Activity and Fitness *http://www.healthypeople.gov.* Online information describing Healthy People 2010 as well as other requirements can be found in section VI.2. Administrative and National Policy Requirements of this document.

Measurable outcomes of the program will be in alignment with the following performance goal for the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) that relates to the NDEP: Increase the capacity of national and regional organizations to address the prevention of diabetes for those at risk and prevention of complications and premature mortality among people with diabetes through awareness and education efforts, including identification and dissemination of lifestyle interventions proven to be effective in preventing or delaying type 2 diabetes.

Activities

Recipient activities for this program are as follows:

A. Implement strategies for promoting diabetes awareness and delivering diabetes education messages, interventions and products to targeted populations using a variety of culturally effective community-based approaches that increase and improve health care utilization within communities. This should include but is not limited to presentations at CDC conferences/meetings and having CDC present at the recipient's conferences/meetings.

B. Establish coalitions and partnerships with community-based organizations (CBOs), State and local health departments, other national and regional organizations and other appropriate organizations. Partner with and engage State diabetes prevention and control programs (DPCPs) to expand programs that capitalize on current diabetes education efforts. Actively bring together members to identify community needs, barriers to care and resources using community mobilization models such as Diabetes Today and Racial and Ethnic Approaches to Community Health (REACH). More information on these programs can be found at *http://www.cdc.gov/diabetes/projects/index.htm.*

C. Develop program activities that are consistent with those proven to be effective for diabetes education within community settings such as Diabetes Today. Include the development of action plans and identify activities to engage affiliates, chapters and community-based organization (CBO)

partners. More information on Diabetes Today can be found at *http://www.diabetestodayntc.org/program_info.htm.*

D. Identify and address the capacity-building needs of your program with the goal of long-term sustainability of activities.

E. Attend and participate in CDC sponsored training and meetings and serve as an active participant on NDEP Workgroups. *See* section VIII. A. Other Information for a description of NDEP Workgroup member roles and responsibilities.

F. Develop and implement community-based intervention strategies which include lifestyle interventions to prevent or delay diabetes that can be designed to improve the knowledge, attitude, skills and behaviors related to the prevention, early detection and control of diabetes complications. These intervention strategies can include new and creative approaches that are coordinated with NDEP Workgroups, supportive of the NDEP Strategic Plan, workgroup goals and objectives. The materials and messages should be linguistically and culturally appropriate.

G. Describe the activities that will be conducted to ensure that proposed activities with partners will work synergistically with existing effective diabetes intervention and strategies.

H. Promote and disseminate NDEP and local diabetes health care resources and educational materials, translate and/or tailor materials into specific languages and utilize existing diabetes awareness messages, interventions, products and strategies that are culturally and linguistically appropriate for the targeted population based on current science.

I. Develop strategies that strengthen relationships with health care providers and assist them in providing culturally and linguistically appropriate diabetes education and support to diverse racial and ethnic minority populations. This may include the production of materials providing current scientific information regarding diabetes (if these materials do not already exist), other chronic diseases linked to diabetes such as cardiovascular disease (heart disease and stroke), high blood pressure and high cholesterol. Provide up-to-date, comprehensive diabetes resource guides, as well as general information on the populations served (*i.e.*, customs, norms and languages spoken). Development of new materials should be coordinated with NDEP Workgroups so that the materials have maximal reach as joint products with NDEP. Any new materials developed should be supportive of the NDEP Strategic Plan, workgroup goals and objectives.

J. Develop a well-designed evaluation plan to monitor the progress and to evaluate the impact of activities and strategies and to measure the accomplishments of the applicant and funded partner CBOs. The evaluation plan should include (but need not be limited to) the following:

1. Identify existing data sources that can be used to establish baseline and evaluate the impact of interventions, possibly including Behavioral Risk Factor Surveillance System (BRFSS) data; hospital discharge data; medical care practice data; vital statistics data; Women, Infants, and Children (WIC) data; community health center data; Medicaid and Medicare data; and other sources of information about community health status, needs, and resources relevant to the NDEP Strategic Plan.

2. Participate in the evaluation of NDEP. The cooperative agreement recipients will be involved in gathering and submitting information on process and impact measures surrounding NDEP initiatives. Recipients will also contribute to other evaluation activities that may include development of tools to assess individual workgroup products and share success stories to support evaluation capacity building within NDEP.

3. Evidence-Based Decisionmaking. Recipients are expected to use all the information above to design and modify program objectives and intervention strategies; participate in pilot testing and implement and evaluate revised materials and interventions created in conjunction with NDEP Workgroups; revise budgets and work plans as needed; and recruit new members to the NDEP Partnership Network.

K. Disseminate pertinent program information to appropriate partner organizations and other agencies at the national, regional, State and local levels.

1. Identify and share promising practices and results including successful strategies for building community engagement, mobilization, ownership, and organization with other NDEP partner organizations in an effort to sustain the program in lieu of NDEP funding.

2. Ensure effective, timely communication and exchange of information, experiences, and results through the use of the Internet (*e.g.*, the NDEP Web Board and *http://www.cdc.gov/diabetes/ndep*); documentation in the CDC Management Information System (MIS), *see* section M; presentations at regional and national meetings on activities including NDEP promotion; workshops relevant to NDEP objectives; and other activities.

L. Respond to public inquiries regarding program activities as appropriate.

M. Management Information System (MIS): The MIS will be used to assist in the post award administration, technical assistance and programmatic decisionmaking processes. Programs will be expected to ensure that information is entered into the MIS in a timely manner. **Note:** Currently, NDEP funded organizations are not using this system; however, a MIS specifically designed for programs funded under this announcement may be implemented before the end of the project period and recipients will be expected to participate. Training will be provided as needed.

N. Demonstrate quality activities linked to two or more of the CDC Division of Diabetes Translation's (DDT) National Objectives (*see* section VIII. B. Other Information). Recipients should document these activities in the program activities section of their application.

In a cooperative agreement, CDC staff is substantially involved in the program activities, above and beyond routine grant monitoring.

CDC Activities for this program are as follows:

A. Ensure that successful prevention interventions, program models and lessons learned are shared between grantees and others through meetings, workshops, conferences, newsletters, Internet and other avenues of communication.

B. Provide periodic updates of national activities related to the prevention and control of diabetes in targeted populations. Provide linkage to communities funded through other mechanisms (*e.g.*, communities funded by the Steps to a Healthier US Initiative *http://www.healthierus.gov/steps/*, community health centers involved in the Diabetes Collaborative *http://www.healthdisparities.net/*) to facilitate on-going evaluation in a collaborative process.

C. Assist in identifying and developing culturally and linguistically appropriate diabetes educational materials for community based programs that reach the targeted populations.

D. Provide programmatic consultation and guidance related to the development, implementation, and evaluation and monitoring of proposed program activities. This includes access to an Evaluation Tool Kit (ETK) developed by CDC DDT personnel to

assist in evaluation strategies and identify sources of data for decisionmaking.

E. Provide technical assistance relative to the coordination of activities between recipients and other national and community programs including State and local health departments to facilitate effective communication and integration between state DPCPs and national and regional organizations.

F. Provide support in the maintenance of an information system for funded organizations to input information for the purpose of planning and sharing. This includes initial training in the use of the MIS and ongoing training updates as needed for new staff or when additional features are installed.

II. Award Information

Type of Award: Cooperative Agreement. CDC involvement in this program is listed in the "Activities" section above.

Fiscal Year Funds: 2005.

Approximate Total Funding: $3,000,000.

Approximate Number of Awards: Six to eight.

Approximate Average Award: $375,000 (This amount is for the first 12-month budget period, and includes both direct and indirect costs).

Floor of Award Range: $250,000.

Ceiling of Award Range: $550,000.

Anticipated Award Date: February 27, 2005.

Budget Period Length: 12 months.

Project Period Length: Up to five years. Throughout the project period, CDC's commitment to continuation of awards will be conditioned on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the Federal government.

III. Eligibility Information

III.1. Eligible Applicants

• Applications may only be submitted by national, regional, State, multi-State, and faith based organizations and institutions that are private health, education or social service organizations (professional or voluntary); qualify as a non-profit 501(c)(3) entity; have affiliate offices or chapters at the local, State and/or regional level in five or more geographically distinct communities serving a high concentration of the targeted population and have the capacity and experience to assist their affiliate offices and chapters. Geographically distinct communities must be located in different areas. Applicants should consider available resources when determining the population size and the number of geographically distinct communities to include in their proposal. Affiliate and chapter offices may not apply in lieu of or on behalf of their parent national office. However, this does not exclude affiliates from assisting with the development of the application.

III.2. Cost Sharing or Matching

Matching funds are not required for this program.

III.3. Other

If you request a funding amount greater than the ceiling of the award range, your application will be considered non-responsive, and will not be entered into the review process. You will be notified that your application did not meet the submission requirements.

If your application is incomplete or non-responsive to the requirements listed in section IV. Application and Submission Information, it will not be entered into the review process. You will be notified that your application did not meet submission requirements.

Note: Title 2 of the United States Code section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, or loan.

IV. Application and Submission Information

IV.1. Address to Request Application Package

To apply for this funding opportunity, use application form PHS 5161. Application forms and instructions are available on the CDC Web site, at the following Internet address: *http://www.cdc.gov/od/pgo/forminfo.htm.* If you do not have access to the Internet, or if you have difficulty accessing the forms on-line, you may contact the CDC Procurement and Grants Office Technical Information Management Section (PGO–TIM) staff at (770) 488–2700. Application forms can be mailed to you.

IV.2. Content and Form of Submission

Letter of Intent (LOI): Your LOI must be written in the following format:

- *Maximum number of pages:* One.
- *Font size:* 12-point unreduced.
- Double spaced.
- *Paper size:* 8.5 by 11 inches.
- *Page margin size:* One inch.
- Printed only on one side of page.
- Written in plain language, avoid jargon.

Your LOI must contain the following information:

- Your organization name, address, executive director and contact information.
- A description of the population your organization plans to target.
- A statement of your intent to apply.
- Indicate whether your agency is a national or regional organization.
- Your application should not accompany your LOI.

Application: You must submit a project narrative with your application forms. The narrative must be submitted in the following format:

- Maximum number of pages: 35.

Note: If your narrative exceeds the page limit, only the first 35 pages will be reviewed.

- *Font size:* 12 point unreduced.
- Doubled spaced.
- *Paper size:* 8.5 by 11 inches.
- *Page margin size:* One inch.
- Printed only on one side of page.
- Held together only by rubber bands or metal clips; not bound in any other way.

Your narrative should address activities to be conducted over the entire project period, and must include the following items in the order listed:

- Justification of Need—Describe the problem(s) being addressed by the proposed activities. Describe the need for the proposed activities in the geographical area(s) within which the activities will be implemented. Who is your proposed target population? Describe the characteristics of the targeted population relative to their racial and ethnic diversity and knowledge, attitudes, beliefs and health practices relative to diabetes.
- Organization Capacity—The purpose of this section is to assess your organization's ability to effectively sustain your proposed program. Describe the organization's mission, structure and function to include:

1. Describe past experience serving racial and ethnic minority populations through its offices, affiliates, chapters or participating organizations at the national/regional level for at least 12 months prior to submission of the application. Please include outcomes or expected outcomes if the project/intervention is ongoing.

2. Number of affiliate or chapter organizations, location of affiliate or chapter organizations, and how affiliates or chapters work with the national and/or regional organization decisions makers, methods of routine communication with affiliates or chapters and description of how the infrastructure will be used to support

successful implementation of the proposed program activities.

3. Describe the organization's past and present abilities to work with affiliates, chapters, CBOs and other governmental and non-governmental organizations including other national or local diabetes related agencies, State diabetes prevention and control programs (DPCPs) and local health departments. Explain how existing effective diabetes messages, interventions and products will be incorporated and how the proposed activities will expand rather than duplicate present activities.

4. Include the nature and extent of affiliates, chapters, etc. support for past and present activities relative to awareness and/or educational activities or describe how affiliates, chapters, etc. support will be obtained for the proposed program activities.

5. Provide a copy of a letter of commitment from the organization's board president or appropriate designee acknowledging their support of the applicant's activities and organization. The letter should address the organization's support and commitment to develop a plan and policy that will be adopted by affiliates, chapter membership organizations and CBO partners. If a diabetes control policy and plan currently exists within the organization's office, it should be submitted in lieu of a letter of commitment.

• Objectives

Objectives are tangible statements that describe the activities the program is attempting to achieve. Objectives should be written in a manner to be evaluated at the conclusion of a project to determine if they were achieved. Relative to objectives the applicant should:

1. Describe the five year (long term) specific, measurable, achievable, relevant, time-phased objectives for the program consistent with the purpose of this program announcement.

2. Describe specific, measurable, achievable, relevant, time-phased objectives for each budget year (short term).

• Program Activities

1. Describe how the affiliates, chapters or CBOs will be involved in the implementation of the proposed program activities.

2. Describe the specific activities that will be undertaken to achieve each of the program's objectives during the first year consistent with the recipient activities.

3. Briefly describe the activities planned for budget years two through five. Include the linkages to the Division of Diabetes Translation (DDT) National Objectives.

• Project Management

1. Submit a work plan that outlines the main implementation steps and activities to be completed by recipient and affiliates, chapters, or partner CBOs by specified targeted dates to achieve the objectives for the budget year. Identify the name(s) or position(s) responsible for carrying out the activities.

2. Describe each proposed position for this program that will support this work plan by job title, function, general duties and the responsibilities of the position.

3. Describe the qualifications for the project coordinator position in terms of education, experience and desired skills.

4. Include the level of effort and allocation of time for each project activity by staff position.

Minimal staffing should include a full-time project coordinator and one program assistant.

• Program Evaluation Plan

This section should be described in terms of how the recipient will engage in the six-step CDC Framework for Evaluation: engage stakeholders, describe the program, spotlight the evaluation design, gather credible evidence, justify conclusions and ensure use and share lessons learned. More information on this evaluation framework can be found at: *http://www.cdc.gov/eval/steps.htm.* Additionally, recipients will be responsible for working with appropriate NDEP Workgroup(s) to develop evaluation plans designed to measure process and impact measures for implementation of NDEP.

1. Identify methods for attaining measurable, time phased short and long term objectives. Identify methods for accomplishing program activities and monitoring program quality. The evaluation plan should include qualitative and quantitative data collection and assessment methods. As appropriate, this plan should include baseline data for the proposed objectives or the methods that will be used to establish the baseline data; the minimum data to be collected to evaluate the achievement of proposed program objectives; and the systems for collecting and analyzing the data. Data to be reported will be dependent on the proposed program objectives and activities; however, examples of potential data include, but are not limited to the following:

a. The number of individuals expected to be reached in the targeted population and the plan for evaluating the number actually reached.

b. Information about the national, regional, state and local health organizations, providers reached and populations served.

c. Number and types of community activities implemented (when, where, and how activities are conducted).

d. Information on the change in knowledge, attitudes and self-management and/or care utilization practices among people with diabetes.

e. Information on the number of affiliates, chapters, organizations, coalitions and partnerships that are participating in program activities and how activities complement national education efforts.

• Budget and Narrative Justification

1. Provide a detailed line-item budget and justification for all operating expenses consistent with the proposed objectives and activities. Provide precise information regarding the purpose of each budget item and provide itemized calculations when appropriate.

2. Applicants should budget for the following cost: Out-of-state travel, participation in CDC sponsored trainings, workshops and meetings. Travel funds should be budgeted for:

a. Two persons to attend the CDC Diabetes Translation Conference held during the spring (4 days).

b. At least one person to attend one NDEP Minority Workgroup face-to-face meeting (2 days).

c. At least one person to attend NDEP Steering Committee meetings (twice a year: 1–2 days).

d. At least one person to attend the Division of Diabetes Translation Annual Program Director's meeting. (3 days).

e. Two persons to attend the first year program orientation meeting, preferably attended by the program coordinator and evaluation lead (2 days).

f. Organizations are also encouraged to attend and participate in non-conference training such as Diabetes Today and the Diabetes Collaborative which is relevant to the goals and objectives of NDEP.

3. Local travel as necessary to meet program objectives and activities.

• Additional information may be included in the application appendices. The appendices will not be counted toward the narrative page limit. This additional information includes curriculum vitaes, resumes, organizational charts, letters of support, etc. Please include the following information as appendices:

1. Provide an organization chart and one page resume of each current staff member who will work on this project. Include a one-page job description of proposed staff. This must include the identification of a lead person for

creating and implementing evaluation or a description with timeline of plans to hire or contract an individual to function as an evaluation lead.

2. A list of applicant's affiliates/chapters by regional, state and local organizations or a description of each CBO partner.

3. Evidence of collaboration with other organizations that serve the same targeted populations. Include Memoranda of Agreement and letters of support.

4. A description of funding from other sources to conduct similar activities.

a. Describe how funds requested under this announcement will be used differently or in ways that will expand on the funds already received, applied for or being received.

b. Identify proposed personnel devoted to this project who are supported by other funding sources and the activities they support.

c. Written statement that the funds being requested will not duplicate or supplant funds received from any other sources.

5. Proof of eligibility (*see* section III. Eligible Applicants).

You are required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the Federal government. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access *http://www.dunandbradstreet.com* or call 1–866–705–5711. For more information, see the CDC Web site at: *http://www.cdc.gov/od/pgo/funding/pubcommt.htm*. If your application form does not have a DUNS number field, please write your DUNS number at the top of the first page of your application, and/or include your DUNS number in your application cover letter.

Additional requirements that may require you to submit additional documentation with your application are listed in section "VI.2. Administrative and National Policy Requirements."

IV.3. Submission Dates and Times

LOI Deadline Date: October 14, 2004.

CDC requests that you send a LOI if you intend to apply for this program. Although the LOI is not required, not binding, and does not enter into the review of your subsequent application, the LOI will be used to gauge the level of interest in this program, and to allow CDC to plan the application review.

Application Deadline Date: November 18, 2004.

Explanation of Deadlines: Applications must be received in the CDC Procurement and Grants Office by 4 p.m. eastern time on the deadline date. If you send your application by the United States Postal Service or commercial delivery service, you must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If CDC receives your application after closing due to: (1) Carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time, or (2) significant weather delays or natural disasters, you will be given the opportunity to submit documentation of the carriers guarantee. If the documentation verifies a carrier problem, CDC will consider the application as having been received by the deadline.

This announcement is the definitive guide on application submission address and deadline. It supersedes information provided in the application instructions. If your application does not meet the deadline above, it will not be eligible for review, and will be discarded. You will be notified that your application did not meet the submission requirements.

CDC will not notify you upon receipt of your application. If you have a question about the receipt of your application, first contact your courier. If you still have a question, contact the PGO–TIM staff at (770) 488–2700. Before calling, please wait two to three days after the application deadline. This will allow time for applications to be processed and logged.

IV.4. Intergovernmental Review of Applications

Executive Order 12372 does not apply to this program.

IV.5. Funding restrictions

Restrictions, which must be taken into account while writing your budget, are as follows:

- Funding may not be expended for the purchase or lease of land or buildings, construction of facilities, renovation of existing space, or the delivery of clinical and therapeutic services. The purchase of equipment is discouraged but will be considered for approval if justified on the basis of being essential to the program and not available from any other source.

If you are requesting indirect costs in your budget, you must include a copy of your indirect cost rate agreement. If your indirect cost rate is a provisional rate, the agreement should be less than 12 months of age.

Awards will not allow reimbursement of pre-award costs. Guidance for completing your budget can be found on the CDC Web site, at the following Internet address: *http://www.cdc.gov/od/pgo/funding/budgetguide.htm*.

IV.6. Other Submission Requirements

LOI Submission Address: Submit your LOI by express mail, delivery service, fax, or e-mail to: Shirl Ellis, Public Health Advisor, CDC, National Center for Chronic Disease Prevention and Health Promotion, Division of Diabetes Translation, National Diabetes Education Program, 4770 Buford Highway, NE., MS K–10, Atlanta, GA 30341, telephone: (770) 488–5035, fax: (770) 488–5195, e-mail: *sfe9@cdc.gov*.

Application Submission Address: Submit the original and two hard copies of your application by mail or express delivery service to: Technical Information Management–RFA 05014, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, telephone: (770) 488–2700.

Applications may not be submitted electronically by e-mail or faxed at this time.

V. Application Review Information

V.1. Criteria (100 Points)

You are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement. Measures of effectiveness must relate to the performance goals stated in the "Purpose" section of this announcement. Measures must be objective and quantitative, and must measure the intended outcome. These measures of effectiveness must be submitted with the application and will be an element of evaluation.

Your application will be evaluated against the following criteria:

A. Capacity (20 Points)

Extent to which the applicant describes:

1. The capacity of the applicant's infrastructure to support successful implementation of the proposed program activities in high risk populations.

2. Applicant's relationship with target population; a primary or direct relationship is preferred. Secondary relationships that are limited to fundraising or philanthropy have less preference.

3. The success of the applicant's past and present experiences in working with the high risk populations, conducting awareness and/or other educational activities, collaborating

with public and private sector partners and the potential contribution of these experiences to the success of the proposed program activities.

4. The success of the applicant in generating affiliate or chapter support for past and present organizational activities and the likelihood that strong support can be secured for the proposed program activities.

5. The reach of affiliates and chapters, national and regional organizations and number of states or jurisdictions covered.

B. Program Activities (20 Points)

Extent to which proposed activities are appropriate for the targeted population, achievable and that implementation will lead to accomplishment of the proposed objectives within the project period.

C. Project Management (20 Points)

1. Extent to which the work plan outlined is adequate to implement the program within the time lines described by the positions and and individuals identified.

2. Extent to which the proposed personnel time allocation is sufficient to accomplish the program activities.

D. Objectives (15 Points)

Extent to which the proposed objectives are specific, measurable, achievable, appropriate and relevant for the targeted audience and consistent with the stated purpose of this program announcement. The objectives must also be time related.

E. Program Evaluation Plan (15 Points)

Extent to which the applicant describes an evaluation plan for monitoring the program's progress, quality, accomplishments relative to achieving the objectives and completing the proposed program activities within the project period.

F. Justification of Need (10 Points)

Extent to which the applicant demonstrates an understanding of the program's purpose, objectives, describes the target population characteristics, diabetes burden, needs of the targeted population and justify the need for the proposed activities.

G. Budget and Justification (Not Weighted)

Extent to which the budget is reasonable and consistent with the purpose of the program announcement and proposed objectives and activities.

V.2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) staff, and for responsiveness by the National Center for Chronic Disease Prevention and Health Promotion. Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. Applicants will be notified that their application did not meet submission requirements.

An objective review panel will evaluate complete and responsive applications according to the criteria listed in the "V.1. Criteria" section above.

In addition, the following factors may affect the funding decision: Preference for funding will be given to ensure that:

- Funded organizations are balanced in terms of the racial/ethnic minority groups they target. The number of funded national and regional organizations serving each racial/ethnic minority group may be adjusted based on the burden of diabetes in that target group as measured by U.S. Department of Health and Human Services (HHS)reporting sources.
- Funded national and regional organizations are balanced in terms of geographic distribution within the United States, including the District of Columbia and United States Territories. Consideration will be given to high prevalence areas; the number of funded organizations may be adjusted based on the burden of diabetes in the jurisdiction as measured by HHS reporting sources.

V.3. Anticipated Announcement and Award Dates

It is expected that the awards will begin on or about February 27, 2005, and will be made for a 12 month budget period within a project period of up to five years. Funding estimates may vary depending on availability of funds.

VI. Award Administration Information

VI.1. Award Notices

Successful applicants will receive a Notice of Grant Award (NGA) from the CDC Procurement and Grants Office. The NGA shall be the only binding, authorizing document between the recipient and CDC. The NGA will be signed by an authorized Grants Management Officer, and mailed to the recipient's fiscal officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review by mail.

VI.2. Administrative and National Policy Requirements

45 CFR Part 74 and Part 92

For more information on the Code of Federal Regulations, *see* the National Archives and Records Administration at the following Internet address: *http://federal.access.gpo.gov/nara/cfr/cfr-table-search.html.*

The following additional requirements apply to this project:

- AR–9 Paperwork Reduction Act Requirements
- AR–10 Smoke-Free Workplace Requirements
- AR–11 Healthy People 2010
- AR–12 Lobbying Restrictions
- AR–14 Accounting System Requirements
- AR–15 Proof of Non-Profit Status
- AR–21 Small, Minority, and Women-Owned Business Additional information on these requirements can be found on the CDC Web site at the following Internet address: *http://federal.cdc.gov/od/pgo/funding/ARs.htm.*

VI.3. Reporting Requirements

You must provide CDC with an original, plus two hard copies of the following reports:

1. Interim progress report, no later than September 27 of each year. The progress report will serve as your non-competing continuation application, and must contain the following elements:

a. Current Budget Period Activities Objectives.

b. Current Budget Period Financial Progress.

c. New Budget Period Program Proposed Activity Objectives.

d. Budget.

e. Additional Requested Information.

f. Measures of Effectiveness.

2. Financial status report and annual progress report no more than 90 days after the end of the budget period.

3. Final financial and performance reports, no more than 90 days after the end of the project period.

These reports must be mailed to the Grants Management Specialist listed in the "Agency Contacts" section of this announcement.

VII. Agency Contacts

For general questions about this announcement, contact: Technical Information Management Section, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, telephone: (770) 488–2700.

For program technical assistance, contact: Shirl Ellis, Project Officer, CDC, National Center for Chronic Disease Prevention and Health Promotion, Division of Diabetes Translation, National Diabetes Education Program,

4770 Buford Highway, NE., MS K–10, Atlanta, GA 30341, telephone: (770) 448–5035, e-mail: *sfe9@cdc.gov.*

For financial, grants management, or budget assistance, contact: Tiffney Esslinger, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, telephone: (770) 488–2686, e-mail: *tesslinger@cdc.gov.*

VIII. Other Information

VIII.A. NDEP Workgroup Member Position Description and Requirements

Workgroup members serve as advisors/consultants for the development of NDEP materials, and implement strategic intervention activities for the NDEP program through their NDEP partner organizations. In addition, workgroup members serve as conduits for promoting the NDEP messages and the principles of NDEP. Workgroup members participate on conference calls, face-to-face meetings and the annual Partnership Network conference.

Workgroup membership roles and responsibilities include a commitment to do the following:

- Represent an organization invited to participate as an NDEP partner.
- Notify the workgroup chair if the workgroup member no longer represents the NDEP partner organization or if the organization selects another representative.
- Communicate with the organization which the member represents about NDEP campaigns and activities.
- Communicate with NDEP about members' organizational activities in support of the NDEP goals and objectives.
- Participate in workgroup conference calls. In most workgroups this represents a commitment of one hour monthly.
- Participate in face-to-face meetings, which usually will include one workgroup meeting and one Partnership Network meeting annually. It is not acceptable to invite a substitute to participate on a call or at a meeting if the NDEP member is not available.
- Facilitate partnerships that promote NDEP activities.
- Serve as a spokesperson for NDEP.
- Encourage networking in professional associations and organizations to promote NDEP.
- Assist with language translation or review of translated materials (if needed and applicable).
- Provide feedback and input for materials development.
- Contribute to NDEP's overall evaluation effort by reporting back to NDEP staff about activities promoting, disseminating or implementing NDEP campaigns and interventions.

VIII.B. CDC Division of Diabetes Translation National Objectives

1. By 2008, demonstrate success in achieving an increase in the percentage of people with diabetes in your jurisdiction who receives the recommended foot exams.
2. By 2008, demonstrate success in achieving an increase in the percentage of people with diabetes in your jurisdiction who receives the recommended eye exams.
3. By 2008, demonstrate success in achieving an increase in the percentage of people with diabetes in your jurisdiction who receive the recommended vaccinations (influenza and pneumococcal).
4. By 2008, demonstrate success in achieving an increase in the percentage of people with diabetes in your jurisdiction who receives the recommended A1C tests.
5. By 2008, demonstrate success in reducing health disparities for high-risk populations with respect to diabetes prevention and control.
6. By 2008, demonstrate success in linking to programs for promotion of wellness and physical activity, weight and blood pressure control and smoking cessation for people with diabetes.

To find out more about the National Diabetes Education Program (NDEP), visit the following Web sites at: *http://www.ndep.nih.gov, http://www.cdc.gov/diabetes/ndep, http://www.betterdiabetescare.nih.gov, http://www.diabetesatwork.org.*

To find out more about the CDC Division of Diabetes Translation, visit the Web site at: *http://www.cdc.gov/diabetes.*

Dated: September 28, 2004.

William P. Nichols,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 04–22259 Filed 10–1–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Diseases Transmitted Through the Food Supply

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of annual update of list of infectious and communicable diseases that are transmitted through handling the food supply and the methods by which such diseases are transmitted.

SUMMARY: Section 103(d) of the Americans with Disabilities Act of 1990, Pub. L. 101–336, requires the Secretary to publish a list of infectious and communicable diseases that are transmitted through handling the food supply and to review and update the list annually. The Centers for Disease Control and Prevention (CDC) published a final list on August 16, 1991 (56 FR 40897) and updates on September 8, 1992 (57 FR 40917); January 13, 1994 (59 FR 1949); August 15, 1996 (61 FR 42426); September 22, 1997 (62 FR 49518–9); September 15, 1998 (63 FR 49359), September 21, 1999 (64 FR 51127); September 27, 2000 (65 FR 58088), September 10, 2001 (66 FR 47030), September 27, 2002 (67 FR 61109) and November 6, 2003 (68 FR 62809). No new information that would warrant additional changes has been received; therefore the list, as set forth in the last update and below, remains unchanged.

EFFECTIVE DATE: October 4, 2004.

FOR FURTHER INFORMATION CONTACT: Dr. Art Liang, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop G–24, Atlanta, Georgia 30333, telephone (404) 639–2213

SUPPLEMENTARY INFORMATION: Section 103(d) of the Americans with Disabilities Act of 1990, 42 U.S.C. 12113(d), requires the Secretary of Health and Human Services to:

1. Review all infectious and communicable diseases which may be transmitted through handling the food supply;
2. Publish a list of infectious and communicable diseases which are transmitted through handling the food supply;
3. Publish the methods by which such diseases are transmitted; and,
4. Widely disseminate such information regarding the list of diseases and their modes of transmissibility to the general public.

Additionally, the list is to be updated annually.

Since the last publication of the list on November 6, 2003 (68 FR 62809), CDC has received no information to indicate that additional unlisted diseases are transmitted through handling the food supply. Therefore, the list set forth below is unchanged from

the list published in the **Federal Register** on November 6, 2003.

I. Pathogens Often Transmitted by Food Contaminated by Infected Persons Who Handle Food, and Modes of Transmission of Such Pathogens

The contamination of raw ingredients from infected food-producing animals and cross-contamination during processing are more prevalent causes of foodborne disease than is contamination of foods by persons with infectious or contagious diseases. However, some pathogens are frequently transmitted by food contaminated by infected persons. The presence of any one of the following signs or symptoms in persons who handle food may indicate infection by a pathogen that could be transmitted to others through handling the food supply: diarrhea, vomiting, open skin sores, boils, fever, dark urine, or jaundice. The failure of food-handlers to wash hands (in situations such as after using the toilet, handling raw meat, cleaning spills, or carrying garbage, for example), wear clean gloves, or use clean utensils is responsible for the foodborne transmission of these pathogens. Non-foodborne routes of transmission, such as from one person to another, are also major contributors in the spread of these pathogens. Pathogens that can cause diseases after an infected person handles food are the following:

Noroviruses
Hepatitis A virus
*Salmonella Typhi**
Shigella species
Staphylococcus aureus
Streptococcus pyogenes

II. Pathogens Occasionally Transmitted by Food Contaminated by Infected Persons Who Handle Food, But Usually Transmitted by Contamination at the Source or in Food Processing or by Non-foodborne Routes

Other pathogens are occasionally transmitted by infected persons who handle food, but usually cause disease when food is intrinsically contaminated or cross-contaminated during processing or preparation. Bacterial pathogens in this category often require a period of temperature abuse to permit their multiplication to an infectious dose before they will cause disease in consumers. Preventing food contact by persons who have an acute diarrheal illness will decrease the risk of transmitting the following pathogens:

Campylobacter jejuni
Cryptosporidium parvum
Entamoeba histolytica
Enterohemorrhagic *Escherichia coli*
Enterotoxigenic *Escherichia coli*
Giardia lamblia
Nontyphoidal *Salmonella*
Taenia solium
Vibrio cholerae 01
Yersinia enterocolitica

* Kauffmann-White scheme for designation of Salmonella serotypes

References

1. World Health Organization. Health surveillance and management procedures for food-handling personnel: report of a WHO consultation. World Health Organization technical report series; 785. Geneva: World Health Organization, 1989.

2. Frank JF, Barnhart HM. Food and dairy sanitation. In: Last JM, ed. Maxcy-Rosenau public health and preventive medicine, 12th edition. New York Appleton-Century-Crofts, 1986:765–806.

3. Bennett JV, Holmberg SD, Rogers MF, Solomon SL. Infectious and parasitic diseases. In: Amler RW, Dull HB, eds. Closing the gap: the burden of unnecessary illness. New York: Oxford University Press, 1987:102–114.

4. Centers for Disease Control and Prevention. Locally acquired neurocysticercosis—North Carolina, Massachusetts, and South Carolina, 1989–1991. MMWR 1992; 41:1–4.

5. Centers for Disease Control and Prevention. Foodborne Outbreak of Cryptosporidiosis-Spokane, Washington, 1997. MMWR 1998; 47:27.

Dated: September 24, 2004.

James D. Seligman,

Associate Director for Program Services, Centers for Disease Control and Prevention (CDC).

[FR Doc. 04–22260 Filed 10–1–04; 8:45 am]
BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Clinical Pharmacology Subcommittee of the Advisory Committee for Pharmaceutical Science; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Clinical Pharmacology Subcommittee of the Advisory Committee for Pharmaceutical Science.

General Function of the Subcommittee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 3, 2004, from 8 a.m. to 5:30 p.m., and on November 4, 2004, from 8 a.m. to 1:30 p.m.

Location: Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066. 5630 Fishers Lane, Rockville, MD.

Contact Person: Hilda Scharen, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX 301–827–6776, e-mail: *SCHARENH@cder.fda.gov* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572) in the Washington, DC area), code 3014512539. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 3, 2004, the subcommittee will: (1) Receive topic updates for ongoing FDA activities previously presented to the subcommittee; (2) discuss and provide comments on the evidence for updating labels of approved drugs to include integrating pharmacogenetic, pharmacokinetic, and prognostic biomarkers for the purpose of optimizing therapeutic response and reducing risks of toxicity; and (3) discuss and provide comments on metabolism- and transporter-based drug-drug interactions included as recommendations in a draft guidance for industry being prepared by FDA. On November 4, 2004, the subcommittee will discuss and provide comments on a new critical path project related to general aspects of the transition of biomarkers to surrogate endpoints, with a focus on planning and process, rather than on specific biomarkers or surrogate endpoints.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by October 25, 2004. Oral presentations from the public will be scheduled between approximately 12:30 p.m. and 1 p.m. on November 3, 2004, and between 1 p.m. and 1:30 p.m. on November 4, 2004. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 25, 2004, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and

addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee 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 contact Hilda Scharen at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 24, 2004.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 04–22214 Filed 10–1–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0431]

Draft Guidance for Industry and the Food and Drug Administration; Current Good Manufacturing Practices for Combination Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Current Good Manufacturing Practices for Combination Products." Once finalized, this guidance will provide guidance to industry and FDA staff on the applicability of current good manufacturing practices (CGMP) for combination products.

DATES: Submit written or electronic comments on the draft guidance by December 3, 2004. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Combination Products (HFG–3), 15800 Crabbs Branch Way, suite 200, Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Patricia Y. Love, Office of Combination Products (HFG–3), Food and Drug Administration, 15800 Crabbs Branch Way, suite 200, Rockville, MD 20855, 301–427–1934, FAX 301–427–1935, e-mail: *patricia.love@oc.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Current Good Manufacturing Practices for Combination Products." Combination products are defined under 21 CFR 3.2(e). This draft guidance document makes recommendations for achieving compliance with applicable CGMPs for the drug, device, or biological product constituent parts of a combination product. In addition, the draft guidance document makes recommendations for achieving compliance with applicable CGMPs for combination products where the constituent parts of a combination product are joined together. The applicable regulations include the CGMP regulations for finished pharmaceuticals, or drug products, and most biological products (21 CFR parts 210 and 211); the biological product regulations for biological products (21 CFR parts 600–680); and the quality system regulations for devices (21 CFR part 820).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on CGMP for combination products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two paper copies of mailed comments are to be submitted, 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. The draft guidance 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 document at either *http://www.fda.gov/oc/combination/default.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: September 28, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–22205 Filed 9–29–04; 1:51 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0440]

Draft Guidance for Industry on Computerized Systems Used In Clinical Trials; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Computerized Systems Used in Clinical Trials." This document provides guidance about computerized systems that are used to create, modify, maintain, archive, retrieve, or transmit clinical data required to be maintained and/or submitted to FDA. This draft guidance, when finalized, will supercede the guidance of the same name issued in April 1999.

DATES: Submit written or electronic comments on the draft recommendations by January 3, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Training and Communications, Division of Communications Management, Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857; to 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; to the Office of Health and Industry Programs,

Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, 1350 Piccard Dr., Rockville, MD 20850–4307, Manufacturers Assistance: 800–638–2041 or 301–443–6597; or the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. Submit telephone requests to 800–835–4709 or 301–827–1800. Submit written comments on the draft guidance 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Joseph Salewski, Center for Drug Evaluation and Research (HFD–45), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301–594–0020; or

Patricia Holobaugh, Center for Biologics Evaluation and Research (HFM–664), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–6347; or

John Murray, Jr., Center for Devices and Radiological Health (HFZ–340), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4646, ext. 107; or

John Welsh, Center for Food Safety and Applied Nutrition (HFS–205), Food and Drug Administration, 1110 Vermont Ave., NW, Washington, DC 20005, 202–418–3057; or

Vernon Toelle, Center for Veterinary Medicine (HFV–234), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20835, 301–827–0312; or

James McCormack, Office of Enforcement (HFC–230), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20857, 301–827–0425; or

Patricia Beers Block, Good Clinical Practice Programs (HF–34), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3340.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Computerized Systems Used in Clinical Trials." This document provides guidance about computerized systems that are used to create, modify, maintain, archive, retrieve, or transmit clinical data required to be maintained and/or submitted to FDA. These data form the basis for the agency's decisions regarding the safety and effectiveness of new human and animal drugs, biological products, medical devices, and certain food and color additives. As such, these data have broad public health significance and are expected to be of the highest quality and integrity.

This draft guidance, when finalized, will supercede the guidance of the same name issued in April 1999. This draft guidance is being revised to make it consistent with agency policy as reflected in the guidance for industry on "Part 11, Electronic Records; Electronic Signatures—Scope and Application," which issued in August 2003. It also reflects policy consistent with regard to the agency's international harmonization efforts.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance, when finalized, will represent the agency's current thinking on computerized systems used in clinical trials. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if the approach satisfies the requirements of the applicable statute and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two paper copies of any comments are to be submitted, 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. The draft guidance 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

Copies of this draft guidance for industry are available on the Internet at *http://www.fda.gov/cder/guidance/index.htm, http://www.fda.gov/cber/guidelines.htm, http://www.fda.gov/cvm/guidance/guidance.html*, and *http://www.fda.gov/oc/gcp/draft.html*.

Dated: September 28, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–22204 Filed 9–29–04; 1:51 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0226]

Food and Drug Administration Modernization Act of 1997; Modifications to the List of Recognized Standards, Recognition List Number: 011

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a publication containing modifications the agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA recognized consensus standards). This publication, entitled "Modifications to the List of Recognized Standards, Recognition List Number: 011" (Recognition List Number: 011), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit written or electronic comments concerning this document at any time. See section VII of this document for the effective date of the recognition of standards announced in this document.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of "Modifications to the List of Recognized Standards, Recognition List Number: 011" to the Division of Small Manufacturers Assistance, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 301–443–8818. Submit written comments concerning this document, or recommendations for additional standards for recognition, to the contact person (see **FOR FURTHER INFORMATION CONTACT**). Submit electronic comments by e-mail: *standards@cdrh.fda.gov*. This document may also be accessed on FDA's Internet site at *http://www.fda.gov/cdrh/fedregin.html*. See section VI of this document for electronic access to the searchable database for the current list of FDA recognized consensus standards, including Recognition List Number: 011 modifications and other standards related information.

FOR FURTHER INFORMATION CONTACT: Carol L. Herman, Center for Devices and Radiological Health (HFZ–84), Food and

Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4766, ext.156.

SUPPLEMENTARY INFORMATION:

I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360d). Amended section 514 allows FDA to recognize consensus standards, developed by international and national organizations, for use in satisfying portions of device premarket review submissions or other requirements.

In a notice published in the **Federal Register** of February 25, 1998 (63 FR 9561), FDA announced the availability of a guidance entitled "Recognition and Use of Consensus Standards." The notice described how FDA will implement its standard recognition program and provided the initial list of FDA recognized consensus standards.

In **Federal Register** notices published on October 16, 1998 (63 FR 55617), July 12, 1999 (64 FR 37546), November 15, 2000 (65 FR 69022), May 7, 2001 (66 FR 23032), January 14, 2002 (67 FR 1774), October 2, 2002 (67 FR 61893), April 28; 2003 (68 FR 22391), March 8, 2004 (69 FR 10712), and June 18, 2004 (69 FR 34176), FDA modified its initial list of FDA recognized consensus standards. These notices described the addition, withdrawal, and revision of certain standards recognized by FDA. The agency maintains "hypertext markup language" (HTML) and "portable document format" (PDF) versions of the list of FDA recognized consensus standards. Both versions are publicly accessible at the agency's Internet site. See section VI of this document for electronic access information. Interested persons should review the supplementary information sheet for the standard to understand fully the extent to which FDA recognizes the standard.

II. Modifications to Recognition List Number: 011

FDA is announcing the addition, withdrawal, correction, and revision of certain consensus standards the agency will recognize for use in satisfying premarket reviews and other requirements for devices. FDA will incorporate these modifications in the list of FDA recognized consensus standards in the agency's searchable database. FDA will use the term "Recognition List Number: 011" to identify these current modifications.

In table 1 of this document, FDA describes the following modifications: (1) The withdrawal of standards and their replacement by others, (2) the correction of errors made by FDA in listing previously recognized standards, and (3) the changes to the supplementary information sheets of recognized standards that describe revisions to the applicability of the standards.

In section III of this document, FDA lists modifications the agency is making that involve the initial addition of standards not previously recognized by FDA.

TABLE 1.

Old Item No.	Standard	Change	Replacement Item No.
A. Anesthesia			
1	ASTM F920–93 (1999), Standard Specification for Minimum Performance and Safety Requirements for Resuscitators Intended for Use With Humans	Withdrawn and replaced with newer version	50
2	ASTM F1100–90 (1997), Standard Specification for Ventilators Intended for Use in Critical Care	Withdrawn and replaced with newer version	51
5	ASTM F1463–93 (1999), Standard Specification for Alarm Signals in Medical Equipment Used in Anesthesia and Respiratory Care	Withdrawn and replaced with newer version	52
6	ASTM F1464–93 (1999), Standard Specification for Oxygen Concentrators for Domiciliary Use	Withdrawn and replaced with newer version	53
8	PVHO–1–2002, Safety Standard for Pressure Vessels for Human Occupancy	Withdrawn and replaced with newer version	54
23	ASTM F1054–01, Standard Specification for Conical Fittings	Withdrawn and replaced with newer version	55
24	ASTM F1456–01, Standard Specification for Minimum Performance and Safety Requirements for Capnometers	Withdrawn and replaced with newer version	59
25	ASTM F1462–93, Specification for Oxygen Analyzers	Withdrawn	
34	ASTM PS127: 2000, Standard Test Method for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Regulators Used for Medical and Emergency Applications	Withdrawn	
40	CGA V–7.1: 1997 (reaffirmed 2003), Standard Method for Determining Cylinder Valve Outlet Connections for Medical Gases	Withdrawn and replaced with newer version	56
45	ASTM 1101–90 (2003) e1, Standard Specification for Ventilators Intended for Use During Anesthesia	Withdrawn and replaced with newer version	57
B. Cardiovascular/Neurology			

TABLE 1.—Continued

Old Item No.	Standard	Change	Replacement Item No.
1	ANSI/AAMI EC12: 2000, Disposable Electrocardiogram (ECG) Electrodes	Withdrawn and replaced with newer version	52
4	AAMI SP10: 1992, Electronic or Automated Sphygmomanometers	Change in processes affected and contact person	
44	ANSI/AAMI BP22: 1994 (R2001), Blood Pressure Transducers	Change in processes affected and contact person	
C. Dental/Ear, Nose, and Throat			
22	ASTM/F1377–92, Standard Specification for Cobalt-Chromium-Molybdenum Powder for Coating of Orthopaedic Implants	Transfer to materials	
42	ANSI/ADA Specification No. 3: 1994, Dental Impression Compound	Withdrawn	
43	ANSI/ADA Specification No. 5: 1997, Dental Casting Alloys	Change date of standard	
44	ANSI/ADA Specification No. 11: 1997, Agar Impression Material	Withdrawn and replaced with newer version	110
45	ANSI/ADA Specification No. 13: 1999, Dental Cold-Curing Repair Resin	Withdrawn and replaced with newer version	111
48	ANSI/ADA Specification No. 16: 1999, Dental Impression Paste Zinc Oxide-Eugenol Materials	Withdrawn and replaced with newer version	112
51	ANSI/ADA Specification No. 20: 1995, Dental Duplicating Material	Withdrawn and replaced with newer version	113
55	ANSI/ADA Specification No. 48: 1989, Ultraviolet Activator and Disclosing Lights	Withdrawn and replaced with newer version	114
67	ISO 6871–1: 1994, Dental Base Metal Casting Alloys—Part 1: Cobalt-Based Alloys—Technical Corrigendum 1: 1998	Title correction	
80	ISO 9917–1: 2003, Dental Water Based Cements—Part 1: Powder/Liquid Acid-Base Cements—first edition	Withdrawn and replaced with newer version	115
81	ISO 10139–1: 1999, Dentistry—Resilient Lining Materials for Removable Dentures—Part 1: Short-Term Materials	Withdrawn and replaced with newer version	116
90	ANSI/ASA S3.39: 1987 (R2002), Specification for Instruments to Measure Aural Acoustic Impedance and Admittance (Aural Acoustic Immittance)	Change date of standard	
103	ANSI/ADA Specification No. 12: 2002, Denture Base Polymers	Withdrawn and replaced with newer version	117
105	ANSI/ADA Specification No. 75: 1997 (R2003), Resilient Lining Materials for Removable Dentures—Part 1: Short-Term Materials	Title correction	
106	ANSI/ADA Specification No. 82: 2003, Dental Reversible/Irreversible Hydrocolloid Impression Material System	Withdrawn and replaced with newer version	119
108	ISO 10139–2: 1999, Dentistry—Soft Lining Materials for Removable Dentures—Part 2: Materials for Long-Term Use	Withdrawn and replaced with newer version	120
D. General			
10	AAMI/ISO 14971–1, Medical Devices—Risk Management—Part 1: Application of Risk Analysis	Withdrawn	
21	CEN EN 1441: 1997, Medical Devices—Risk Management	Withdrawn	
E. In Vitro Diagnostic			
23	NCCLS H1–A5, Tubes and Additives for Venous Blood Specimen Collection; Approved Standard	Withdrawn and replaced with newer version	102

TABLE 1.—Continued

Old Item No.	Standard	Change	Replacement Item No.
69	NCCLS H3–A5, Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard	Withdrawn and replaced with newer version	103
24	NCCLS H7–A3, Procedure for Determining Packed Cell Volume by the Microhematocrit Method; Approved Standard—third edition	Withdrawn and replaced with newer version	104
33	NCCLS H30–A2, Procedure for the Determination of Fibrinogen in Plasma; Approved Guideline—second edition	Withdrawn and replaced with newer version	105
57	NCCLS M2–A8, Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard—eighth edition	Withdrawn and replaced with newer version	106
75	NCCLS M11–A6, Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically, Approved Standard—sixth edition	Withdrawn and replaced with newer version	107
56	NCCLS M7–A6, Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria; Approved Standard—sixth edition	Withdrawn and replaced with newer version	108
F. Materials			
5	ASTM F138–03, Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)	Withdrawn and replaced with newer version	76
6	ASTM F139–03, Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Sheet and Strip for Surgical Implants (UNS S31673)	Withdrawn and replaced with newer version	77
7	ASTM F560–04, Standard Specification for Unalloyed Tantalum for Surgical Implant Applications (UNS R05200, UNS R05400)	Withdrawn and replaced with newer version	78
13	ASTM F648–00e1, Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants	Change date of standard	
16	ASTM F746–87 (1999), Standard Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials	Change in processes affected	
19	ASTM F961–03, Standard Specification for Cobalt-35 Nickel-20 Chromium-10 Molybdenum Alloy Forgings for Surgical Implants (UNS R30035)	Withdrawn and replaced with newer version	79
21	ASTM F1088–04, Standard Specification for Beta-Tricalcium Phosphate for Surgical Implantation	Withdrawn and replaced with newer version	80
33	ASTM F1609–03, Standard Specification for Calcium Phosphate for Coatings for Implantable Materials	Withdrawn and replaced with newer version	81
34	ASTM F1659–95, Standard Test Method for Bending and Shear Fatigue Testing of Calcium Phosphate Coatings on Solid Metallic Substrates	Change in processes affected	
35	ASTM F1713–03, Standard Specification for Wrought Titanium-13 Niobium-13 Zirconium Alloy for Surgical Implant Applications	Withdrawn and replaced with newer version	82
40	ASTM F2063–00, Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical implants	Change in extent of recognition, contact person, and processes affected	
42	ASTM F2119–01, Standard Test Method for Evaluation of MR Image Artifacts From Passive Implants	Change in processes affected	
48	ASTM F899–02, Standard Specification for Stainless Steel for Surgical Instruments	Change in processes affected	
70	ASTM F2052–02, Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment	Withdrawn	
72	ASTM F2213–04, Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment	Change in processes affected	
Ortho #91	ASTM F561–97 (2003), Practice for Retrieval and Analysis of Implanted Medical Devices and Associated Tissues	Transferred to materials	73

TABLE 1.—Continued

Old Item No.	Standard	Change	Replacement Item No.
Ortho #93	ASTM 601–03, Standard Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants	Transferred to materials	94
Ortho #107	ASTM F1147–99, Standard Test Method for Tension Testing of Calcium Phosphate and Metal Coating	Transferred to materials	84
Ortho/PM #113 Dental # 22	ASTM F1377–98a, Standard Specification for Cobalt-28 Chromium-6 Molybdenum Powder for Coating of Orthopedic Implants (UNS R30075)	Transferred to materials	74
Ortho #124	ASTM F86–01, Standard Practice for Surface Preparation and Marking of Metallic Surgical Implants	Transferred to materials	93
Ortho #131	ASTM F1044–99, Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings	Transferred to materials	83
Ortho #152	ASTM F1160–00e1, Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic Coatings	Transferred to materials	75
Ortho #160	ASTM F629–02, Standard Practice for Radiography of Cast Metallic Surgical Implants	Transferred to materials	95
G. OB–GYN/Gastroenterology			
16	AAMI/ANSI ID54: 1996 (R)2001, Enteral Feeding Set Adapters and Connectors	Withdrawn and replaced with newer version	31
H. Orthopaedic			
58	ASTM F1781–03, Standard Specification for Elastomeric Flexible Hinge Finger Total Joint Implants	Withdrawn and replaced with newer version	168
91	ASTM F561–97, Practice for Retrieval and Analysis of Implanted Medical Devices and Associated Tissues	Transferred to materials	73
93	ASTM F601–98, Standard Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants	Transferred to materials	94
107	ASTM F1147–99, Standard Test Method for Tension Testing of Calcium Phosphate and Metal Coatings	Transferred to materials	84
111	ASTM F1814–97a (2003), Standard Guide for Evaluating Modular Hip and Knee Joint Components	Withdrawn and replaced with newer version	171
113	ASTM F1377–98a, Standard Specification for Cobalt-28 Chromium-6 Molybdenum Powder for Coating of Orthopedic Implants (UNS R30075)	Transferred to materials	74
114	ASTM F1798–97 (2003), Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants	Withdrawn and replaced with newer version	172
115	ASTM F1800–97 (2003), Standard Test Method for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements	Withdrawn and replaced with newer version	173
120	ASTM F382–99 (2003), Standard Specification and Test Method for Metallic Bone Plates	Withdrawn and replaced with newer version	174
124	ASTM F86–01, Standard Practice for Surface Preparation and Marking of Metallic Surgical Implants	Transferred to materials	93
131	ASTM F1044–99, Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings	Transferred to materials	83
140	ASTM F1582–98 (2003), Standard Terminology Relating to Spinal Implants	Withdrawn and replaced with newer version	175
145	ASTM F565–00 (2003), Standard Practice for Care and Handling of Orthopedic Implants and Instruments	Withdrawn and replaced with newer version	176

TABLE 1.—Continued

Old Item No.	Standard	Change	Replacement Item No.
152	ASTM F1160–00e1, Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic Coatings	Transferred to materials	75
160	ASTM F629–02, Standard Practice for Radiography of Cast Metallic Surgical Implants	Transferred to materials	95
161	ASTM F1264–03, Standard Specification and Test Methods for Intramedullary Fixation Devices	Withdrawn and replaced with newer version	177
165	ISO 7206–4: 2002, Implants for Surgery—Partial and Total Hip Joint Prostheses—Part 4: Determination of Endurance Properties of Stemmed Femoral Components	Withdrawn	
I. Physical Medicine			
1	ANSI/RESNA WC/volume—1998, Section 1: Determination of Static Stability	Withdrawn and replaced with newer version	31
2	ANSI/RESNA WC/volume 2—1998, Section 2: Determination of Dynamic Stability of Electric Wheelchairs	Withdrawn and replaced with newer version	32
3	ANSI/RESNA WC/volume 2—1998, Section 3: Test Methods and Requirements for the Effectiveness of Brakes	Withdrawn and replaced with newer version	33
4	ANSI/RESNA WC/volume 2—1998, Section 4: Determination of Energy Consumption of Electric Wheelchairs and Scooters—Theoretical Range	Withdrawn and replaced with newer version	34
5	ANSI/RESNA WC/volume 1—1998, Section 5: Determination of Overall Dimensions, Mass, and Turning Space	Withdrawn and replaced with newer version	35
6	ANSI/RESNA WC/volume 2—1998, Section 6: Determination of Maximum Speed, Acceleration, and Retardation of Electric Wheelchairs	Withdrawn and replaced with newer version	36
7	ANSI/RESNA WC/volume 1—1998, Section 7: Method of Measurement of Seating and Wheel Dimensions	Withdrawn and replaced with newer version	37
8	ANSI/RESNA WC/volume 1—1998, Section 8: Requirements and Test Methods for Static, Impact, and Fatigue Strengths	Withdrawn and replaced with newer version	38
9	ANSI/RESNA WC/volume 2—1998, Section 9: Climatic Tests for Electric Wheelchairs	Withdrawn and replaced with newer version	39
10	ANSI/RESNA WC/volume 2—1998, Section 10: Determination of Obstacle-Climbing Ability of Electric Wheelchairs	Withdrawn and replaced with newer version	40
11	ANSI/RESNA WC/volume 1—1998, Section 11: Test Dummies	Withdrawn and replaced with newer version	41
12	ANSI/RESNA WC/volume 1—1998, Section 13: Determination of Coefficient of Friction of Test Surfaces	Withdrawn and replaced with newer version	42
13	ANSI/RESNA WC/volume 2—1998, Section 14: Power and Control Systems for Electric Wheelchairs—Requirements and Test Methods	Withdrawn and replaced with newer version	43
14	ANSI/RESNA WC/volume 1—1998, Section 15: Requirements for Information Disclosure, Documentation, and Labeling	Withdrawn and replaced with newer version	44
15	ANSI/RESNA WC/volume 1—1998, Section 16: Resistance to Ignition of Upholstered Parts—Requirements and Test Methods	Withdrawn and replaced with newer version	45
18	ISO 7176–3: 2003, Wheelchairs—Part 3: Determination of Effectiveness of Brakes	Withdrawn and replaced with newer version	50
J. Radiology			
39	IEC 60601–2–17, Medical Electrical Equipment—Part 2: Particular Requirements for the Safety of Remote-Controlled Automatically-Drive Gamma-Ray Afterloading Equipment (1989) Amendment No. 1 to IEC 601–2–17 (1996)	Withdrawn	
71	NEMA UD 2–2004, Revision 3: Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment	Withdrawn and replaced with newer version	105

TABLE 1.—Continued

Old Item No.	Standard	Change	Replacement Item No.
72	NEMA UD 3–2004, Revision 2: Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment	Withdrawn and replaced with newer version	100
78	NEMA PS 3, Set: Digital Imaging and Communications in Medicine (DICOM) Set	Withdrawn and replaced with newer version	119
86	IEC 60601–2–33 (2002–05), Medical Electrical Equipment—Part 2–33: Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis	Withdrawn and replaced with newer version	104
88	IEC 60601–2–17 (2004–01), Medical Electrical Equipment—Part 2–17: Particular Requirements for the Safety of Automatically-Controlled Brachytherapy Afterloading Equipment	Withdrawn and replaced with newer version	118
94	IEC 60731 Amendment 1 (2002–06), Medical Electrical Equipment—Dosimeters With Ionization Chambers as Used in Radiotherapy	Withdrawn and replaced with newer version	98
K. Sterility			
16	ANSI/AAMI ST35: 2003, Safe Handling and Biological Decontamination of Reusable Medical Devices in Health Care Facilities and in Nonclinical Settings	Withdrawn and replaced with newer version	117
17	ANSI/AAMI ST44: 1992, BIER/EO Gas Vessels	Withdrawn	
18	ANSI/AAMI ST45: 1992, BIER/Steam Vessels	Withdrawn	
20	ANSI/AAMI ST50: 2004, Dry Heat (Heated Air) Sterilizers	Withdrawn and replaced with newer version	118
21	ANSI/AAMI ST55: 2003, Table-Top Steam Sterilizers	Withdrawn and replaced with newer version	119
48	ANSI/AAMI ST40: 1992/(R)1998, Table-Top Dry Heat (Heated Air) Sterilizers and Sterility Assurance in Dental and Medical Facilities	Change in relevant guidance and contact person	
50	ANSI/AAMI ST42: 1998, Steam Sterilization and Sterility Assurance Using Table-Top Sterilizers in Office-Based, Ambulatory-Care Medical, Surgical, and Dental Facilities	Contact person	
52	ANSI/AAMI ST59: 1999, Sterilization of Health Care Products—Biological Indicators—Part 1: General Requirements	Change in relevant guidance	
53	ANSI/AAMI ST66: 1999, Sterilization of Health Care Products—Chemical Indicators—Part 2: Class 2 Indicators for Air Removal Test Sheets and Packs	Contact person	
56	ASTM D3078: 2002, Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission	Withdrawn and replaced with newer version	120
57	ASTM D4169: 2004, Standard Practice for Performance Testing of Shipping Containers and Systems	Withdrawn and replaced with newer version	121
58	ASTM F88: 2000, Standard Test Method for Seal Strength of Flexible Barrier Materials	Withdrawn and replaced with newer version	122
63	ASTM F1886: 1998 (2004), Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection	Reaffirmation	
64	ASTM F1929: 1998 (2004), Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	Reaffirmation	
72	ANSI/AAMI ST33: 1996, Guidelines for the Selection and Use of Reusable Rigid Sterilization Container Systems for Ethylene Oxide Sterilization and Steam Sterilization in Health Care Facilities	Contact person	
74	ANSI/AAMI ST60: 1996, Sterilization of Health Care Products—Chemical Indicators—Part 1: General Requirements	Contact person	
75	ANSI/AAMI/ISO 11137: 1994, Sterilization of Health Care Products—Requirements for Validation and Routine Control—Radiation Sterilization and ANSI/AAMI/ISO 11137: 1994/Amendment 1: 2002	Change in title, relevant guidance, and contact person	

TABLE 1.—Continued

Old Item No.	Standard	Change	Replacement Item No.
91	ASTM F2096: 2004, Standard Test Method for Detecting Gross Leaks in Porous Medical Packaging by Internal Pressurization (Bubble Test)	Withdrawn and replaced with newer version	123
103	AAMI/ANSI/ISO 11607: 2000, Packaging for Terminally Sterilized Medical Devices	Change in relevant guidance	
105	ANSI/AAMI ST46: 2002, Steam Sterilization and Sterility Assurance in Health Care Facilities	Contact person	
106	USP 27: 2004, Biological Indicator for Dry Heat Sterilization, Paper Carrier	Withdrawn and replaced with newer version	124
107	USP 27: 2004, Biological Indicator for Ethylene Oxide Sterilization, Paper Carrier	Withdrawn and replaced with newer version	125
108	USP 27: 2004, Biological Indicator for Steam Sterilization, Paper Carrier	Withdrawn and replaced with newer version	126
109	USP 27: 2004, <61> Microbial Limits Test	Withdrawn and replaced with newer version	127
110	USP 27: 2004, <71> Microbiological Tests, Sterility Tests	Withdrawn and replaced with newer version	128
111	USP 27: 2004, <85> Biological Tests and Assays, Bacterial Endotoxin Test (LAL)	Withdrawn and replaced with newer version	129
112	USP 27: 2004, <151> Pyrogen Test (USP Rabbit Test)	Withdrawn and replaced with newer version	130
113	USP 27: 2004, <1211> Sterilization and Sterility Assurance of Compendial Articles	Withdrawn and replaced with newer version	131
114	USP 27: 2004, <161> Transfusion and Infusion Assemblies and Similar Medical Devices	Withdrawn and replaced with newer version	132
115	USP 27: 2004, Biological Indicator for Steam Sterilization—Self-Contained	Withdrawn and replaced with newer version	133
116	ANSI/AAMI ST72: 2002, Bacterial Endotoxins—Test Methodologies, Routine Monitoring, and Alternatives to Batch Testing	Change in relevant guidance	

III. Listing of New Entries

The listing of new entries and consensus standards added as modifications to the list of recognized standards, under Recognition List Number: 011, follows:

TABLE 2.

Item No.	Title of Standard	Reference No. and Date
A. Anesthesia		
58	Standard Test Method for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Regulators Used for Medical and Emergency Applications	ASTM G175–03
B. Dental/ENT		
121	Dentistry—Dental Units—Part 2: Water and Air Supply	ISO 7494–2: 2003
C. General Hospital/General Plastic Surgery		
112	Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilitates	ANSI/AAMI PB70: 2003
113	Standard Specification for Performance of Materials Used in Medical Face Masks	ASTM F2100–04
D. Materials		

TABLE 2.—Continued

Item No.	Title of Standard	Reference No. and Date
85	Standard Test Method for Stereological Evaluation of Porous Coatings on Medical Implants	ASTM F1854–01
86	Standard Test Method for Evaluation of the Environmental Stability of Calcium Phosphate Coatings	ASTM F1926–03
87	Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the TaberT Abraser	ASTM F1978–00e1
88	Standard Practice for X-Ray Diffraction Determination of Phase Content of Plasma-Sprayed Hydroxyapatite Coatings	ASTM F2024–00
89	Standard Specification for High-Purity Dense Yttria Tetragonal Zirconium Oxide Polycrystal (Y–TZP) for Surgical Implant Applications	ASTM F1873–98
90	Standard Test Method for Strength Properties of Tissue Adhesives in Lap Shear by Tension Loading	ASTM F2255–03
91	Standard Test Method for Strength Properties of Tissue Adhesives in T-Peel by Tension Loading	ASTM F2256–03
92	Standard Test Method for Strength Properties of Tissue Adhesives in Tension	ASTM F2258–03
96	Standard Test Method for In Vitro Degradation Testing of Poly (L-lactic Acid) Resin and Fabricated Form for Surgical Implants	ASTM 1635–95 (2000)
97	Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices	ASTM F2129–04
98	Standard Specification for Acrylic Bone Cement	ASTM F451–99ae1
99	Standard Test Method for Transformation Temperature of Nickel-Titanium Alloys by Thermal Analysis	ASTM F2004–03
100	Standard Terminology for Nickel-Titanium Shape Memory Alloys	ASTM F2005–00
101	Test Method for Constant Amplitude of Force Controlled Fatigue Testing of Acrylic Bone Cement Materials	ASTM F2118–03
102	Standard Test Method for Determination of Transformation Temperature of Nickel-Titanium Shape Memory Alloys by Bend and Free Recovery	ASTM F2082–03
E. OB–GYN/Gastroenterology		
30	Water Treatment Equipment for Hemodialysis Applications	ANSI/AAMI RD62: 2001
F. Ophthalmic		
33	Contact Lens Care Products—Vocabulary, Performance Specifications, and Test Methodology	ANSI Z80.18
G. Orthopaedic		
178	Standard Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components Without Torsion	ASTM F1440–92 (2002)
179	Standard Specification for Femoral Prostheses—Metallic Implants	ASTM F2068–03
H. Physical Medicine		
46	Determination of Performance of Stand-Up Type Wheelchairs	ANSI/RESNA WC/volume 1—1998, section 20
47	Set Up Procedures	ANSI/RESNA WC/volume 1—1998, section 22
48	Maximum Overall Dimensions	ANSI/RESNA WC/volume 1—1998, section 93
49	Nomenclature, Terms, and Definitions	ANSI/RESNA WC/volume 1—1998, section 0
I. Radiology		

TABLE 2.—Continued

Item No.	Title of Standard	Reference No. and Date
101	Recommended Practice for Photobiological Safety for Lamps and Lamp Systems—General Requirements	ANSI/ESNA RP–27.1.96
102	Recommended Practice for Photobiological Safety for Lamps and Lamp Systems—Measurement Techniques	ANSI/ESNA RP–27.2.00
103	Recommended Practice for Photobiological Safety for Lamps and Lamp Systems—Risk Group Classification and Labeling	ANSI/ESNA RP–27.3.96
106	Optics and Optical Instruments—Lasers and Laser-Related Equipment—Lifetime of Lasers	ISO 17526: 2003
107	Lasers and Laser-Related Equipment—Test Methods for Laser Beam Parameters—Beam Widths, Divergence Angle, and Beam Propagation Factor	ISO 11146: 1999
108	Lasers and Laser-Related Equipment—Determination of Laser-Induced Damage Threshold of Optical Surfaces—Part 1: 1-on-1 Test	ISO 11254–1: 2000
109	Lasers and Laser-Related Equipment—Determination of Laser-Induced Damage Threshold of Optical Surfaces—Part 2: S-on-1 Test	ISO 11254–2: 2001
110	Optics and Optical Instruments—Lasers and Laser-Related Equipment—Test Method for Absorptance of Optical Laser Components (revision of ISO 11551: 1997)	ISO 11551: 2003
111	Optics and Optical Instruments—Lasers and Laser-Related Equipment—Test Methods for Laser Beam Power, Energy, and Temporal Characteristics (revision of ISO 11554: 1998)	ISO 11554: 2003
112	Lasers and Laser-Related Equipment—Test Methods for Laser Beam Parameters—Beam Positional Stability (revision of ISO 11670: 1999)	ISO 11670: 2003
113	Lasers and Laser-Related Equipment—Test Methods for Laser Beam Parameters—Polarization (revision of ISO 12005: 1999)	ISO 12005: 2003
114	Optics and Optical Instruments—Lasers and Laser-Related Equipment—Test Methods for Laser Beam Power (Energy) Density Distribution	ISO 13694: 2000
115	Optics and Photonics—Lasers and Laser-Related Equipment—Test Methods for the Spectral Characteristics of Lasers	ISO 13695: 2004
116	Optics and Optical Instruments—Test Methods for Radiation Scattered by Optical Components	ISO 13696: 2002
117	Lasers and Laser-Related Equipment—Test Methods for Determination of the Shape of a Laser Beam Wavefront—Part 1: Terminology and Fundamental Aspects	ISO 15367–1: 2003
120	Particular Requirements for the Safety of X-Ray Equipment for Computed Tomography	IEC 60601–2–44 (ed. 2.1)
J. Sterility		
134	Resistometers Used for Characterizing the Performance of Biological and Chemical Indicators	ANSI/AAMI ST44: 2002
135	Sterilization of Health Care Products—Requirements for the Development, Validation, and Routine Control of an Industrial Sterilization Process for Medical Devices—Dry Heat	ANSI/AAMI ST63: 2002
136	Sterilization of Health Care Products—Requirements for Products Labeled "Sterile"	ANSI/AAMI ST67: 2003
137	Sterilization of Health Care Products—Vocabulary	ANSI/AAMI/ISO TIR 11139: 2002
138	Aseptic Processing of Health Care Products—Part 2: Filtration	ISO 13408–2: 2003
139	Cleanrooms and Associated Controlled Environments—Part 1: Classification of Air Cleanliness	ISO 14644–1: 1999
140	Cleanrooms and Associated Controlled Environments—Part 2: Specifications for Testing and Monitoring to Prove Continued Compliance With ISO 14644–1	ISO 14644–2: 2000
141	Cleanrooms and Associated Controlled Environments—Part 4: Design, Construction, and Start-Up	ISO 14644–4: 2001
142	Cleanrooms and Associated Controlled Environments—Biocontamination Control—Part 1: General Principles and Methods	ISO 14698–1: 2003
143	Cleanrooms and Associated Controlled Environments—Biocontamination Control—Part 2: Evaluation and Interpretation of Biocontamination Data	ISO 14698–2: 2003

TABLE 2.—Continued

Item No.	Title of Standard	Reference No. and Date
K. Tissue Engineering		
5	Standard Guide for Characterization and Testing of Hyaluronan as Starting Material Intended for Use in Biomedical and Tissue Engineered Medical Product Applications	ASTM F2347–2003

IV. List of Recognized Standards

FDA maintains the agency's current list of FDA recognized consensus standards in a searchable database that may be accessed directly at FDA's Internet site at *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm*.

FDA will incorporate the modifications and minor revisions described in this document into the database and, upon publication in the **Federal Register**, this recognition of consensus standards will be effective. FDA will announce additional modifications and minor revisions to the list of recognized consensus standards, as needed, in the **Federal Register** once a year, or more often, if necessary.

V. Recommendation of Standards for Recognition by FDA

Any person may recommend consensus standards as candidates for recognition under the new provision of section 514 of the act by submitting such recommendations, with reasons for the recommendation, to the contact person (see **FOR FURTHER INFORMATION CONTACT**). To be properly considered, such recommendations should contain, at a minimum, the following information: (1) Title of the standard, (2) any reference number and date, (3) name and address of the national or international standards development organization, (4) a proposed list of devices for which a declaration of conformity to this standard should routinely apply, and (5) a brief identification of the testing or performance or other characteristics of the device(s) that would be addressed by a declaration of conformity.

VI. Electronic Access

In order to receive "Guidance on the Recognition and Use of Consensus Standards" via your fax machine, call the Center for Devices and Radiological Health (CDRH) Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number 321 followed by the pound sign. Follow the remaining voice prompts to complete your request.

You may also obtain a copy of "Guidance on the Recognition and Use of Consensus Standards" by using the Internet. CDRH maintains a site on the Internet for easy access to information including text, graphics, and files that you may download to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the guidance as well as the current list of recognized standards and other standards related documents. After publication in the **Federal Register**, this document announcing "Modifications to the List of Recognized Standards, Recognition List Number: 011," will be available on the CDRH home page. You may access the CDRH home page at *http://www.fda.gov/cdrh*.

You may access "Guidance on the Recognition and Use of Consensus Standards," and the searchable database for FDA recognized consensus standards, through the hyperlink at *http://www.fda.gov/cdrh/stdsprog.html*.

This **Federal Register** document on modifications in FDA's recognition of consensus standards is available at *http://www.fda.gov/cdrh/fedregin.html*.

VII. Submission of Comments and Effective Date

Interested persons may submit to the contact person (see **FOR FURTHER INFORMATION CONTACT**) written or electronic comments regarding this document. Two copies of any mailed comments are to be submitted, 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. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 011. These modifications to the list or recognized standards are effective upon publication of this document in the **Federal Register**.

Dated: September 21, 2004.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 04–22183 Filed 10–1–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0117]

Guidance for Industry, Food and Drug Administration 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; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is revising the criteria the agency will use to accredit persons for the purpose of conducting inspections of eligible device manufacturers under the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), which established an "inspection by accredited persons" program. FDA is also announcing the availability of a revised guidance document that will provide information for those interested in participating in this program. The guidance is entitled "Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria." This revised guidance document is immediately in effect, but it remains subject to comment in accordance with the agency's good guidance practices. FDA is taking these actions to implement recent technical amendments to MDUFMA.

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled "Implementation of the Inspection by

Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance 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.* Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: John F. Stigi, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597, ext. 124.

SUPPLEMENTARY INFORMATION:

I. Background

MDUFMA (Public Law 107–250) was signed into law on October 26, 2002. Section 201 of MDUFMA adds a new paragraph ''g'' to section 704 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 374), directing FDA to accredit third parties (accredited persons or APs) to perform inspections of eligible manufacturers of class II or class III devices. This is a voluntary program; eligible manufacturers have the option of being inspected by an AP or by FDA. In the **Federal Register** of April 28, 2003 (68 FR 22400), in accordance with section 704(g)(2) of the act, FDA published the criteria that it would apply to accredit or deny accreditation to persons who request to perform these inspections. Under section 704(g)(2) of the act, through publication of this **Federal Register** document, the criteria set out in section II of this document are binding on those persons who apply to become APs under this program.

On April 1, 2004, the Medical Devices Technical Corrections Act (Public Law 108–214) was signed into law by the President. This law made changes to several sections of the act, including section 704(g). Most significantly, section 704(g) of the act as amended permits an establishment that markets at least one class II or III device in the United States and markets or intends to market at least one such device in one or more foreign countries to use an accredited third party if one or both of the following conditions are met: (1) One of the foreign countries certifies, accredits, or recognizes the AP as a person authorized to conduct inspections of device establishments or (2) the establishment submits a statement that the law of a country where the device is marketed or intended to be marketed recognizes an inspection by FDA or an AP. Before the technical correction, it was necessary that both of these conditions be met before an establishment would be eligible to use an AP under this program. FDA is now issuing revised criteria as set out in section II of this document and a revised guidance document that incorporates the changes made by the Medical Device Technical Corrections Act.

This guidance document supersedes the guidance document that FDA issued on April 28, 2003. FDA received three comments on the April 28, 2003, guidance. FDA reviewed those comments and has addressed them as appropriate in this revised guidance.

FDA is making this guidance document immediately available because prior public participation is not feasible. MDUFMA requires that FDA implement this program immediately and this guidance is needed to help effect such implementation.

II. Accreditation Criteria

This section describes the criteria FDA will apply when making decisions about whether to accredit persons who request to conduct inspections of eligible class II and class III device manufacturers in lieu of an FDA inspection. The guidance document entitled ''Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria'' repeats these criteria and provides suggestions on how applicants may address them in their application.

A. Minimum Requirements

Section 704(g)(3) of the act describes the minimum requirements that an AP must meet in order to be accredited by FDA. These requirements are that an AP:

- May not be a Federal Government employee;
- Shall be an independent organization not owned or controlled by a manufacturer, supplier, or vendor of articles regulated under the act and have no organizational, material, or financial affiliation (including a consultative affiliation) with such a manufacturer, supplier, or vendor;
- Shall be a legally constituted entity permitted to conduct the activities for which it seeks accreditation;
- Shall not engage in the design, manufacture, promotion, or sale of articles regulated under the act;
- Shall operate in accordance with generally accepted professional and ethical business practices and agree in writing that, at a minimum, it will:

Certify that the reported information accurately reflects data reviewed, inspection observations made, other matters that relate to or may influence compliance with the act, and recommendations made during an inspection or at an inspection's closing meeting;

Limit work to that for which competence and capacity are available;

Treat information received, records, reports, and recommendations as confidential commercial or financial information or trade secret information, except such information may be made available to FDA;

Respond promptly and attempt to resolve complaints regarding its activities for which it is accredited;

Protect against the use of any officer or employee of the AP to conduct inspections who has a financial conflict of interest regarding any product regulated under the act, and annually make available to the public disclosures of the extent to which the AP, and the officers and employees of the person, have maintained compliance with requirements relating to financial conflicts of interest.

B. Additional Criteria

In addition to the minimum requirements specified in section 704(g)(3) of the act for becoming an AP, this document also establishes the following additional criteria:

1. Personnel Qualifications

FDA expects APs to have sufficient personnel, with the necessary education, training, skills, and experience to review records and perform inspections. FDA will consider several factors when accrediting applicants. These factors include:

- Whether personnel have knowledge of the following:

The act (21 U.S.C. 321 *et seq.*);

The Public Health Service Act (42 U.S.C. 201 *et seq.*);

Regulations implementing these statutes, particularly parts 11 and 800–1271 (21 CFR parts 11 and 800–1271), with special emphasis on parts 11, 801, 803, 806, 807, 809, 814, 820, and 821;

FDA Compliance Program 7382.845, Inspection of Medical Device Manufacturers;

Guide to Inspection of Quality Systems (QS): Quality System Inspection Technique (QSIT); and

FDA Investigations Operations Manual, Chapter 5 "Establishment Inspection."

Whether the applicant:

Has established, documented, and executed policies and procedures to ensure that inspections are performed by qualified personnel, and will maintain records on the relevant education, training, skills, and experience of all personnel who contribute to the performance of inspections;

Has available to its personnel clear, written instructions for duties and responsibilities with respect to inspections;

Has identified personnel who, as a whole, are qualified in all of the quality system disciplines for the inspections under the AP scope of work; and

Has identified at least one individual who is responsible for providing supervision over inspections and who has sufficient authority and competence to assess the quality and acceptability of inspection reports.

2. Infrastructure

APs need the capability to interface with FDA's electronic data systems, including FDA's Internet Web sites and the Center for Devices and Radiological Health (CDRH) Facts-On-Demand system. At a minimum, this would entail a computer system with a modem and an independent fax machine. FDA will rely extensively on the use of our electronic systems for timely dissemination of guidance documents to APs and other interested parties. APs must also have physical security and safeguards to protect trade secret and confidential commercial or financial information, as well as personal identifier information in medical records, such as adverse event reports, that would reveal the identity of individuals if disclosed.

3. Prevention of Conflicts of Interest (COI)

An AP must be impartial and free from any commercial, financial, and other pressures that might present a COI or an appearance of a COI. To that end, when deciding whether to accredit a person, we will consider whether they have established, documented, and executed policies and procedures to prevent any individual or organizational COI, including conflicts that their contractors or individual contract employees may have.

Although it is not feasible to identify all of the circumstances that would raise concerns about COI in this document, the most common conditions that indicate an actual or a potential COI are as follows:

- The AP is owned, operated, or controlled by a manufacturer, supplier, or vendor of any article regulated under the act. Please see *http://www.fda.gov/ohrms/dockets/yellow/yellotoc.htm* for examples of firms that are regulated by FDA and, therefore, would create a conflict. This includes manufacturers of radiation-emitting electronic products such as televisions, microwave ovens, compact disk players, laser printers, industrial lasers, as well as foods, drugs, biologics, cosmetics, veterinary products, and medical devices;
- The AP has any ownership or financial interest in any product, manufacturer, supplier or vendor regulated under the act (see section II.B.3 of this document);
- Any personnel of the AP involved in inspections or their spouse or minor children have an ownership or other financial interest regarding any product regulated under the act (see link at section II.B.3 of this document);
- The AP or any of its personnel involved in inspections participates in the design, manufacture, promotion or sale of any product regulated under the act;
- The AP or any of its personnel involved in inspections provides consultative services to any manufacturer, supplier or vendor of products regulated under the act (see link at section II.B.3 of this document);
- Any personnel of the AP involved in the inspection process participate in an inspection of a firm they were employed by within the last 12 months; and
- The fees charged or accepted are contingent or based upon the report made by the AP.

When the AP uses the services of a contractor in connection with an inspection, it is responsible for the work of the contractor and its personnel. It will be the AP's responsibility to assure that the contractor meets the same criteria for freedom from COI as the AP and its personnel.

In addition to conducting inspections as an AP, an AP may also conduct other activities, such as objective laboratory testing of products regulated under the act or assessment of conformance to standards, if those other activities do not affect the impartiality of inspections. Examples of conflicted laboratory testing, i.e., activities an AP may not perform, are those tests linked to the manufacturing process that are usually performed by manufacturers, such as routine quality production tests, validation/verification studies, and quality assurance related testing.

Information on the COI standards FDA applies to its own personnel is included in appendix 1 of the guidance entitled "Standards for Ethical Conduct for Employees of the Executive Branch." An AP may adopt these standards, utilize the model COI policy FDA has provided as another appendix to the guidance, or demonstrate how alternative equivalent procedures will safeguard against COI.

4. Training

An AP will not be eligible to conduct independent inspections until they have successfully completed the classroom training required by FDA and conducted a satisfactory performance inspection under FDA observation. Firms identified on FDA's list of APs to perform inspections will designate employees to participate in the classroom training and joint qualifying inspections.

Training for APs will be "modeled" after training of European Union Conformity Assessment Bodies (EU CABs) under the Mutual Recognition Agreement (MRA) Implementation Plan. (See *http://www.fda.gov/cdrh/mra/guidance/mraprocedure.html.*) EU CABs that have been accredited as APs and whose personnel have successfully completed the required training and/or joint inspections under the MRA program should state this in their application. If confirmed by FDA, the AP will not be required to have a representative repeat the classroom training or joint qualifying inspections. However, FDA does recommend that the AP send a representative to the FDA investigator training module as an update. Personnel trained by FDA under the MRA program who do not attend the current training will need to review a videotaped FDA presentation on evidence development.

The FDA training will consist of a two-tiered program.

Tier one will include formal classroom training for AP inspectional staffers (trainees). At a minimum, this will include:

- The Association for the Advancement of Medical Instrumentation (AAMI) Good Manufacturing Practice (GMP)/Quality System: Requirements and Industry Practice (or equivalent). AAMI will be conducting this training throughout the United States and in foreign countries. (See the AAMI Web site at *http://*

www.aami.org/meetings/courses/gmp.html[1] for specific dates and locations.) Please note that you must register separately for the training session and the examination.

- FDA's QSIT training module.
- FDA investigator training, which will include training on:

Food and Drug Law,
Advanced QSIT,
FDA inspectional procedures,
FDA policies and device regulations, and
Evidence development.

FDA will periodically provide either "face to face" or electronic training for AP inspectors. Each applicant to this program should make tentative plans to send appropriate representatives to the FDA investigator training. However, only those applicants whose applications are approved will be eligible to nominate employees to attend the training. Applicants should advise FDA in their AP application of the names of the employee(s) who have either successfully completed this training or those who will be nominated to participate in this training. AP trainees will not qualify to enter the second tier unless they successfully pass a test at the end of each tier, which is one training session.

The second tier will involve the completion of three joint inspections, during which FDA and the AP will address the relevant parts of Compliance Program 7382.845—Inspection of Medical Device Manufacturers and the QSIT guidance—Guide to Inspection of Quality Systems. The three joint inspections will include:

- Collaborative inspection—The FDA investigator will be the lead inspector and the AP trainee will act primarily as an observer. The FDA investigator will prepare a list of any nonconformities and an inspection report. The trainee will prepare a "practice" list of nonconformities and an inspection report.
- Modified performance inspection—Using established criteria, the FDA investigator will observe and evaluate the trainee performance of an inspection and may provide assistance. The trainee will prepare a list of any nonconformities to be presented to the facility and an inspection report. The FDA investigator will review the list of nonconformities and provide feedback before it is presented. In addition, the FDA investigator will review the inspection report and, if necessary, write an addendum to supplement the inspection report.
- Full performance inspection—The AP trainee will perform an independent inspection and will be observed and evaluated by the FDA investigator using established criteria. The FDA investigator may not provide assistance to the trainee. The trainee will prepare a list of any nonconformities to be presented to the facility and an inspection report. The FDA investigator will review the list of nonconformities and provide feedback before it is presented. In addition, the FDA investigator will review the inspection report and, if necessary, write an addendum to supplement the inspection report. The FDA investigator's evaluation of the trainee and report will be presented to FDA's Office of Regulatory Affairs (ORA) certifier in FDA's Division of Human Resource Development who will determine if the trainee is qualified to perform independent inspections.

The criteria FDA will use to evaluate the joint inspections will be addressed at FDA's training sessions.

5. Evaluation of the AP Application

After FDA receipt of the AP application:

- The third party recognition board (TPRB) Chairman will e-mail the applicant's contact person within 24 hours of receipt of the AP application, acknowledging receipt.
- Members of the TPRB will perform an initial review to determine if the request for accreditation addresses the information set forth in section II.B.6 of this document and is adequate for review by the full TPRB.
- The TPRB Chairman will advise the contact individual, via e-mail, within 60 days after the receipt of such request for accreditation, whether the request is adequate for review by the TPRB or whether additional information is needed.
- If the application is deficient, FDA will identify its shortcomings and advise the applicant to submit additional information within the designated time period. FDA may deem the application incomplete and deny the request for accreditation if the applicant fails to respond to a request for additional information in a timely manner. All information submitted to FDA in response to any requests for additional information should be received by the date indicated in FDA's request. Once such information is received, FDA will file the application for full review, rating, and ranking by the TPRB.

A rating criteria checklist will be used to assess the relevant qualifications and competence of persons applying to become APs. The agency has assigned a weight (5, 15 or 20) to each of eight elements. The eight elements are addressed in section II.B.6 of this document. The weight of the element is based on how essential the information is in determining if the applicant is suitable to perform QS/GMP inspections on behalf of FDA. Each member of the TPRB will assess each of the eight elements and will vote a "quality level" score from 0 to 4 (0 = unsatisfactory, 2 = satisfactory, 4 = exceeds) for each element. The final quality level score will be determined by a majority vote of the TPRB (quality level score x weight = element score). The eight element scores will be totaled to yield an "Application Rating" (maximum rating attainable is 400). Any application with one or more elements rated as unsatisfactory will be deemed to have failed to meet the criteria established by the AP.

- FDA may deny the request for accreditation if we determine that the application does not meet the criteria established for APs.

6. Contents of an AP Application

Applicants should include the following information:

- Administrative information;
- Application in English;
- Name and address of the organization seeking accreditation;
- Telephone number and e-mail address of the contact person. The contact person should be the individual to whom questions about the content of the application may be addressed and to whom a letter of determination and general correspondence will be directed;
- Name and title of the most responsible individual at the AP. Foreign applicants may wish to identify an authorized representative located within the United States who will serve as the AP's contact with FDA;
- Name and title of the most responsible individual at the parent organization, if applicable;
- Brief description of the applicant, including: Type of organization (e.g., not-for-profit institution, commercial business); size of organization (number of employees); organizational charts showing the relationship of the organization involved in the AP inspection program and its relationship with parent or affiliate companies; number of years in operation; nature of work (e.g., conformity assessment testing or certification laboratory); and sufficient information regarding ownership, operation, and control of the

[1] FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.

organization to assess its degree of independence from manufacturers and distributors of products regulated under the act. Please include your annual report or, if it is available electronically on the Internet, please include the appropriate Web site address. If the applicant's organization has offices in numerous locations, please be specific and name all locations that would participate in the AP inspection process for your firm. Applicants may include all locations under one application if they will operate under the same processes and procedures for AP inspections. Include curriculum vitae (CVs) for all supervisory personnel and explain where supervisory oversight will be located;

• List of countries that have certified, accredited or recognized the applicant for quality system or GMP inspections/auditing of medical devices, and the date of such certification, accreditation, or recognition;

• Specification of any accreditation for assessment of quality systems that you may have, such as accreditation to ISO/IEC Guide 62. If you are accredited to standards other then Guide 62, please provide copies of the standards in English.

• Activities for which the AP seeks accreditation. This includes a list identifying the devices the applicant seeks to inspect. Applicants may simply state "all devices" or identify the devices they wish removed from their scope of work by classification panel or by classification name (e.g., all devices except cardiovascular devices under part 870 or except §§ 870.3620, 870.3630, 870.3640, and 870.3670).

Prevention of Conflict of Interest

The applicant should submit a copy of the written policies, procedures, and sample certification/compliance statements established to prevent conflicts of interest. MDUFMA requires that the AP and its employees (including contract employees) involved in the performance of inspections and the preparation and approval of reports be free from conflicts of interest and the appearance of conflicts of interest that might affect the inspection process. No personnel of an AP involved in inspections, nor their spouses or minor children, may have ownership of or other financial interest in any product regulated under the act. In accordance with section 704(g)(3)(E) of the act, APs will annually make available to the public the extent to which the AP complies with conflict of interest requirements.

Technical Competence

FDA will consider several factors with respect to personnel qualifications and the preparedness of the applicant to conduct technically competent inspections. The applicant should document these factors in its application and include:

• The written policies and procedures established to ensure that manufacturers are inspected by qualified personnel;

• The written instructions for the duties and responsibilities of personnel, including inspectors, with respect to the inspection of device manufacturing facilities;

• The written personnel qualification standards established to ensure that inspectors and other designated personnel are qualified in all of the regulatory and technical disciplines needed to effectively inspect for compliance with FDA's regulatory requirements for medical devices;

• The documentation (e.g., CVs) to establish that the inspectors and other involved nonsupervisory personnel meet the established criteria for qualified personnel. This includes documentation of knowledge, education, training, skills, abilities and experience, including specialized education and experience needed for the inspection of medical device manufacturing facilities;

• The documentation (e.g., CVs) to establish that the supervisor(s) of inspectors have sufficient authority and meet the established criteria for qualified supervisory personnel. This includes documentation of knowledge, education, training, skills, abilities and experience, including any specialized education and experience needed to supervise the inspection and review records prepared by inspectors;

• A description of the applicant's management structure and that of any contractor used for inspection work. The application should describe the position of the individual(s) providing supervision within the management structure and explain how that structure provides for the supervision of the inspectors and other personnel involved in the inspection process. (If the applicant plans to utilize contractors, please address the additional information described at section II.B.6 of the document);

• A description of the inspection team. This includes documentation for any members of the team who may already have training and experience relevant to the assessment of compliance with FDA's regulatory requirements for medical devices (e.g., compliance programs, the QS regulation, and general auditing principles). The description should include documentation of the ability of the team to recognize, collect, and identify evidence of noncompliance and adequately communicate with the manufacturer regarding the inspection;

• Documentation that personnel involved in inspections have basic quality systems knowledge and are qualified in accordance with generally accepted quality assurance standards, (e.g., ISO 13485 or part 820) and capable of functioning in accordance with the relevant parts of these standards;

• Documentation of training plan to assure technical competence;

• Documentation of records that demonstrate the appropriate experience and training of each inspector.

Resources

The applicant should identify what reference materials are available to inspectors and other personnel involved in inspections, (e.g., the act, regulations, manuals, standards). Also, the application should identify equipment and resources available that will enable the inspector to perform technical and administrative tasks. At a minimum, this should include a computer system with a modem and an independent facsimile machine. FDA will rely extensively on the use of our electronic systems for timely dissemination of guidance documents to APs and other interested parties.

APs should have physical security and safeguards in place to protect trade secret and confidential commercial and financial information, as well as personal identifier information in medical records, such as adverse event reports, that would reveal the identity of individuals if disclosed.

Confidentiality

The applicant should include established procedures to ensure confidentiality of reports and all information obtained during an inspection. These should address aspects of authorized disclosure and the procedures by which the applicant maintains confidentiality between itself and the manufacturer. In addition, the applicant should describe the procedures through which the applicant's personnel and any contractors are made aware of confidentiality requirements.

Contractors

FDA will consider several factors to determine whether the applicant ensures that contractors are properly qualified, utilized, and monitored. Special emphasis will be placed on personnel qualifications and preparedness to conduct technically competent inspections, and on conflict of interest controls. The applicant should document these factors in the application and include:

• The written policies and procedures established to ensure that contractors conform to the same requirements (e.g., education, training, and experience) that would apply to the applicant if it were performing the inspection or aspects of the inspection contracted. These policies and procedures should ensure that the contractor conducts inspections in accordance with the same procedures under which the applicant operates. The applicant should include assurances that it will maintain documentary evidence that the contractor has the necessary technical competence and resources to carry out contracted activities;

• Written policies and procedures documenting that the applicant will not contract the overall responsibility for reviewing the results of the inspections;

• Documentation of an agreement delineating the duties, responsibilities, and accountability of the contractor; and

• The written policies and procedures for establishing a register of qualified contractors.

AP QS

FDA will consider the following factors to determine whether the applicant has established an adequate quality system to ensure compliance with FDA policies and procedures relevant to inspections:

• The applicant should establish a documented quality system to ensure that there are processes and procedures in place to demonstrate compliance with section 704(g) of the act;

• The policies and procedures the applicant follows are adequate to maintain control of all quality system documentation and to ensure that a current version is available at all locations; and

• The policies and procedures for internal auditing to ensure the quality system is implemented effectively and that resources are available for conducting such audits.

Certification Agreement Statement

The applicant should provide a copy of a documented statement, which will be signed by the most responsible individual, certifying that:

• The AP has appropriate policies and procedures to meet FDA's conflict of interest provisions, has the appropriate staff and procedures in place to ensure technical competence for conducting inspections under section 704(g) of the act, and has the quality system in place to ensure acceptable and consistent inspections;

• Where the AP uses the services of a contractor for QS/GMP inspections, the AP should also certify that its contractor(s) meets the APs established criteria for freedom from conflicts of interest and technical competence;

• The AP consents to FDA inspection and copying of all records, correspondence, and other materials relating to any inspections conducted by the AP under this program, including records on personnel, education, training, skills, and experience and all documentation on prevention of conflicts of interest, including certification/compliance statements; and

• The AP will protect trade secret and confidential commercial or financial information, and will treat as private information about specific patient identifiers in records such as adverse event reports, except that such information may be made available to FDA.

III. The Guidance

We are issuing a revised guidance entitled "Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria," which repeats the AP criteria set out in section II of this document. In addition, the guidance provides other useful information such as suggestions about the format and content of the accreditation applications. The revised guidance reflects changes to the law made by the Medical Device Technical Corrections Act.

The guidance represents the agency's current thinking on the "Implementation of the Inspection by Accredited Persons Program under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria." The issuance of this guidance is consistent with FDA's good guidance practices regulation (21 CFR 10.115). It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

IV. Electronic Access

To receive "Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria" by fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1200) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

V. Paperwork Reduction Act of 1995

This document and the guidance entitled "Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria" contain a proposed collection of information that requires clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under OMB control number 0910–0510.

VI. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this guidance document at any time. Submit 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. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 24, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–22211 Filed 10–1–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0443]

Draft Guidance for Industry on Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations." The draft guidance describes the key elements of a robust quality systems model and shows how persons implementing such a model can achieve compliance with the CGMP regulations.

DATES: Submit written or electronic comments on the draft guidance by December 3, 2004. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance 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 one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Monica Caphart, Center for Drug Evaluation and Research (HFD–320), Food and Drug Administration, 11919 Rockville Pike, Rockville, MD 20852, 301–827–9047; or

Robert Sausville, Center for Biologics Evaluation and Research (HFM–624), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6201; or

June Liang, Center for Veterinary Medicine (HFV–12), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–8789; or

Patricia Maroney-Benassi, Office of Regulatory Affairs (HFC–240), 15800 Crabbs Branch Way, Rockville MD 20855, 240–632–6819.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations." The draft guidance illustrates where FDA can harmonize across agency centers and with other non-U.S. pharmaceutical quality management requirements. This draft guidance was developed by the quality systems group formed as part of the CGMP for the 21st Century initiative. The draft guidance is intended to encourage the use of modern quality management system principles by the regulated industry and foster innovation and continuous improvements in pharmaceutical manufacturing.

The Pharmaceutical CGMPs for the 21st Century: A Risk Based Approach initiative was announced in August 2002 (*http://www.fda.gov/cder/gmp/2ndProgressRept_Plan.htm*). Among the many CGMP issues identified at that time were: (1) The increase in the number of pharmaceutical products and in the role of medicines in health care; (2) the decrease in the frequency of FDA manufacturing inspections resulting from fewer available resources; (3) FDA's increasing experience with, and lessons learned from, various approaches to the regulation of product quality; (4) advances in the pharmaceutical sciences and manufacturing technologies; (5) the increasing application of biotechnology in drug discovery and manufacturing; (6) advances in the science and management of quality; and (7) the globalization of the pharmaceutical industry.

At the outset, the agency established a set of guiding principles for the initiative:

- Maintain a risk-based orientation;
- Policies and standards must be science based;
- The agency's orientation must be toward integrated quality systems;
- International cooperation is very important; and
- Protection of the public health must remain top priority.

The initiative's announcement stated that 21 CFR parts 210, 211, and parts 600 and 610 are flexible and will allow the agency to embark on a science-based risk management approach to CGMPs. This draft guidance, developed by a cross-center working group established by the initiative, is key in achieving the agency's goals. By showing how modern quality systems approaches relate to the existing CGMP regulation, the agency can help manufacturers meet the requirements of the agency's CGMP while using a robust quality systems approach to the production of human and animal medical products. Such a comprehensive approach should foster flexibility and allow for continued innovation, while maintaining the principles of the CGMP regulations.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two paper copies of mailed comments are to be submitted, 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. The draft guidance 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 document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: September 28, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–22206 Filed 9–29–04; 1:51 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0380]

Guidance for Industry: Process Analytical Technology—A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "Guidance for Industry: PAT—A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance." The guidance explains a science-based, risk-based framework, "Process Analytical Technology, or PAT," to support innovation and efficiency in pharmaceutical development, manufacturing, and quality assurance. This framework is founded on process understanding, with the goal of facilitating innovation and risk-based regulatory decisions by industry and the agency. Working with existing regulations, this guidance describes a regulatory approach that will enable the agency and the pharmaceutical industry to address technical and regulatory issues and questions anticipated during the implementation of PAT.

DATES: General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:
Chris Watts, Center For Drug Evaluation and Research (HFD–003), 5600 Fishers Lane, Rockville, MD 20857, 301–443–5197; or
Dennis Bensley, Center for Veterinary Medicine (HFV–143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6956; or
Robert Coleman, Office of Regulatory Affairs (HFR–SE150), Food and Drug Administration, 60 8th St. North East Atlanta, GA 30309, 404–253–1200, ext. 1295.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled "Guidance for Industry: PAT—A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance." The guidance explains a science-based, risk-based framework, "Process Analytical Technology, or PAT," that supports innovation and efficiency in pharmaceutical development, manufacturing, and quality assurance. The framework is founded on process understanding, which can be used to facilitate innovation and risk based regulatory decisions by industry and the agency.

Conventional pharmaceutical manufacturing is generally accomplished using batch processing with laboratory testing conducted on collected samples to evaluate quality. This conventional approach has been successful in providing quality pharmaceuticals to the public. However, today significant opportunities exist for improving pharmaceutical development, manufacturing, and quality assurance through innovation in product and process development, process analysis, and process control. Unfortunately, the pharmaceutical industry generally has been hesitant to introduce innovative systems into the manufacturing sector for a number of reasons. One reason often cited is regulatory uncertainty, which may result from the perception that the existing regulatory system is rigid and unfavorable to the introduction of innovative systems. In August 2002, recognizing the need to eliminate the hesitancy to innovate, FDA launched a new initiative entitled "Pharmaceutical Current Good Manufacturing Practices for the 21st Century: A Risk-Based Approach." Development of this guidance was part of that initiative.

Pharmaceutical development and manufacturing is evolving with increased emphasis on science and engineering principles. Effective use of pharmaceutical science and engineering principles and knowledge, throughout the life cycle of a product, can improve the efficiencies of both manufacturing and regulatory processes. FDA's initiative is designed to do just that using an integrated systems approach to regulating pharmaceutical product quality. This approach is based on science and engineering principles for assessing and mitigating risks related to poor product and process quality. The desired future state of pharmaceutical manufacturing may be characterized as the following: (1) Product quality and performance achieved and ensured through the design of effective and efficient manufacturing processes, (2) product and process specifications based on a mechanistic understanding of how formulation and process factors affect product performance, (3) continuous real time quality assurance, (4) regulatory policies and procedures tailored to recognize the level of scientific knowledge supporting products and processes, (5) risk-based regulatory approaches that recognize the level of scientific understanding of how formulation and manufacturing process factors affect product quality and performance, as well as, the capability of process control strategies to prevent or mitigate the risk of producing a poor quality product. This guidance is intended to facilitate progress to this desired state.

II. Comments Received on the Draft Guidance

In the **Federal Register** of September 5, 2003 (68 FR 52781), FDA published a document announcing the availability of a draft version of this guidance. The draft guidance was issued with the goal of soliciting comments from the public on related issues. The agency received a number of comments on the draft guidance, and those comments were considered carefully as the guidance was finalized. A number of changes were made to the guidance. Most of them were of an editorial nature. The following three substantive changes were made to the guidance as a result of the comments: (1) The scope of the guidance was expanded to include the Center for Drug Evaluation and Research's Office of Biotechnology Products, (2) links were established to ASTM Technical Committee E55 entitled "Pharmaceutical Application of Process Analytical Technology," and (3) the section on process understanding was moved forward to emphasize the guidance's focus.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative

approach may be used if the approach satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: September 28, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–22203 Filed 9–29–04; 1:51 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. 2003D–0382]

Food and Drug Administration

Guidance for Industry on Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice." This guidance explains FDA's current thinking on manufacturing of sterile drug products produced by aseptic processing in the context of complying with certain sections of the current good manufacturing practice (CGMP) regulations for drug and biological products. This guidance is issued with the goal of providing clear and consistent communication of regulatory expectations to promote voluntary compliance with current FDA requirements.

DATES: General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance 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 one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Richard Friedman, Center for Drug Evaluation and Research (HFD–320), Food and Drug Administration, 11919 Rockville Pike, Rockville, MD 20852, 301–827–9031; or

Robert Sausville, Center for Biologics Evaluations and Research (HFM–624), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6201; or

Robert Coleman, Office of Regulatory Affairs (HFC–240), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 404–253–1295.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Sterile Drug Products Produced by Aseptic Processing— Current Good Manufacturing Practice." This guidance explains FDA's current thinking on manufacturing of sterile drug products produced by aseptic processing in the context of complying with certain sections of the CGMP regulations for drug and biological products (21 CFR parts 210, 211, and 600 through 680, respectively).

In the **Federal Register** of September 5, 2003 (68 FR 52782), FDA announced the availability of a draft guidance entitled "Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice." The draft guidance was finalized after consideration of received public comments. Consistent with the objectives of FDA's CGMPs for the 21st Century initiative, this guidance provides updated information regarding CGMP expectations for aseptic processing facilities, reflects the latest science in the area of sterile drug quality, and promotes innovations in manufacturing that achieve increased sterility assurance. Through this guidance, FDA hopes to facilitate a higher assurance of process consistency and promote better contamination prevention practices.

Sterile drug products are a high priority in FDA's risk-based inspectional program. These drug products are generally of high therapeutic significance. Clarifying relevant regulatory standards for sterile drug products will help reduce the incidence of manufacturing problems with this class of pharmaceuticals, thus facilitating the ready availability of these therapeutically significant pharmaceuticals and avoiding drug shortages.

This guidance document is the product of extensive public input. FDA first published a preview of its current thinking in the form of a concept paper on September 23, 2003. We presented our CGMP approach for aseptic processing at the Advisory Committee for Pharmaceutical Science on October 22, 2002. At this meeting, the concept paper was discussed in a public forum and critiqued by the advisory committee's members as well as a panel of invited aseptic processing experts. The advisory committee meeting yielded a number of issues that provided impetus for further discussion. In December 2002, an aseptic processing working group was formed under Product Quality Research Institute (PQRI) to address these issues. The working group, composed of 41 prominent aseptic processing experts from industry, academia, and FDA, prepared technical recommendations on the guidance document. The PQRI Steering Committee forwarded the working group's final report to FDA on March 19, 2003, and it was subsequently posted on PQRI's Web site (*www.pqri.org*).[1] The draft guidance was published on September 3, 2003.

The advisory committee and PQRI Working Group recommendations provided valuable contributions and many of these recommendations have been adopted in the guidance.

II. Comments Received on the Draft Guidance

A number of comments were received on the draft guidance, most of which concerned the need to further enhance the precision of guidance provided on certain topics. As a result, many clarifying changes were made. Major changes include the revision of the Sterility Testing section of the guidance to clearly emphasize and reference the United States Pharmacopeial Sterility Test <71>. In the guidance, table 1 entitled "Air Classifications," which

[1] FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.

summarizes clean area air classifications and recommended microbiological action levels, has been modified to acknowledge that alternate action levels can be justified depending on the method of analysis used. Further clarifications have been made regarding process simulations. In addition, the guidance recommends "building quality into products" through science-based facility, equipment, and systems design for sterile drug manufacture. We underscore our encouragement of alternate approaches and innovations to achieve increased sterility assurance.

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if the approach satisfies the requirements of the applicable statute and regulations.

III. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The collection of information in this guidance was approved under OMB control number 0910–0139, until August 31, 2005.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: September 28, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–22207 Filed 9–29–04; 2:14 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0414]

Guidance for Industry on Food and Drug Administration Review of Vaccine Labeling Requirements for Warnings, Use Instructions, and Precautionary Information; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Guidance for Industry: FDA Review of Vaccine Labeling Requirements for Warnings, Use Instructions, and Precautionary Information," dated September 2004. The guidance document provides to vaccine manufacturers, medical practitioners, and consumers an overview of the vaccine labeling review process, a description of FDA's review of childhood vaccine labeling, and a discussion of the type of data FDA examines when determining the adequacy of vaccine labeling.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance 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: Astrid Szeto, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, suite 200N, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled "Guidance for Industry: FDA Review of Vaccine Labeling Requirements for Warnings, Use Instructions, and Precautionary Information," dated September 2004. The guidance document provides to vaccine manufacturers, medical practitioners, and consumers an overview of the vaccine labeling review process, a description of FDA's review of childhood vaccine labeling under section 314 of the National Childhood Vaccine Injury Act (NCVIA), and a discussion of the type of data FDA examines when determining the adequacy of vaccine labeling. The processes described represent current FDA practices and do not represent any new interpretation of existing labeling statutes, regulations, or guidances.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Comments

In accordance with 21 CFR 10.115(g)(4)(i), FDA is immediately implementing this guidance. Interested persons may, at any time, submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**) regarding this guidance. 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 the brackets in the heading of this document. A copy of the guidance 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 guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: September 20, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–22213 Filed 10–1–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Children's Hospitals Graduate Medical Education Payment Program (CHGME PP)

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of Children's Hospitals Graduate Medical Education Payment Program (CHGME PP) conference call.

SUMMARY: This document announces a scheduled CHGME PP conference call for Federal fiscal year (FY) 2005. The

purpose of this conference call is to provide technical assistance related to the CHGME PP.

DATES: The conference call will be held on Wednesday, October 20, 2004 from 1:30 p.m. to 3:30 p.m. EST.

FOR FURTHER INFORMATION CONTACT: Ayah E. Johnson, Ph.D., telephone: (301) 443–1058; Division of Medicine and Dentistry, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, 5600 Fishers Lane, Room 9A–05, Rockville, Maryland 20857; or by e-mail at: *ajohnson@hrsa.gov*.

SUPPLEMENTARY INFORMATION: The CHGME PP, as authorized by section 340E of the Public Health Service (PHS) Act (the Act) (42 U.S.C. 256e), provides funds to children's hospitals to address disparity in the level of Federal funding for children's hospitals that result from Medicare funding for graduate medical education (GME). Pub. L. 106–310 amended the CHGME statute to extend the program through FY 2005.

The statute authorized $280 million for both direct and indirect medical education payments in FY 2000, $285 million in FY 2001, and for each of the FY 2002 through FY 2005 such sums as necessary. Congress appropriated $303 million in FY 2004 for the CHGME PP. These funds have supported over 4,000 residents receiving training in children's teaching hospitals in 31 States.

The agenda for the conference calls will include but not be limited to: (1) Welcome and opening comments; (2) news releases/updates; (3) reminders; and (4) "on the horizon" topics of interest. Time will also be available for a question and answer period. Agenda items will be determined as priorities dictate.

Interested parties must register, in advance, but not later than 5 days prior to the scheduled conference call. Conference call registration forms and information about the Program can be found on the CHGME PP Web site. The Web address is *http://bhpr.hrsa.gov/childrenshospitalgme*.

Dated: September 28, 2004.

Elizabeth M. Duke,

Administrator.

[FR Doc. 04–22282 Filed 10–1–04; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Infant Mortality; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), notice is hereby given of the following meeting:

Name: Advisory Committee on Infant Mortality (ACIM).

Dates and Times: November 11, 2004, 9 a.m.–5 p.m., November 12, 2004, 8:30 a.m.–3 p.m.

Place: The Latham Hotel, 3000 M Street, NW., Washington, DC 20007 (202) 726–5000.

Status: The meeting is open to the public.

Purpose: The Committee provides advice and recommendations to the Secretary of Health and Human Services on the following: Department programs that are directed at reducing infant mortality and improving the health status of pregnant women and infants; factors affecting the continuum of care with respect to maternal and child health care, including outcomes following childbirth; strategies to coordinate the variety of Federal, State, local and private programs and efforts that are designed to deal with the health and social problems impacting on infant mortality; and the implementation of the Healthy Start program and *Healthy People 2010* infant mortality objectives.

Agenda: Topics that will be discussed include the following: Infant Mortality Differentials; Social Factors and Racial Disparities; and Perinatal Outreach Strategies. Agenda items are subject to change as priorities are further determined.

FOR FURTHER INFORMATION CONTACT: Anyone requiring information regarding the Committee should contact Peter C. Van Dyck, M.D., M.P.H., Executive Secretary, ACIM, Health Resources and Services Administration (HRSA), Room 18–05, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, telephone: (301) 443–2170.

Individuals who are interested in attending any portion of the meeting or who have questions regarding the meeting should contact Ann M. Koontz, C.N.M., Dr.P.H., HRSA, Maternal and Child Health Bureau, telephone: (301) 443–6327.

Dated: September 29, 2004.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 04–22283 Filed 10–1–04; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Training in Primary Care Medicine and Dentistry; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), notice is hereby given of the following meeting:

Name: Advisory Committee on Training in Primary Care Medicine and Dentistry.

Dates and Times: October 21, 2004, 8:15 a.m.–4:30 p.m., October 22, 2004, 8 a.m.–2 p.m.

Place: The Hilton in Gaithersburg, 620 Perry Parkway, Gaithersburg, Maryland 20877.

Status: The meeting will be open to the public.

Purpose: The Advisory Committee provides advice and recommendations on a broad range of issues dealing with programs and activities authorized under section 747 of the Public Health Service Act as amended by The Health Professions Education Partnership Act of 1998, Public Law 105–392. At this meeting the Advisory Committee will work on its draft fifth report which will be submitted to Congress and the Secretary of the Department of Health and Human Services in November 2005 and which focuses on measuring outcomes of Title VII, section 747 grant programs.

Agenda: The meeting on Thursday, October 21, will begin with opening comments from the Chair of the Advisory Committee. A plenary session will follow in which Advisory Committee members will hear speakers address the topic of outcomes measurement from various perspectives. The Advisory Committee will work on its fifth report, both in plenary session and in smaller workgroups. An opportunity will be provided for public comment.

On Friday, October 22, the Advisory Committee will continue work on the report. An opportunity will be provided for public comment.

For Further Information Contact: Anyone interested in obtaining a roster of members or other relevant information should write or contact Jerilyn K. Glass, M.D., Ph.D., Division of Medicine and Dentistry, Bureau of Health Professions, Health Resources and Services Administration, Room 9A–27, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–6326. The web address for information on the Advisory Committee is *http://bhpr.hrsa.gov/medicine-dentistry/actpcmd*.

Dated: September 27, 2004.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 04–22184 Filed 10–1–04; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

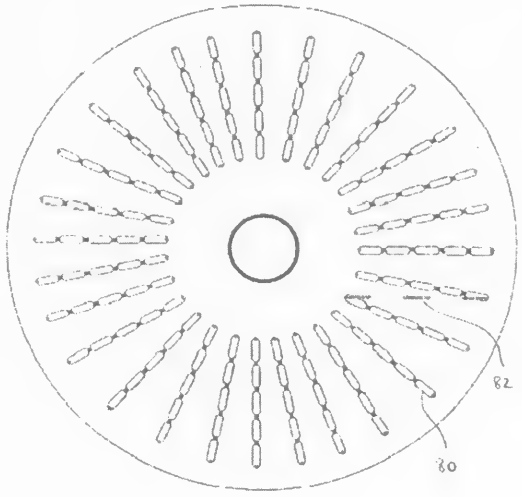
Chromatography Apparatus and Method

Yoichiro Ito (NHLBI)

U.S. Provisional Application Filed 24 Aug 2004 (DHHS Reference No. E–277–2004/0–US–01)

Licensing Contact: Michael Shmilovich; 301/435–5019; *shmilovm@mail.nih.gov.*

Available for licensing for industrial scale-up production and commercial distribution is an improved countercurrent chromatography apparatus comprising a disk having a series of interconnected and elongated compartments coupled by ducts that form a portion of a groove in a surface of the disk. At least some of the elongated compartments have an aspect ratio of at least greater than two and a width greater than twice the width of the connecting ducts and a length of about 10 to 20 times the length of the connecting ducts. This apparatus may also be used for a large-scale industrial separation by coaxially rotating in centrifugal or gravitational fields.



HIV–1 Infection Detection Assay for Seroconverted HIV–1 Vaccine Recipients

Hana Golding, Surender Khurana (FDA/CBER)

U.S. Provisional Application Filed 08 Sep 2004 (DHHS Reference No. E–259–2004/0–US–01)

Licensing Contact: Michael Shmilovich; 301/435–5019; *shmilovm@mail.nih.gov.*

Available for licensing and commercial distribution is an assay method and kit having diagnostic peptide fragments derived from human immunodeficiency virus-1 (HIV–1). The new serology assay includes HIV–1 peptide fragments epitopes that map to HIV–1 GAG–p6, and gp41 genes. These epitopes are broadly reactive with early sera from HIV infected individuals, do not illicit protective antibodies, do not illicit immunologic cytotoxicity and are readily removable from current and future HIV–1 candidates. The assay is advantageous in detecting HIV–1 early breakthrough infections in seroconverted vaccine recipients while being able to distinguish between individuals with bonafide breakthrough infections versus non-HIV infected vaccine recipients presenting only vaccine borne antibodies. For example, 90% of vaccine recipients receiving a Canarypox construct expressing a plurality of HIV antigens (Env, Gag, Pol, HIV Protease, Nef) followed by an envelope protein boost, scored positive in FDA licensed enzyme immunoassay, rapid test, and Western blot (Marta-Louise Ackers *et al.*, J Infect Dis. 187:879 (2003)). Such seroconversion has a negative impact on phase III efficacy trials of prophylactic HIV vaccines that require early detection of breakthrough infections and also exclude non-HIV infected vaccine recipients from the pool of potential blood donors.

Flow-Through, Thermal-Expansion-Compensated Microcells for Analytical Transmission Infrared and Other Light Spectroscopies

Edward Mertz (NICHD), James Sullivan (ORS)

U.S. Patent Application No. 10/926,405 Filed 26 Aug 2004 (DHHS Reference No. E–096–2004/0–US–01)

Licensing Contact: Michael Shmilovich; 301/435–5019; *shmilovm@mail.nih.gov.*

Available for licensing and commercial distribution are optical cells that are spectroscopically, thermally and mechanically stable and can be used for spectroscopic measurement in transmission, reflection, transmission-reflection, emission, or scattering modes without modification of standard spectrometers. The cell handles liquid samples and biological or solid samples equilibrated with bathing fluid which does not interfere with the light beam, allows liquid sample or bathing fluid to be exchanged without cell reassembly, requires only a small amount of sample (down to 0.1µl), allows for different sample gaps (0.2–1000µm) to be easily and inexpensively set, and allows spectral measurements to be taken over wavelengths ranging at least from the mid-infrared to the vacuum ultraviolet. The inventive cell and methods allows sensitive and reproducible monitoring spectra and their changes (down to at least 10^{-4} absorbance units) caused by changes in temperature or in composition of bathing fluid or by fast kinetic processes.

This research is described, in part, in Mertz E.L., Leikin S. "Interactions of Inorganic Phosphate and Sulfate Anions with Collagen", Biochemistry, in press.

Device for Sequential Protein Transfer From a Gel

Jozsef Antal, Zsuzsanna Buzas, Andreas Chrambach (NICHD)

DHHS Reference No. E–346–2003/0–US–01 filed 09 July 2004

Licensing Contact: Michael Shmilovich; 301/435–5019; *shmilovm@mail.nih.gov.*

Available for licensing and commercialization is a device for sequentially eluting proteins and peptides. The device comprises a separation medium having an outlet, and a collector having a first receptacle and second receptacle that can be sequentially brought into contact with the outlet of the separation medium by translating (rotating) the first receptacle and the second receptacle in relation to the outlet of the separation medium. The invention is adaptable to capillary electrophoresis as well. Multiple sequential protein transfer from SDS–PAGE gel to a mass spectrometer is made possible. Separated protein bands sequentially electrophorese into low melting agarose plugs distributed along the surface of a plastic drum. The effective electroelution of a protein from a gel band to an agarose filled slot. The drum is rotated to receive each band individually. Migrating SDS linearized proteins are electrophoresed into the receptacle slot drum. The drum is rolled until each protein of interest is separated. Agarose plugs are lifted from the drum slots; enzymatically dissolved, and loaded directly onto a MALDI spectrometer. Between two agarose layers, gel free collection chambers can be formed inside the drum providing solution phase fraction collection.

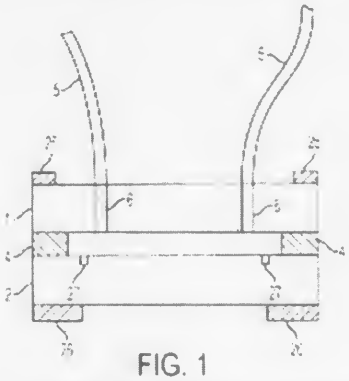


FIG. 1

This research is described in: Buzas Z, Antal J, Gilligan JJ, Backlund PS, Yergey AL, Chrambach A. An electroelution apparatus for sequential transfer of sodium dodecyl sulfate-proteins into agarose and mass spectrometric identification of Li-Na-dodecyl sulfate-proteins from solubilized agarose. Electrophoresis. 2004 Apr;25(7–8):966–9.

Simultaneous HDL/LDL/Total Lipoprotein Single Tube Homogeneous Assay

Alan T. Remaley, Maureen Sampson, Gyorgy Csako (CC)

DHHS Reference No. E–090–1999: U.S. Patent App. 09/980,751 Filed 01 Nov 2001; European Patent App. Ser. No. 00939404.0 Filed 26 May 2000; Canadian Patent. App. 2375210 Filed 26 May 2000; Australian Pat. App. 54493/00 filed 26 May 2000; Japanese Patent App. 2001–500866 filed 26 May 2000

Licensing Contact: Michael Shmilovich; 301/435–5019; *shmilovm@mail.nih.gov.*

Available for licensing is an invention in which a single tube assay is used for determining high-density lipoprotein HDL-cholesterol (HDL–C), low density lipoprotein (LDL–C) and total cholesterol (total-C), from a single serum sample. This assay is an efficient tool for use in determining patient risk factors for heart disease. Previously, multiple costly tests were performed in order to determine low-density lipoprotein LDL–C and HDL–C by measuring total-C, total triglyceride, and HDL–C. That method of testing had limitations and was complex. Using this methodology, the homogeneous assay for HDL–C does not require physically separating HDL. The new assay developed is efficient, less costly, and compares favorably to current assays for HDL–C, total cholesterol, and triglyceride. This technology may also be used to simplify the procedure for the point of care testing of hyperlipidemia.

Dated: September 22, 2004.

Steven M. Ferguson,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 04–22151 Filed 10–1–04; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Prevention Correction of Meeting Notice

Pursuant to Pub. L. 92–463, notice is hereby given of a correction of a notice of a meeting of the Substance Abuse Prevention (CSAP) National Advisory Council to be held in October 2004.

Public notice was given in the **Federal Register** on September 27, 2004 (Volume 69, Number 186, page 57711) that the CSAP National Advisory Council would be meeting on October 5 and 6, 2004 at The Times Building, One Times Square, Third Floor, New York, New York. The place for this meeting has subsequently changed to The Renaissance New York Hotel Times Square, Two Times Square, 714 Seventh Avenue at W. 48th Street, New York, New York. The agenda and date of the meeting and contact for additional information remain as announced.

Dated: September 30, 2004.

Toian Vaughn,

SAMHSA Committee Management Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 04–22339 Filed 10–1–04; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Availability of Final Comprehensive Conservation Plan for Fish Springs National Wildlife Refuge, Dugway, UT

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability.

SUMMARY: The U.S. Fish and Wildlife Service announces that a Comprehensive Conservation Plan (CCP) and Summary for Fish Springs National Wildlife Refuge is available. This CCP, prepared pursuant to the National Wildlife Refuge System Improvement Act of 1997 and the National Environmental Policy Act of 1969, describes how the U.S. Fish and Wildlife Service intends to manage this Refuge for the next 15 years.

ADDRESSES: A copy of the Plan or Summary may be obtained by writing to U.S. Fish and Wildlife Service, Fish Springs National Wildlife Refuge, PO Box 568, Dugway, Utah, 84022; or download from *http://mountain-prairie.fws.gov/planning.*

FOR FURTHER INFORMATION CONTACT: Jay Banta, Refuge Manager, U.S. Fish and Wildlife Service, Fish Springs National Wildlife Refuge, PO Box 568, Dugway, Utah, 84022. Phone 435–831–5353; fax 435–831–5354; or e-mail: *jay_banta@fws.gov.*

SUPPLEMENTARY INFORMATION:

Background

Fish Springs National Wildlife Refuge (NWR), comprised of 17,992 acres, is located in western Utah in Juab County. Springs flowing from the eastern base of the Fish Springs Range feed a 10,000-acre saline marsh divided into nine impoundments. The remaining portion comprises 6,000 acres of mud and alkali flat and 2,000 acres of semidesert upland. The Refuge provides the only important wetland habitat for a 70-mile radius, attracting hundreds of wetland-dependent species during migration. Since Refuge establishment, more than 278 species of birds have been seen at Fish Springs NWR, 61 of which nest on the Refuge. Fish Springs NWR was established by the Migratory Bird Conservation Commission in 1959 "* * * for use as an inviolate sanctuary, or for any other management purpose, for migratory birds."

The availability of the Draft CCP and Environmental Assessment (EA) for 30-day public review and comment was announced in the **Federal Register** on July 20, 2004 in Volume 69, Number 138. The Draft CCP/EA identified and evaluated three alternatives for managing Fish Springs NWR for the next 15 years. Alternative A, the No Action Alternative, would have continued current management of the Refuge. Alternative C (Preferred Alternative) emphasizes providing habitat for maximum wildlife diversity including migratory birds, and native mammal, mollusk, invertebrate, and amphibian communities. Alternative B, Marsh Restoration, would have restored the Refuge's original hydrological system and high-desert shrubland habitat to a condition resembling their historical nature prior to Refuge development.

Based on this assessment and comments received, the preferred Alternative C was selected for implementation. The preferred alternative was selected because it best meets the purpose and goals of the Refuge, as well as the goals of the National Wildlife Refuge System. The preferred alternative will also benefit migratory birds and native mammal, mollusk, invertebrate, and amphibian communities. Increased efforts in visitor services and the addition of a goose hunt will result in improved wildlife-dependent recreational opportunities. Cultural and historical resources will be protected.

Dated: September 1, 2004.

Mary G. Henry,

Regional Director, Region 6, Denver, Colorado.

[FR Doc. 04–22262 Filed 10–1–04; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Southern Conservation Corporation's Candidate Conservation Agreement With Assurances and Enhancement of Survival Permit Application for the Greater Adams Cave Beetle and Lesser Adams Cave Beetle

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability.

SUMMARY: We, the Fish and Wildlife Service, have received an application from Southern Conservation Corporation (Applicant) for an enhancement of survival permit (ESP) pursuant to section 10(a)(1)(A) of the Endangered Species Act of 1973 (U.S.C. 1531 *et seq.*), as amended (Act). With our assistance, the Applicant proposes to implement conservation measures for the greater Adams Cave beetle (*Pseudanophthalmus pholeter*) and lesser Adams Cave beetle (*Pseudanophthalmus cataryctos*), collectively known as the "the covered species," by removing the threats to the survival of these species and protecting their habitat. We are announcing our receipt of the ESP application as well as the availability of a proposed Candidate Conservation Agreement with Assurances (CCAA) that is intended to facilitate the implementation of conservation measures for the species by the Applicant and the Service in support of on-going efforts to remove threats to their survival and provide protection of their habitat.

DATES: Written comments on the CCAA and ESP application should be sent to the Service's Regional Office (see **ADDRESSES**) and should be received on or before November 3, 2004.

ADDRESSES: Persons wishing to review the CCAA and ESP application may obtain copies by writing the Service's Southeast Regional Office, Atlanta, Georgia at the address below. Documents will also be available for public inspection by appointment during normal business hours at the Regional Office, 1875 Century Boulevard, Suite 200, Atlanta, Georgia 30345 (Attn: Endangered Species Permits), or Field Supervisor, Fish and Wildlife Service, 3761 Georgetown Road, Frankfort, Kentucky 40601. Written data or comments concerning the CCAA or ESP application should be submitted to the Regional Office at the address listed above and must be submitted in writing to be adequately considered in the Service's decision-making process. Please reference permit number TE–088168–0 in your comments, or in requests of the documents discussed herein.

FOR FURTHER INFORMATION CONTACT: Mr. Rick Gooch, Regional CCAA Coordinator, (see **ADDRESSES** above), telephone: (404) 679–7124, facsimile: (404) 679–7081; or Dr. Michael Floyd, Fish and Wildlife Biologist, Kentucky Field Office, Frankfort, Kentucky (see **ADDRESSES** above), telephone: (502) 695–0468.

SUPPLEMENTARY INFORMATION:

Public Review and Comments Solicited

Individuals wishing copies of the ESP application and/or copies of the full text of the proposed Agreement should contact the office and personnel listed in the **ADDRESSES** section above. Documents also will be available for public inspection, by appointment, during normal business hours at this office (see **ADDRESSES**). We provide this notice pursuant to section 10(c) of the Act and pursuant to implementing regulations for the National

Environmental Policy Act (NEPA) found at (40 CFR 1506.6). All comments received on the permit application and proposed Agreement, including names and addresses, will become part of the administrative record and may be released to the public. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. All submissions from organizations or companies, or from individuals representing organizations or companies, are available for public inspection in their entirety.

Background

The greater Adams Cave beetle (*Pseudanophthalmus pholeter*) and lesser Adams Cave beetle (*Pseudanophthalmus cataryctos*) are small, blind, predatory ground beetles (Family Carabidae) that are endemic to Adams Cave in Madison County, Kentucky. They were first collected in Adams Cave in 1964 and were later described by C. Krekler in 1973. The area surrounding Adams Cave is largely rural but is developing rapidly due to its close proximity to the city of Lexington, Kentucky. The cave is located on an approximate 1-acre parcel (Lot 3) within Adams Place subdivision, approximately 6 miles southwest of the city of Richmond, Kentucky. Construction is occurring on many of the building lots in the subdivision. Adams Cave is a large cave for the Bluegrass Region of Kentucky, with its passageways varying in height from approximately 5 to 60 feet and extending over 1,500 feet in length. The terrestrial habitat surrounding Adams Cave is dominated by abandoned pasture containing scattered groups of trees, including black walnut (*Juglans nigra*) and Kentucky coffee tree (*Gymnocladus dioieus*), and small clumps of cane (*Arundinaria* sp.).

Historically, Adams Cave has experienced extensive vandalism and was littered with trash and other debris, affecting the quality of available habitat for cave beetles. In 2002, a specially designed cave gate was installed to prevent unwanted human entry. Under the CCAA, Southern Conservation Corporation has agreed to implement several conservation measures that will reduce and/or eliminate potential threats to the species. Southern Conservation Corporation will: (1) Maintain the Adams Cave property in a natural state; (2) maintain the metal gate at the entrance to Adams Cave; and (3) control and limit access to Adams Cave and the enrolled property. Implementation of the CCAA is expected to protect and conserve habitat for the covered species, eliminate unauthorized human disturbances within Adams Cave that are believed to impact the covered species, and provide important monitoring data that can be used to develop and/or improve management strategies for the covered species and other cave-dependent species. These benefits will be obtained through restoration and protection of the above- and below-ground habitats on the enrolled property.

We will make our final determination after the end of the 30-day comment period and will fully consider all comments received during the comment period. If the final analysis shows the CCAA to be consistent with our policies and applicable regulations, we will sign the CCAA and issue the ESP. The proposed ESP would, in compliance with the CCAA Policy, only become valid on such date as the greater Adams Cave beetle and/or lesser Adams Cave beetle is listed as a threatened or endangered species under the Act.

This notice also advises the public that we have made a preliminary determination that issuance of the ESP will not result in significant environmental, economic, social, historical, or cultural impacts and is, therefore, categorically excluded from review under NEPA, pursuant to 516 Departmental Manual 2, Appendix 1 and 516 Departmental Manual 6, Appendix 1. We specifically request information, views, and opinions from the public via this notice. Further, we specifically solicit information regarding the adequacy of the CCAA as measured against our CCAA Policy.

Author

The primary author of this notice is Rick Gooch (see **ADDRESSES** section).

Authority: The authority for this action is the Endangered Species Act, (16 U.S.C. 1531 *et seq.*)

Dated: September 16, 2004.

Sam D. Hamilton,

Regional Director.

[FR Doc. 04–22261 Filed 10–1–04; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Geological Survey

Request for Public Comments on Extension of Existing Information Collection To Be Submitted to OMB for Review Under the Paperwork Reduction Act

The proposal for the information collection described below will be submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). Copies of the proposed collection of information may be obtained by contacting the Bureau's clearance officer at the phone number listed below. Comments on the proposal should be made within 60 days to the Bureau Clearance Officer, U.S. Geological Survey, 807 National Center, 12201 Sunrise Valley Drive, Reston, Virginia, 20192, telephone (703) 648–7313.

As required by OMB regualtions at 5 CFR 1320.8(d)(1), the U.S. Geological Survey solicits specific public comments as to:

1. Whether the collection of information is necessary faor the proper performance of the functions on the bureaus, including whether the information will have practical utility;

2. The accuracy of the bureau's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

3. The quality, utility, and clarity of the information to be collected; and

4. How to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other forms of information technology.

Title: North American Breeding Bird Survey.

Current OMB Approval Number: 1028–0079.

Summary: The North American Breeding Bird Survey (BBS) is a long-term, large-scale avian monitoring program that was initiated in 1966 to track the status and trends of continental bird populations. Each spring, interested volunteers conduct 3-minute point counts of birds along roadsides across the United States. Data can be submitted electronically via the Internet or on hard copy. These data provide an index of population abundance that can be used to estimate population trends and relative abundances at various geographic scales. Declining population trends act as an early warning system to galvanize reserach to determine the causes of these declines and reverse them before populations reach critically low levels. The BBS currently lprovides population trend estimates for 420 bird species and raw data for more than 650 species via the web.

Estimated Annual Number of Respondents: 2500.

Estimated Annual Burden Hours: 12,500 hours.

Affected Public: Primarily U.S. residents.

For Further Information Contact: To obtain copies of the survey, contact the Bureau clearance officer, U.S. Geological Survey, 807 National Center, 12201 Sunrise Valley Drive, Reston, Virginia, 20192, telephone (703) 648–7313.

Dated: September 22, 2004.

Susan Haseltine,

Associate Director for Biology.

[FR Doc. 04–22180 Filed 10–1–04; 8:45 am]

BILLING CODE 4310–Y7–M

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Information Collection Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: This notice announces that the Bureau of Indian Affairs (BIA) has submitted the proposed renewal of the information collection request for the Housing Assistance Application, to the Office of Management and Budget (OMB) for approval under the Paperwork Reduction Act.

DATES: Comments must be submitted on or before November 3, 2004.

ADDRESSES: Your comments and suggestions on the requirements should be made directly to the attention: Desk Officer for the Department of the Interior, Office of Information and Regulatory Affairs, Office of Management and Budget, either by facsimile at 202–395–6566, or by e-mail to *OIRA_DOCKET@omb.eop.gov*. Please provide a copy to Frank Joseph, Bureau of Indian Affairs, Department of the Interior, 1951 Constitution Avenue NW., Washington, DC 20240. Telephone: (202) 513–7620.

FOR FURTHER INFORMATION CONTACT: Copies of the collection of information form may be obtained by contacting Frank Joseph, Bureau of Indian Affairs, Department of the Interior, 1951 Constitution Avenue, NW., MS–335B–SIB, Washington, DC 20240. Telephone: (202) 513–7620.

SUPPLEMENTARY INFORMATION:

I. Abstract

This information collection has been re-evaluated and our estimates of the burden have been revised based on field experience. We have added the time the tribes spend in reviewing applications, the cost of soliciting applications and the cost of house inspection for each possible recipient. This additional cost is incurred regardless of whether or not the applicant is awarded a home improvement grant. These changes are an adjustment to the burden because the added burden was there before.

The information is needed to establish an applicant's eligibility to receive services under the Housing Improvement Program and to establish the priority order in which eligible applicants may receive services under the program. 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.

II. Request for Comments

We specifically request your comments be submitted to OMB at the address provided above with a copy to the Bureau of Indian Affairs within 30 days concerning the following:

1. Whether the collection of information is necessary for the proper performance of the functions of the BIA, including whether the information will have practical utility;
2. The accuracy of the BIA's estimate of the burden to collect the information, including the validity of the methodology and assumptions used;
3. The quality, utility and clarity of the information to be collected;
4. How to minimize the burden of the information collection on those who are to respond, including the use of appropriate automated electronic, mechanical or other forms of information technology.
5. OMB is required to respond to this request within 60 days after publication of this notice in the **Federal Register**, but may respond after 30 days; therefore, your comments should be submitted to OMB within 30 days of publication to assure maximum consideration.

III. Data

Title of the Collection of Information: Department of the Interior, Bureau of Indian Affairs, Housing Assistance Application.

OMB Number: 1076–0084

Affected Entities: Individual members of Federally recognized Indian tribes who are living within a designated tribal or legally defined service area.

Frequency of Response: At least annually

Estimated Number of Annual Responses: 3500

Estimated Time per Application: 30 minutes by applicant and 30 minutes by tribe for 1 hour.

Estimated Total Annual Burden Hours: 3,500 hours.

Dated: August 4, 2004.

David W. Anderson,

Assistant Secretary—Indian Affairs.

[FR Doc. 04–22229 Filed 10–1–04; 8:45 am]

BILLING CODE 4310–4J–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

Quarterly Status Report of Water Service, Repayment, and Other Water-Related Contract Negotiations

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice.

SUMMARY: Notice is hereby given of contractual actions that have been proposed to the Bureau of Reclamation (Reclamation) and are new, modified, discontinued, or completed since the last publication of this notice on July 26, 2004. This notice is one of a variety of means used to inform the public about proposed contractual actions for capital recovery and management of project resources and facilities consistent with section 9(f) of the Reclamation Project Act of 1939. Additional announcements of individual contract actions may be published in the **Federal Register** and in newspapers of general circulation in the areas determined by Reclamation to be affected by the proposed action.

ADDRESSES: The identity of the approving officer and other information pertaining to a specific contract proposal may be obtained by calling or writing the appropriate regional office at the address and telephone number given for each region in the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Sandra L. Simons, Manager, Contract Services Office, Bureau of Reclamation, PO Box 25007, Denver, Colorado 80225–0007; telephone (303) 445–2902.

SUPPLEMENTARY INFORMATION: Consistent with section 9(f) of the Reclamation Project Act of 1939 and the rules and regulations published in 52 FR 11954, April 13, 1987 (43 CFR 426.22), Reclamation will publish notice of proposed or amendatory contract actions for any contract for the delivery of project water for authorized uses in newspapers of general circulation in the affected area at least 60 days prior to contract execution. Announcements may be in the form of news releases, legal notices, official letters, memorandums, or other forms of written material. Meetings, workshops, and/or hearings may also be used, as appropriate, to provide local publicity. The public participation procedures do

not apply to proposed contracts for the sale of surplus or interim irrigation water for a term of 1 year or less. Either of the contracting parties may invite the public to observe contract proceedings. All public participation procedures will be coordinated with those involved in complying with the National Environmental Policy Act. Pursuant to the "Final Revised Public Participation Procedures" for water resource-related contract negotiations, published in 47 FR 7763, February 22, 1982, a tabulation is provided of all proposed contractual actions in each of the five Reclamation regions. When contract negotiations are completed, and prior to execution, each proposed contract form must be approved by the Secretary of the Interior, or pursuant to delegated or redelegated authority, the Commissioner of Reclamation or one of the regional directors. In some instances, congressional review and approval of a report, water rate, or other terms and conditions of the contract may be involved.

Public participation in and receipt of comments on contract proposals will be facilitated by adherence to the following procedures:

(1) Only persons authorized to act on behalf of the contracting entities may negotiate the terms and conditions of a specific contract proposal.

(2) Advance notice of meetings or hearings will be furnished to those parties that have made a timely written request for such notice to the appropriate regional or area office of Reclamation.

(3) Written correspondence regarding proposed contracts may be made available to the general public pursuant to the terms and procedures of the Freedom of Information Act, as amended.

(4) Written comments on a proposed contract or contract action must be submitted to the appropriate regional officials at the locations and within the time limits set forth in the advance public notices.

(5) All written comments received and testimony presented at any public hearings will be reviewed and summarized by the appropriate regional office for use by the contract approving authority.

(6) Copies of specific proposed contracts may be obtained from the appropriate regional director or his designated public contact as they become available for review and comment.

(7) In the event modifications are made in the form of a proposed contract, the appropriate regional director shall determine whether republication of the notice and/or extension of the comment period are necessary.

Factors considered in making such a determination shall include, but are not limited to: (i) The significance of the modification; and (ii) the degree of public interest which has been expressed over the course of the negotiations. At a minimum, the regional director shall furnish revised contracts to all parties who requested the contract in response to the initial public notice.

The February 27, 2004, notice should be used as a reference point to identify changes. The numbering system in this notice corresponds with the numbering system in the February 27, 2004, notice.

Definitions of Abbreviations Used in This Document

BCP Boulder Canyon Project
Reclamation Bureau of Reclamation
CAP Central Arizona Project
CVP Central Valley Project
CRSP Colorado River Storage Project
FR **Federal Register**
IDD Irrigation and Drainage District
ID Irrigation District
M&I Municipal and Industrial
O&M Operation and Maintenance
P–SMBP Pick-Sloan Missouri Basin Program
PPR Present Perfected Right
SOD Safety of Dams
WD Water District

Pacific Northwest Region

Bureau of Reclamation, 1150 North Curtis Road, Suite 100, Boise, Idaho 83706–1234, telephone (208) 378–5223.

Modified contract action:

15. Vale and Warmsprings IDs, Vale Project, Oregon: Repayment contract for reimbursable cost of SOD modifications to Warm Springs Dam.

Mid-Pacific Region

Bureau of Reclamation, 2800 Cottage Way, Sacramento, California 95825–1898, telephone (916) 978–5250.

New contract action:

41. PacifiCorp, Klamath Basin Area Office, Klamath Project, Oregon: Execution of long-term agreement for lease of power privilege and the O&M of Link River Dam. This agreement will provide for operations of Link River Dam, coordinated operations with the non-Federal Keno Dam, and provision of power by PacifiCorp for Klamath Project purposes to ensure project water deliveries and to meet Endangered Species Act requirements.

Modified contract actions:

7. City of Roseville, CVP, California: Execution of long-term Warren Act contract for conveyance of nonproject water provided from the Placer County Water Agency. The contract will allow CVP facilities to be used to deliver nonproject water to the City of Roseville for use within its service area.

9. El Dorado ID, CVP, California: Execution of long-term Warren Act contracts for conveyance of nonproject water (one contract for ditch rights in the amount of 3,344 acre-feet, and one contract for Project 184 in the amount of 11,000 acre-feet). The contracts will allow CVP facilities to be used to deliver nonproject water to El Dorado ID for use within its service area.

25. Sacramento Suburban WD, CVP, California: Execution of long-term Warren Act contract for conveyance of nonproject water. The contract will allow CVP facilities to be used to deliver nonproject water to the Sacramento Suburban WD for use within its service area.

39. Pershing County Water Conservation District, Pershing County, Lander County, and the State of Nevada; Humboldt Project; Nevada: Title transfer to lands and features of the Humboldt Project.

Lower Colorado Region

Bureau of Reclamation, PO Box 61470 (Nevada Highway and Park Street), Boulder City, Nevada 89006–1470, telephone (702) 293–8536.

Completed contract action:

30. Harquahala Valley ID, CAP, Arizona: The District has requested that Reclamation transfer title to the District's CAP distribution system and to assign to the District permanent easements acquired by the United States. Title transfer of the District's CAP distribution system is authorized by Pub. L. 101–628 and contract No. 3–07–30–W0289 between the District and Reclamation, dated December 8, 1992.

Upper Colorado Region

Bureau of Reclamation, 125 South State Street, Room 6107, Salt Lake City, Utah 84138–1102, telephone (801) 524–3864.

New contract actions:

1.(f) Oxbow Mining, LLC, Aspinall Storage Unit, CRSP: Oxbow Mining, LLC has requested 242 acre-feet of M&I water out of Blue Mesa Reservoir, which requires submission of a Plan of Augmentation to the Division 4 Water Court.

1.(g) United Companies, Aspinall Storage Unit, CRSP: United Companies has requested 7 acre-feet of M&I water out of Blue Mesa Reservoir for the Delta No. 1 Gravel Pit.

1.(h) Mountain View Amish-Mennonite Church, Aspinall Storage Unit, CRSP: The Church has requested 1 acre-foot of M&I water out of Blue

Mesa Reservoir, Water Division 4, case No. 04CW106.

28. U.S. Fish and Wildlife Service, San Juan River Basin Recovery Implementation Program, Aspinall Storage Unit, CRSP: The U.S. Fish and Wildlife Service has requested 14 acre-feet of water out of Blue Mesa Reservoir to be used at the Chipeta Unit ponds at the Hotchkiss National Fish Hatchery. The ponds are to be used to grow out the two San Juan River Basin endangered fish species.

29. Town of Palisade, Palisade ID, Mesa County ID, Reclamation, and the U.S. Fish and Wildlife Service; CRSP: The Colorado River is critical habitat for four endangered fish species. These agencies are entering into an agreement for each to provide the following: Reclamation shall provide cost-share funding for the recovery monitoring and research and O&M (October 30, 2000, 114 Stat. 1602, Pub. L. 106–392); the Districts are willing to allow the U.S. Fish and Wildlife Service and Reclamation to construct the fish passage; and the Town proposes to provide recreational opportunities on or near the fish passage.

30. Public Service Company of New Mexico, Reclamation, and the U.S. Fish and Wildlife Service; San Juan River Basin Recovery Implementation Program: The agreement identifies that Reclamation may provide cost-share funding for the recovery monitoring and research and O&M (October 30, 2000, 114 Stat. 1602, Pub. L. 106–392) of the constructed fish passage.

31. Reclamation, U.S. Fish and Wildlife Service, and the Colorado River Water Conservation District; the Recovery Implementation Program for Endangered Fish Species in the Upper Colorado River Basin: Reclamation will provide cost-share funding for enlargement of Elkhead Reservoir (October 30, 2000, 114 Stat. 1602, Pub. L. 106–392) in a separate grant agreement.

Completed contract action:

27. South Cache Water Users Association, Hyrum Project, Utah: Contract for repayment of 15 percent of SOD costs at Hyrum Dam. Contract executed June 16, 2004.

Great Plains Region

Bureau of Reclamation, PO Box 36900, Federal Building, 316 North 26th Street, Billings, Montana 59107–6900, telephone (406) 247–7730.

New contract actions:

49. City of Fountain, Colorado; Fryingpan-Arkansas Project; Colorado: Consideration of a request for a long-term contract for the use of excess capacity in the Fryingpan-Arkansas Project.

50. Colorado Springs Utilities; Colorado Springs, Colorado; Colorado-Big Thompson Project: Consideration of a request for a long-term agreement for water substitution and power interference in the Colorado-Big Thompson Project.

51. Pueblo West Metropolitan District; Pueblo West, Colorado; Fryingpan-Arkansas Project, Colorado: Consideration of a request for a 5-to 10-year contract for the use of excess capacity in the Fryingpan-Arkansas Project.

Modified contract action:

4. Garrison Diversion Unit, P–SMBP, North Dakota: Renegotiation of the master repayment contract with Garrison Diversion Conservancy District to conform with the Dakota Water Resources Act of 2000; negotiation of repayment contracts with irrigators and M&I users.

Completed contract actions:

34. Debbie A. Axtell (Individual), Boysen Unit, P-SMBP, Wyoming. Renew long-term contract for up to 100 acre-feet of irrigation water to service 17.2 acres. Contract executed July 2, 2004.

38. Kansas-Bostwick ID No. 2 (KBID); Franklin, Superior-Courtland, and Courtland Units; Bostwick Division; P–SMBP; Courtland, Kansas: The District requested a deferment of its 2004 repayment obligation. A request was prepared to amend contract No. 009D6B0120 to defer payments in accordance with the Act of September 21, 1959. Amendatory contract executed August 27, 2004.

Dated: September 13, 2004.

Roseann Gonzales,

Director, Office of Program and Policy Services.

[FR Doc. 04–22263 Filed 10–1–04; 8:45 am]

BILLING CODE 4310–MN–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production act of 1993—American Society for Blood and Marrow Transplantation

Notice is hereby given that, on September 10, 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"), American Society for Blood and Marrow Transplantation ("ASBMT") 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 American Society for Blood and Marrow Transplantation ("ASBMT") Arlington Heights, IL 60005–4460. The nature and scope of ASBMT's standards development activities are to develop, plan, establish, coordinate, and publish voluntary consensus standards applicable to the field of cellular therapy and blood and marrow transplantation. Specifically, ASBMT develops, plans, establishes coordinates, and publishes voluntary consensus standards in the form of: Policy statements relating to the effectiveness of transplant therapies; transplant center guidelines; physician training guidelines; and clinical practice guidelines in the form of evidence-based reviews. Through its standard development activities, ASBMT seeks to ensure the highest quality of medical practice, define commonly accepted medical practice, and develop standards of medical care as related to the field of cellular therapy and blood and marrow transplantation. ASBMT's standards development activities are ongoing in nature, and existing guidelines and policy statements may be updated and/or amended from time to time.

Dorothy B. Fountain,

Deputy Director of Operations, Antitrust Division.

[FR Doc. 04–22157 Filed 10–1–04; 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—Cable Television Laboratories, Inc.

Notice is hereby given that, on August 24, 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"), Cable Television Laboratories, Inc. ("CableLabs") has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership status. The notification

were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.Specifically, Massillon Cable TV, Inc., Massillon, OH; and Community Rebroadcasting Service Association (CRRS TV), Labrador City, Newfoundland, CANADA 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 CableLabs intends to file additional written notifications disclosing all changes in membership.

On August 8, 1988, CableLabs 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 September 7, 1988 (53 FR 34593).

The last notification was filed with the Department on April 21, 2004. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on July 23, 2004 (69 FR 44062).

Dorothy B. Fountain,

Deputy Director of Operations, Antitrust Division.

[FR Doc. 04–22164 Filed 10–1–04; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Reserach and Production Act of 1993—Ethernet in the First Mile Alliance

Notice is hereby given that, on July 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"), Ethernet in the First Mile Alliance ("EFMA") has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership status. 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, Actelis Networks, Fremont, CA; Agilent Technologies, Santa Rosa, CA; Harbour Networks, Beijing, PEOPLE'S REPUBLIC OF CHINA; Tometrix, San Francisco, CA; and University of New Hampshire, InterOperabilty Lab, Durham, NH have been added as parties to this venture. Also, Alloptic, Inc., Livermore, CA; Analog Devices, Norwood MA; BATH Advanced Communications, Yokneam Ilit, ISRAEL; Broadcom, Irvine, CA; Calix, Petaluma, CA; Fiberintheloop, Marlow, UNITED KINGDOM; Finisar Corporation, Sunnyvale, CA; Harmonic, Inc., Sunnyvale, CA; Intel, Santa Clara, CA; National Semiconductor, Santa Clara, CA; Panasonic Semiconductor Dev. Co., San Jose, CA; Paradyne, Alpharetta, GA; Spirent Communications, Calabasas, CA; Texas Instruments, Dallas, TX; and World Wide Packets, Veradale, WA have been dropped 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 EFMA intends to file additional written notifications disclosing all changes in membership.

On January 16, 2002, EFMA 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, 2002 (67 FR 10760).

The last notification was filed with the Department on September 3, 2002. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on October 25, 2002 (67 FR 65603).

Dorothy B. Fountain,

Deputy Director of Operations, Antitrust Division.

[FR Doc. 04–22165 Filed 10–1–04; 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—Gaming Standards Association

Notice is hereby given that, on August 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"), the Gaming Standards Association ("GSA") has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership status. 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, Boss Media AB, Vaxjo, SWEDEN; Corey Investments, LTD, N. Huntington, PA; Densitron Technologies, Plc, Biggin Hill, Kent, UNITED KINGDOM; E-Genting Sdn Bhd, Kuala Lumpur, W. Persekutuan, MALAYSIA; GameLogic, Inc., Cambridge, MA; Greektown Casino, Detroit, MI; Ontario Lottery and Gaming Corporation, Toronto, Ontario, CANADA; Quest Entertainment, Inc., Houston, TX; Summit Amusement & Distributing, Ltd., Billings, MT; Video Gaming Technologies, Inc., Roebuck, SC; and Viejas Casino, Alpine, CA 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 GSA intends to file additional written notification disclosing all changes in membership.

On March 6, 2003, GSA 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 April 1, 2003 (68 FR 15743).

The last notification was filed with the Department on May 7, 2004. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on June 25, 2004 (69 FR 35678).

Dorothy B. Fountain,

Deputy Director of Operations, Antitrust Division.

[FR Doc. 04–22159 Filed 10–1–04; 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 Cooperation for the Integration of Processes in Pre-Press, Press, and Postpress ("CIP4")

Notice is hereby given that, on August 30, 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 International Cooperation for the Integration of Processes in Pre-press, Press, and Postpress ("CIP4") 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: Integration

of Processes in Pre-press, Press, and Postpress (CIP4), Zurich, SWITZERLAND. The nature and scope of CIP4's standard development activities are: to encourage computer based integration and automation of all processes that have to be considered in the graphic arts industry, in particular the specification of standards, such as CIP4's Job Definition Format (JDF). JDF is a comprehensive XML-based industry standard for end-to-end job ticket specification, device messaging and message interchange, and process automation methodologies.

Dorothy B. Fountain,

Deputy Director of Operations, Antitrust Division.

[FR Doc. 04–22154 Filed 10–1–04; 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—NACE International

Notice is hereby given that, on September 2, 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"), NACE International ("NACE") 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: NACE International, Houston, TX. The nature and scope of NACE's standards development activities are: to prepare consensus standards to serve as voluntary guidelines in the field of prevention and control of corrosion; to provide information to aid in reducing the economic losses resulting from corrosion; and to promote the optimal use of natural resources and materials and to prevent their wastage as a result of corrosion.

Additional information concerning NACE's standards development activities may be obtained from Linda Goldberg, Director, Technical Activities, NACE International, at (281) 228–6221.

Dorothy B. Fountain,

Deputy Director of Operations, Antitrust Division.

[FR Doc. 04–22155 Filed 10–1–04; 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—National Biodiesel Accreditation Commission ("NBAC")

Notice is hereby given that, on August 27, 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"), National Biodiesel Accreditation Commission ("NBAC") 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 National Biodiesel Accreditation Commission, Jefferson City, MO. The nature and scope of the NBAC's standards development activities are the administration of a certification program for both the manufacturers and marketers of biodiesel, both neat and blended. Certification by the NBAC indicates the applicant possesses and implements a quality assurance/quality control program meeting the Commission's requirements.

Dorothy B. Fountain,

Deputy Director of Operations, Antitrust Division.

[FR Doc. 04–22153 Filed 10–1–04; 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—National Center for Manufacturing Sciences, Inc.

Notice is hereby given that, on July 13, 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"), National Center for Manufacturing Sciences has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership status. 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, DIT–MCO International, Kansas City, MO; Koops Inc., Holland, MI: and Lockheed Martin Corporation, Oldsmar, FL have been added as parties to this venture. Also, Amatrol, Inc., Jeffersonville, IN; LFX Technologies LLC, Bloomfield Hills, MI; JWH Group, Inc., Peninsula, OH; Telesis Technologies, Inc., Roswell, GA; and Vacuum Instrument Corporation, Ronkonkoma, NY have been dropped 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 National Center for Manufacturing Sciences intends to file additional written notification disclosing all changes in membership.

On February 20, 1987, National Center for Manufacturing Sciences 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 17, 1987 (52 FR 8375).

The last notification was filed with the Department on April 28, 2004. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on May 28, 2004 (69 FR 30721–02).

Dorothy B. Fountain,

Deputy Director of Operations, Antitrust Division.

[FR Doc. 04–22163 Filed 10–1–04; 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—National Fluid Power Association ("NFPA")

Notice is hereby given that, on August 30, 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"), National Fluid Power Association ("NFPA") 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 National Fluid Power Association, Milwaukee, WI. The nature and scope of the NFPA's standards development activities are to develop, plan, establish, and coordinate voluntary consensus standards applicable to the fluid power industry on industry (NEPA), national (American National Standards), and international (ISO) levels. NFPA develops industry and national standard, and coordinates international standards. in order to: Simplify the use of fluid power; help to assure system integrity and safety in the application of fluid power; help educated users on how to correctly size and apply products; determine uniform methods for testing products and expressing their performance, allowing comparison; communicate needs in a commonly understood language; help to improve efficiency of fluid power products and systems; simplify and variety of products and sizes in the marketplace; and encourage new product development. NFPA's standards for fluid power products and systems fall into three basic categories—communicate standards, design standards and performance standards. NFPA develops industry and national standards in the field of fluid power, specifically hydraulic and pneumatic components and systems for application in both industrial (stationary) and mobile equipment. Components covered include, but are not limited to: accumulators, conductors (rigid and flexible), cylinders, electrohydraulic and electropneumatic components and systems, connectors, fluid devices, hose fittings and assemblies, filters and separators, fluids, hydraulic pumps, motors, moving-part fluid-controls, pneumatic lubricators, regulators, quick-action couplings, reservoirs, sealing devices and valves. NFPA is actively involved in coordinating and administering fluid power standards on an international level in the field of fluid power systems and components, comprising terminology, construction, principal dimensions, safety requirements and testing and inspection methods. Covered components include, but are not limited to: Accumulators, compressed air dryers, conductors (rigid and flexible), cylinders, electrohydraulic and electropneumatic components and systems, fittings, fluidic devices, hose fittings and assemblies, filters and separators, fluids, hydraulic pumps, motors, moving-part fluid controls, pneumatic lubricators, regulators, quick-action couplings, reservoirs, sealing devices, and valves.

Dorothy B. Fountain

Deputy Director of Operations, Antitrust Division.

[FR Doc. 04–22156 Filed 10–01–04; 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—Portland Cement Association

Notice is hereby given that, on august 18, 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 Portland Cement Association 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: Portland Cement Association, Skokie, IL. The nature and scope of Portland Cement Association's standards development activities are for the design and construction of assemblies using cement, cement-based products, and associated products.

Additional information concerning the Portland Cement Association may be obtained from Stephen Szoke, P.E., Director, Codes and Standards, Portland Cement Association, 5420 Old Orchard Road, Skokie, IL 60077.

Dorothy B. Fountain,

Deputy Director of Operations, Antitrust Division.

[FR Doc. 04–22162 Filed 10–1–04; 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 August 31, 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"), PXI Systems Alliance, Inc. has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership status. 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, Amplicon Liveline Ltd., Brighton, East Sussex, UNITED-KINGDOM; Mapsuka Industries Co., Ltd., Taipei Hsien, TAIWAN; and PXIdirect GmbH, Ilgen, GERMANY 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. Memberships 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, 2000 (66 FR 13971).

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. 04–22166 Filed 10–1–04; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1933—Sheet Metal and Air Conditioning Contractors' National Association

Notice is hereby given that, on August 18, 2004, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ("Act"), the Sheet Metal and Air Conditioning Contractors' National Association (SMACNA) 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: Sheet Metal and Air Conditioning Contractors' National Association (SMACNA), Chantilly, VA. The nature and scope of SMACNA's standards development activities are to promulgate industry standards to the general public and to initiate, promote and document studies directed toward the solution of present and future problems in the heating, ventilation and air conditioning (HVAC) industry and all facets of the sheet metal industry.

Additional information concerning SMACNA may be obtained from Sue Baker at (703) 803–2980.

Dorothy B. Fountain,

Deputy Director of Operations, Antitrust Division.

[FR Doc. 04–22161 Filed 10–1–04; 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—the Society for Biomolecular Screening, Inc. ("SBS")

Notice is hereby given that, on September 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 Society for Biomolecular Screening, Inc. ("SBS") 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: The Society for Biomolecular Screening, Inc. Danbury, CT. The nature and scope of SBS' standard development activities are: Many science-based industries have implemented a High Throughput Screening (HTS) approach for discovery activities. HTS requires that automated devices and full robotic systems be used for this work. These devices and systems cost from tens of thousands of dollars to millions of dollars. The basic tool for this work is the microtiter plate (MTP) and as such, it is economically critical that these devices/systems work in a seamless manner with this tool as supplied by different manufacturers. However, each manufacturer had originally developed MTPs with slightly different dimensions and features to the extent that these plates performed poorly with automation. Laboratory users found it frustrating to try to use different plates with their equipment and often experienced significant financial losses when doing so. Manufacturers of automated devices tried to build in features that allowed for defining different plates from different manufacturers but there was only so much variation that could be accommodated and these changes were driving costs upwards. In 1995, The Society for Biomolecular Screening, Inc. formed a working group that brought together all of the interested parties, (manufacturers of MTPs, automated device manufacturers and users) to establish standards for microtiter plates that would provide reliable use with all automated equipment and robotics. These standards need to address the various densities of the MTP including 96, 384, and 1536 since it would be expected that the same equipment could work with various formats but not necessarily all formats to contains costs.

Dorothy B. Fountain,

Deputy Director of Operations, Antitrust Division.

[FR Doc. 04–22158 Filed 10–1–04; 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—Tree Care Industry Association ("TCIA")

Notice is hereby given that, on September 8, 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"), Tree Care Industry Association ("TCIA") 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 Tree Care Industry Association, Inc., Manchester, NH. The nature and scope of the TCIA's standards development activities are to serve as the secretariat and SDO for the American National Standards Institute (ANSI) A300 standards for tree, shrub, and other woody plant maintenance operations. The ANSI-accredited Standards Committee (ASC) A300 is the committee that writes the standards. TCIA currently has developed four performance standards addressing tree, shrub, and other woody plant maintenance operations: ANSI A300 Part 1–2001 Pruning; ANSI A300 Part–2004 Fertilization; ANSI A300 Part 3–2000 Support Systems; and ANSI A300 Part 4–2002 Lightning Protection Systems. TCIA also has three standards in development: BSR A300 Part 5–200x Management of Trees and Shrubs during Site Planning, Site Development, and Construction; BSR A300 Part 6–200x

Transplanting; and PINS Part 7–200x Integrated Vegetation Management (IVM). TCIA is the SDO for the TCIA Standards for Accreditation. The TCIA Accreditation Council is the committee that writes the standards. The current Version is TCIA Accreditation Council Standards for Accreditation Draft 4 Version 2. TCIA was formerly the SDO for the NAA Standards for Pruning of Shade Trees; Guying of Shade Trees; Fertilizing Shade and Ornamental Trees; Lightning Protection Installation Systems for Trees; and Hydraulic Sprayer Calibration. The NAA Standard Practices committee was the committee that wrote the standards. The NAA standards were last updated in 1988 and no longer maintained by the TCIA. They are considered obsolete and have been superseded by ANSI 300 standards; however they are still used by some arborists, tree care companies, and governmental agencies.

Dorothy B. Fountain,

Deputy Director of Operations, Antitrust Division.

[FR Doc. 04–22160 Filed 10–1–04; 8:45 am]

BILLING CODE 4410–11–M

LEGAL SERVICES CORPORATION

Notice of Intent To Award—Grant Awards for the Provision of Civil Legal Services to Eligible Low-Income Clients Beginning January 1, 2005

AGENCY: Legal Services Corporation.

ACTION: Announcement of intention to make FY.2005 Competitive Grant Awards.

SUMMARY: The Legal Services Corporation (LSC) hereby announces its intention to award grants and contracts to provide economical and effective delivery of high quality civil legal services to eligible low-income clients, beginning January 1, 2005.

DATES: All comments and recommendations must be received on or before the close of business on November 3, 2004.

ADDRESSES: Legal Services Corporation—Competitive Grants, Legal Services Corporation; 3333 K Street, NW., Third Floor; Washington, DC 20007.

FOR FURTHER INFORMATION CONTACT: Reginald Haley, Office of Program Performance, (202) 295–1545.

SUPPLEMENTARY INFORMATION: Pursuant to LSC's announcement of funding availability on April 16, 2004 (69 FR 20650), July 20, 2004 (69 FR 43456), and Grant Renewal applications due on August 9, 2004, LSC intends to award funds to the following organizations to provide civil legal services in the indicated service areas. Amounts are estimates and are subject to change.

State/service area	Applicant name	Estimated grant amount
Alabama		
AL–4	Legal Services Corporation of Alabama, Inc.	$5,882,590
MAL	Texas RioGrande Legal Aid	30,126
Alaska		
AK–1	Alaska Legal Services Corporation	681,012
NAK–1	Alaska Legal Services Corporation	496,293
American Samoa		
AS–1	Uunai Legal Services Clinic	294,290
Arizona		
AZ–2	DNA-Peoples Legal Services, Inc.	494,186
AZ–3	Community Legal Services, Inc.	3,567,025
AZ–5	Southern Arizona Legal Aid, Inc.	1,720,404
MAZ	Community Legal Services, Inc.	135,948
NAZ–5	DNA-Peoples Legal Services, Inc.	2,394,630
NAZ–6	Southern Arizona Legal Aid, Inc.	584,938
Arkansas		
AR–6	Legal Aid of Arkansas, Inc.	1,370,094
AR–7	Center for Arkansas Legal Services	2,045,186
MAR	Texas RioGrande Legal Aid	72,376
California		
CA–1	California Indian Legal Services, Inc.	31,109
CA–2	Greater Bakersfield Legal Assistance, Inc.	864,263
CA–12	Inland Counties Legal Services, Inc.	3,840,107
CA–14	Legal Aid Society of San Diego, Inc.	2,685,331
CA–19	Legal Aid Society of Orange County, Inc.	3,750,684
CA–26	Central California Legal Services	2,703,939
CA–27	Legal Services of Northern California, Inc.	3,341,144
CA–28	Bay Area Legal Aid	3,938,831
CA–29	Legal Aid Foundation of Los Angeles	7,467,817
CA–30	Neighborhood Legal Services of Los Angeles County	4,411,173
CA–31	California Rural Legal Assistance, Inc.	4,408,242
MCA	California Rural Legal Assistance, Inc.	2,417,178
NCA–1	California Indian Legal Services, Inc.	810,754
Colorado		
CO–6	Colorado Legal Services	3,158,342
MCO	Colorado Legal Services	135,991
NCO–1	Colorado Legal Services	88,130
Connecticut		
CT–1	Statewide Legal Services of Connecticut, Inc.	2,182,768
NCT–1	Pine Tree Legal Assistance, Inc.	14,367
Delaware		
DE–1	Legal Services Corporation of Delaware, Inc.	569,313
MDE	Legal Aid Bureau, Inc.	22,733

State/service area	Applicant name	Estimated grant amount
District of Columbia		
DC–1	Neighborhood Legal Svcs. Prog. of the Dist. of Col.	927,440
Florida		
FL–5	Legal Services of Greater Miami, Inc.	3,250,866
FL–13	Legal Services of North Florida, Inc.	1,334,870
FL–14	Three Rivers Legal Services, Inc.	1,644,159
FL–15	Central Florida Legal Services, Inc.	2,838,100
FL–16	Bay Area Legal Services, Inc.	2,408,141
FL–17	Florida Rural Legal Services, Inc.	2,535,229
FL–18	Coast to Coast Legal Aid of South Florida, Inc.	1,704,591
MFL	Florida Rural Legal Services, Inc.	822,354
Georgia		
GA–1	Atlanta Legal Aid Society, Inc.	2,371,271
GA–2	Georgia Legal Services Program	6,025,712
MGA	Georgia Legal Services Program	358,999
Guam		
GU–1	Guam Legal Services Corporation	294,680
Hawaii		
HI–1	Legal Aid Society of Hawaii	1,211,084
MHI	Legal Aid Society of Hawaii	63,101
NHI–1	Native Hawaiian Legal Corporation	210,209
Idaho		
ID–1	Idaho Legal Aid Services, Inc.	1,088,576
MID	Idaho Legal Aid Services, Inc.	171,149
NID–1	Idaho Legal Aid Services, Inc.	59,619
Illinois		
IL–3	Land of Lincoln Legal Assistance Foundation, Inc.	2,371,100
IL–6	Legal Assistance Foundation of Metropolitan Chicago	5,961,519
IL–7	Prairie State Legal Services, Inc.	2,531,096
MIL	Legal Assistance Foundation of Metropolitan Chicago	228,574
Indiana		
IN–5	Indiana Legal Services, Inc.	4,634,588
MIN	Indiana Legal Services, Inc.	104,111
Iowa		
IA–3	Iowa Legal Aid	2,261,123
MIA	Iowa Legal Aid	34,549
Kansas		
KS–1	Kansas Legal Services, Inc.	2,172,868
MKS	Kansas Legal Services, Inc.	10,884
Kentucky		
KY–2	Legal Aid Society	1,109,858
KY–5	Appalachian Research and Defense Fund of Kentucky	1,922,768
KY–9	Cumberland Trace Legal Services, Inc.	1,151,463
KY–10	Legal Aid of the Bluegrass	1,191,962
MKY	Texas RioGrande Legal Aid	38,970
Louisiana		
LA–1	Capital Area Legal Services Corporation	1,337,342
LA–10	Acadiana Legal Service Corporation	1,914,414
LA–11	Legal Services of North Louisiana, Inc.	1,800,999
LA–12	Southeast Louisiana Legal Services Corporation	2,404,639
MLA	Texas RioGrande Legal Aid	25,214
Maine		
ME–1	Pine Tree Legal Assistance, Inc.	1,081,936
MMX–1	Pine Tree Legal Assistance, Inc.	114,359
NME–1	Pine Tree Legal Assistance, Inc.	59,148
Maryland		
MD–1	Legal Aid Bureau, Inc.	3,632,234
MMD	Legal Aid Bureau, Inc.	83,250
Massachusetts		
MA–4	Merrimack Valley Legal Services, Inc.	759,942
MA–10	Massachusetts Justice Project, Inc.	1,381,241
MA–11	Volunteer Lawyers Project of the Boston Bar Association	1,864,560
MA–12	Legal Services for Cape Cod and Islands, Inc.	835,762
MA–12	New Center for Legal Advocacy, Inc.	835,762
Michigan		
MI–9	Legal Services of Northern Michigan, Inc.	686,410
MI–12	Legal Services of South Central Michigan	1,220,052
MI–13	Legal Aid and Defender Association, Inc.	3,680,653
MI–14	Legal Services of Eastern Michigan	1,340,411
MI–14	Lakeshore Legal Aid	1,340,411
MI–15	Western Michigan Legal Services	1,562,582
MMI	Legal Services of South Central Michigan	551,170

State/service area	Applicant name	Estimated grant amount
NMI–1	Michigan Indian Legal Services, Inc.	151,064
Micronesia		
MP–1	Micronesian Legal Services, Inc.	1,510,302
Minnesota		
MN–1	Legal Aid Service of Northeastern Minnesota	406,291
MN–4	Legal Services of Northwest Minnesota Corporation	373,127
MN–5	Southern Minnesota Regional Legal Services, Inc.	1,147,098
MN–6	Central Minnesota Legal Services, Inc.	1,241,922
MMN	Southern Minnesota Regional Legal Services, Inc.	183,201
NMN–1	Anishinabe Legal Services, Inc.	219,305
Mississippi		
MS–9	North Mississippi Rural Legal Services, Inc.	1,964,847
MS–10	Mississippi Center for Legal Services	2,817,420
MMS	Texas RioGrande Legal Aid	52,258
NMS–1	Mississippi Center for Legal Services	76,283
Missouri		
MO–3	Legal Aid of Western Missouri	1,626,018
MO–4	Legal Services of Eastern Missouri, Inc.	1,795,193
MO–5	Mid-Missouri Legal Services Corporation	357,864
MO–7	Legal Services of Southern Missouri	1,549,120
MMO	Legal Aid of Western Missouri	74,592
Montana		
MT–1	Montana Legal Services Association	1,037,156
MMT	Montana Legal Services Association	49,980
NMT–1	Montana Legal Services Association	146,118
Nebraska		
NE–4	Nebraska Legal Services	1,327,195
MNE	Nebraska Legal Services	38,715
NNE–1	Nebraska Legal Services	30,333
Nevada		
NV–1	Nevada Legal Services, Inc.	1,739,800
MNV	Nevada Legal Services, Inc.	2,303
NNV–1	Nevada Legal Services, Inc.	122,027
New Hampshire		
NH–1	Legal Advice & Referral Center, Inc.	656,025
New Jersey		
NJ–8	Essex-Newark Legal Services Project, Inc.	995,426
NJ–12	Ocean-Monmouth Legal Services, Inc.	609,696
NJ–15	Legal Services of Northwest Jersey	359,711
NJ–16	South Jersey Legal Services	1,224,558
NJ–17	Central Jersey Legal Services, Inc.	999,534
NJ–18	Northeast New Jersey Legal Services Corporation	1,626,610
MNJ	South Jersey Legal Services	110,488
New Mexico		
NM–1	DNA–Peoples Legal Services, Inc.	198,760
NM–5	New Mexico Legal Aid	2,507,253
MNM	New Mexico Legal Aid	79,971
NNM–2	DNA–Peoples Legal Services, Inc.	20,848
NNM–4	New Mexico Legal Aid	426,386
New York		
NY–7	Nassau/Suffolk Law Services Committee, Inc.	1,273,650
NY–9	Legal Services for New York City	13,981,363
NY–20	Westchester/Putnam Legal Services, Inc.	1,638,316
NY–21	Legal Aid Society of Northeastern New York, Inc.	1,230,479
NY–22	Legal Aid Society of Mid-New York, Inc.	1,612,863
NY–23	Monroe County Legal Assistance Corporation	1,581,051
NY–24	Neighborhood Legal Services, Inc.	1,231,139
MNY	Legal Aid Society of Mid-New York, Inc.	253,458
North Carolina		
NC–5	Legal Aid of North Carolina, Inc.	7,628,929
MNC	Legal Aid of North Carolina, Inc.	490,755
NNC–1	Legal Aid of North Carolina, Inc.	200,279
North Dakota		
ND–3	Legal Assistance of North Dakota, Inc.	516,029
MND	Southern Minnesota Regional Legal Services, Inc.	106,134
NND–3	Legal Assistance of North Dakota, Inc.	247,196
Ohio		
OH–5	The Legal Aid Society of Columbus	1,179,430
OH–17	Ohio State Legal Services	1,652,406
OH–18	Legal Aid Society of Greater Cincinnati	1,363,338
OH–20	Community Legal Aid Services, Inc.	1,608,243
OH–21	The Legal Aid Society of Cleveland	1,994,832

State/service area	Applicant name	Estimated grant amount
OH–23	Legal Services of Northwest Ohio, Inc.	2,370,794
MOH	Legal Services of Northwest Ohio, Inc.	115,342
Oklahoma		
OK–3	Legal Aid Services of Oklahoma, Inc.	4,103,348
MOK	Legal Aid Services of Oklahoma, Inc.	57,298
NOK–1	Oklahoma Indian Legal Services, Inc.	751,381
Oregon		
OR–2	Lane County Legal Aid Service, Inc.	325,798
OR–4	Marion-Polk Legal Aid Service, Inc.	321,140
OR–5	Legal Aid Services of Oregon	2,135,550
MOR	Legal Aid Services of Oregon	510,049
NOR–1	Legal Aid Services of Oregon	169,404
Pennsylvania		
PA–1	Philadelphia Legal Assistance Center	2,810,294
PA–5	Laurel Legal Services, Inc.	698,197
PA–8	Neighborhood Legal Services Association	1,521,899
PA–11	Southwestern Pennsylvania Legal Services, Inc.	507,254
PA–23	Legal Aid of Southeastern Pennsylvania	1,031,923
PA–24	North Penn Legal Services, Inc.	1,646,150
PA–25	MidPenn Legal Services, Inc.	2,013,874
PA–26	Northwestern Legal Services	664,217
MPA	Philadelphia Legal Assistance Center	151,761
Puerto Rico		
PR–1	Puerto Rico Legal Services, Inc.	15,389,509
PR–2	Community Law Office, Inc.	317,341
MPR	Puerto Rico Legal Services, Inc.	266,222
Rhode Island		
RI–1	Rhode Island Legal Services, Inc.	1,019,395
South Carolina		
SC–8	The South Carolina Centers for Equal Justice	4,459,205
MSC	The South Carolina Centers for Equal Justice	181,118
South Dakota		
SD–2	East River Legal Services	370,061
SD–4	Dakota Plains Legal Services, Inc.	438,556
MSD	Dakota Plains Legal Services, Inc.	3,634
NSD–1	Dakota Plains Legal Services, Inc.	856,833
Tennessee		
TN–4	Memphis Area Legal Services, Inc.	1,301,693
TN–7	West Tennessee Legal Services, Inc.	607,282
TN–9	Legal Aid of East Tennessee	1,988,371
TN–10	Legal Aid Society of Middle TN and the Cumberlands	2,369,705
MTN	Texas RioGrande Legal Aid	58,077
Texas		
TX–13	Lone Star Legal Aid	8,782,062
TX–14	Legal Aid of NorthWest Texas	6,928,878
TX–15	Texas RioGrande Legal Aid	9,422,589
MTX	Texas RioGrande Legal Aid	1,271,888
NTX–1	Texas RioGrande Legal Aid	28,721
Utah		
UT–1	Utah Legal Services, Inc.	1,685,441
MUT	Utah Legal Services, Inc.	62,108
NUT–1	Utah Legal Services, Inc.	75,497
Vermont		
VT–1	Legal Services Law Line of Vermont, Inc.	462,704
Virgin Islands		
VI–1	Legal Services of the Virgin Islands, Inc.	295,858
Virginia		
VA–15	Southwest Virginia Legal Aid Society, Inc.	751,353
VA–16	Legal Services of Eastern Virginia, Inc.	1,297,991
VA–17	Virginia Legal Aid Society, Inc.	782,140
VA–18	Central Virginia Legal Aid Society, Inc.	922,062
VA–19	Blue Ridge Legal Services, Inc.	650,572
VA–20	Potomac Legal Aid Society, Inc.	1,013,060
MVA	Central Virginia Legal Aid Society, Inc.	144,418
Washington		
WA–1	Northwest Justice Project	4,518,273
MWA	Northwest Justice Project	668,357
NWA–1	Northwest Justice Project	261,416
West Virginia		
WV–5	Legal Aid of West Virginia, Inc.	2,641,229
MWV	Legal Aid of West Virginia, Inc.	33,473
Wisconsin		
WI–2	Wisconsin Judicare, Inc.	861,260

State/service area	Applicant name	Estimated grant amount
WI–5	Legal Action of Wisconsin, Inc.	3,016,900
MWI	Legal Action of Wisconsin, Inc.	83,367
NWI–1	Wisconsin Judicare, Inc.	142,351
Wyoming		
WY–4	Wyoming Legal Services, Inc.	452,556
MWY	Wyoming Legal Services, Inc.	11,391
NWY–1	Wyoming Legal Services, Inc.	158,578

These grants and contracts will be awarded under the authority conferred on LSC by the Legal Services Corporation Act, as amended (42 U.S.C. 2996e(a)(1)). Awards will be made so that each service area is served. None of the listed organizations is guaranteed an award or contract. This public notice is issued pursuant to the LSC Act (42 U.S.C. 2996f(f)), with a request for comments and recommendations concerning the potential grantees within a period of thirty (30) days from the date of publication of this notice. Grants will be distributed on or about January 1, 2005.

Dated: September 28, 2004.

Michael A. Genz,

Director, Office of Program Performance, Legal Services Corporation.

[FR Doc. 04–22185 Filed 10–1–04; 8:45 am]

BILLING CODE 7050–01–P

MORRIS K. UDALL SCHOLARSHIP AND EXCELLENCE IN NATIONAL ENVIRONMENTAL POLICY FOUNDATION

Committee Management; Notice of Renewal

AGENCY: U.S. Institute for Environmental Conflict Resolution, Morris K. Udall Foundation.

ACTION: Notice.

Authority: 5 U.S.C. Appendix 2; 20 U.S.C. 5601–5609.

SUMMARY: This notice is published in accordance with section 9(a) of the Federal Advisory Committee Act of 1972 (Public Law 92–463). The executive director of the Morris K. Udall Scholarship and Excellence in National Environmental Policy Foundation has determined that the renewal of the National ECR Advisory Committee is necessary and in the public interest in connection with the performance of duties imposed upon the U.S. Institute for Environmental Conflict Resolution (U.S. Institute) by 20 U.S.C. 5601 *et seq.* This determination follows consultation with the Committee Management Secretariat, General Services Administration.

Name of Committee: National ECR Advisory Committee.

Purpose and Objective: The committee will provide advice to the director of the U.S. Institute and to the Board of Trustees of the Morris K. Udall Foundation regarding future program directions, including the U.S. Institute's role in connection with the implementation of Section 101 of the National Environmental Policy Act of 1969 (42 U.S.C. 4331).

Balanced Membership Plan: The committee will consist of a maximum of 30 members representing a balanced cross-section of viewpoints concerning environmental issues and the field of environmental conflict resolution. Among the interests represented will be environmental advocates, resource users, affected communities, state and/or local governments, tribes, federal environmental and resource management agencies, the conflict resolution and legal communities, and academic institutions.

Duration: The committee's duration began October 2, 2002, and is being renewed through April 30, 2005.

Responsible Officials: The designated federal officer is Dr. Kirk Emerson, director of the U.S. Institute for Environmental Conflict Resolution, 130 S. Scott Avenue, Tucson, AZ 85701, telephone 520 670–5299.

Dated: September 27, 2004.

Ellen K. Wheeler,

Committee Management Officer.

[FR Doc. 04–22191 Filed 10–1–04; 8:45 am]

BILLING CODE 6820–FN–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (04–110)]

Aerospace Safety Advisory Panel Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration announces a forthcoming meeting of the Aerospace Safety Advisory Panel.

DATES: Thursday, October 21, 2004, 1 p.m. to 3 p.m. central time.

ADDRESSES: This meeting will be conducted via teleconference; hence participation will require contacting Ms. Susan M. Burch on (202) 358–0914 before noon eastern, October 20, 2004, and providing your name, affiliation, and phone number.

FOR FURTHER INFORMATION CONTACT: Mr. Mark D. Erminger, Aerospace Safety Advisory Panel Executive Director, Code Q–1, National Aeronautics and Space Administration, Washington, DC 20546, (202) 358–0914.

SUPPLEMENTARY INFORMATION: The Aerospace Safety Advisory Panel will hold its Quarterly Meeting. This meeting will be open to the public up to the capability of the teleconferencing system. This discussion is pursuant to carrying out its statutory duties for which the Panel reviews, identifies, evaluates, and advises on those program activities, systems, procedures, and management activities that can contribute to program risk. Priority is given to those programs that involve the safety of human flight. The major subjects covered will be: Space Shuttle Program, International Space Station Program, and Cross-Program Areas. The Aerospace Safety Advisory Panel is composed of nine members and one ex-officio member.

Any member of the public is permitted to file a written statement with the Panel at the time of the meeting. Presentations and written comments should be limited to the subject of safety in NASA. To do so, please contact Ms. Susan Burch on (202) 358–0914 at least 24 hours in advance.

R. Andrew Falcon,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 04–22269 Filed 10–1–04; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL SCIENCE FOUNDATION

Advisory Committee for Environmental Research and Education; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Public Law 92–463, as amended), the National Science Foundation announces the following meeting:

Name: Advisory Committee for Environmental Research and Education (9487).

Dates: October 20, 2004, 8:30 a.m.–5 p.m., October 21, 2004, 8:30 a.m.–3:30 p.m.

Place: Stafford I, Room 1235, National Science Foundation, 4201 Wilson Blvd., Arlington, Virginia 22230.

Type of Meeting: Open.

Contact Person: Dr. Margaret Cavanaugh, Directorate for Geosciences, National Science Foundation, Suite 705, 4201 Wilson Blvd., Arlington, Virginia 22230. Phone: (703) 292–8500.

Minutes: May be obtained from the contact person listed above.

Purpose of Meeting: To provide advice, recommendations, and oversight concerning support for environmental research and education.

Agenda:

October 20
- Update on recent NSF environmental activities.
- Report on NSF–DOE Water workshop.
- Discussion of ACERE document on strategies for Complex Environmental Systems research and education and occasional papers.
- AC–ERE task group meetings.

October 21
- AC–ERE task group reports.
- Meeting with the Acting Director.
- Presentation on "MIT–CC Partnership".
- Panel on NSF Diversity Programs.

Dated: September 28, 2004.

Susanne Bolton,

Committee Management Officer.

[FR Doc. 04–22224 Filed 10–1–04; 8:45 am]

BILLING CODE 7555–01–M

NATIONAL SCIENCE FOUNDATION

Committee on Equal Opportunities in Science and Engineering; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Public Law 92–463, as amended), the National Science Foundation announces the following meeting:

Name: Committee on Equal Opportunities in Science and Engineering (1173).

Dates/Time: October 25, 2004, 8:30 a.m.—5:30 p.m. and October 26, 2004, 8:30 a.m.—2 p.m.

Place: National Science Foundation, 4201 Wilson Boulevard, Room 1235 S, Arlington, VA 22230.

Type of Meeting: Open.

Contact Person: Dr. Margaret E.M. Tolbert, Senior Advisor and Executive Liaison, CEOSE, Office of Integrative Activities, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230. Telephone: (703) 292–8040.

Minutes: May be obtained from the Executive Liaison at the above address.

Purpose of Meeting: To provide advice and recommendations concerning broadening participation in science and engineering.

Agenda:

Monday, October 25, 2004

Welcome by the CEOSE Chair.
Introduction of New Members.
Review of the CEOSE Meeting Agenda.
Discussions:
- CEOSE Meetings Held at Little Big Horn and Chief Dull Knife Colleges in Montana;
- Meeting with Dr. Ardent L. Bement, Acting Director of the National Science Foundation.
- Congressionally Required Ten-Year Reports Prepared by CEOSE Members.

Tuesday, October 26, 2004

Opening Statement by the CEOSE Chair.
Presentations:
- Response to Action items in the CEOSE Meeting Minutes;
- Report on Mentoring Workshop;
- Reports on NSF Advisory Committees;
- Changes in SESTAT;
- Data on Persons with Disabilities.

Discussions:
- Plans for the CEOSE 2004 Biennial Report to Congress;
- Recommendations by CEOSE;
- Dates for Future CEOSE Meetings.

Dated: September 28, 2004.

Susanne Bolton,

Committee Management Officer.

[FR Doc. 04–22222 Filed 10–01–04; 8:45 am]

BILLING CODE 7555–01–M

NATIONAL SCIENCE FOUNDATION

Advisory Committee for Geosciences; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Public law 92–463, as amended), the National Science Foundation announces the following meeting:

Name: Advisory Committee for Geosciences (1755).

Dates/Times: October 27, 2004, 2–5:30 p.m., October 28, 2004 8:30 a.m.–5:30 p.m., October 29, 2004, 8:30 a.m.–2 p.m.

Place: National Science Foundation, 4201 Wilson Boulevard, Room 1235, Arlington, VA 22230.

Type of Meeting: Open.

Contact Person: Dr. Thomas Spence, Directorate for Geosciences, National Science Foundation, Suite 705, 4201 Wilson Boulevard, Arlington, Virginia 22230, phone 703–292–8500.

Minutes: May be obtained from the contact person listed above.

Purpose of Meeting: To provide advice, recommendations, and oversight concerning support for research, education, and human resources development in the geosciences.

Agenda:

Day 1
- Directorate Activity Reports
- Meeting with NSF Deputy Director

Day 2
- Planning, Coordination, and Implementation Activities
- Division Subcommittee Meeting and Reports

Day 3
- Education and Diversity Subcommittee Meeting
- Committee of Visitors Reports
- Intersessional Activities

Dated: September 29, 2004.

Susanne Bolton,

Committee Management Officer.

[FR Doc. 04–22225 Filed 10–1–04; 8:45 am]

BILLING CODE 7555–01–M

NATIONAL SCIENCE FOUNDATION

Advisory Committee for Mathematical and Physical Sciences; Notice of Meeting

In accordance with Federal Advisory Committee Act (Public Law 92–463, as amended), the National Science Foundation announces the following meeting:

Name: Directorate for Mathematical and Physical Sciences, Advisory Committee (MPSAC), #66.

Date/Time: November 3, 2004, 8 a.m.–6 p.m.; November 4, 2004, 8 a.m.–6 p.m.; November 5, 2004, 8 a.m.–3 p.m.

Place: National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230, Room 375.

Type of Meeting: Open.

Contact Person: Dr. Morris L. Aizenman, Senior Science Associate, Directorate for Mathematical and Physical Sciences, Room 1005, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230. (703) 292–8807.

Purpose of Meeting: To provide advice and recommendations concerning NSF science and education activities within the Directorate for Mathematical and Physical Sciences.

Agenda:

Briefing to new members about NSF and Directorate.
Update on current status of Directorate.
Overview of Facilities.
Meeting with Education and Human Resources Advisory Committee.
Report on CyberScience and Theory Workshops.
Meeting of MPSAC with Divisions within MPS Directorate.
Discussion of MPS Long-term Planning Activities.

Summary Minutes: May be obtained from the contact person listed above.

Dated: September 28, 2004.

Susanne E. Bolton, .

Committee Management Officer.

[FR Doc. 04–22223 Filed 10–1–04; 8:45 am]

BILLING CODE 7555–01–M

NUCLEAR REGULATORY COMMISSION

[Docket No. 030–29418]

University of Pittsburgh Environmental Assessment and Final Finding of No Significant Impact for Exemption From 10 CFR 35.615(F)(3)

The U.S. Nuclear Regulatory Commission (NRC) is authorizing the University of Pittsburgh, License No. 37–00245–09, an exemption to 10 CFR 35.615(f)(3), to permit the licensee to have a qualified neurosurgeon physically present in place of an Authorized User (AU) during the use of its gamma stereotactic radiosurgery (GSR) units.

Environmental Assessment

Identification of the Proposed Action

The University of Pittsburgh has a NRC license (License No. 37–00245–09) which authorizes the medical use of three GSR units. The licensee has requested, in a letter dated April 9, 2004, that NRC grant a exemption to 10 CFR 35.615(f)(3), which requires an AU and Authorized Medical Physicist (AMP) to be physically present throughout all patients treatments with a GSR unit.

Need for the Proposed Action

The licensee has three GSR units located in the same wing of the hospital. Because of its expanding patient workload, the licensee states that there will be times when it will need to be able to perform simultaneous treatments with the GSR units. The licensee is requesting an exemption to 10 CFR 35.615(f)(3) to allow the use of a qualified neurosurgeon, instead of an AU, to be present throughout patients treatments involving the GSR units, in addition to the presence of the AMP. The AU will be immediately available to respond to an emergency at any of the units.

The exemption is needed so that University of Pittsburgh can continue to provide optimum medical treatment to its patients. The exemption would allow the University of Pittsburgh to perform simultaneous treatments with the GSR units. The exemption would allow better participation of the AU in dose treatment planning and patient set-up, without requiring the addition of a second AU. In evaluating the licensee's performance conforming to the current requirements in 10 CFR 35.615(f)(3), NRC inspections since April 2000 have not identified any violations nor medical events associated with the use of the GSR units.

Environmental Impacts of the Proposed Action

The gamma stereotactic radiosurgery sources are sealed sources and no material will be released to the environment. All the sources are contained within the unit, as verified by periodic spot checks performed by the licensee. The proposed action does not increase public radiation exposure. There will be no impact on the environment as a result of the proposed action.

Alternatives to the Proposed Action

As required by Section 102(2)(E) of NEPA (42 USC 4322(2)(E)), a possible alternative to the final action has been considered. The alternative is to deny the exemption request, which would require the licensee to have at least two AUs and two AMPs physically present when simultaneous treatments are conducted at the licensed facility, which would significantly increase the cost of patient care. The alternative option would not produce a gain in protecting the human environment, and it would negatively impact the licensee's provision of medical care to it patients.

Alternative Use of Resources

No alternative use of resources was considered because of the reasons stated above.

Agencies and Persons Consulted

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) has been consulted to evaluate this exemption request. ACMUI's recommendation has been considered in responding to the licensee's request.

Identification of Source Used

Letters from the University of Pittsburgh, to NRC, Region I, dated April 9, 2004, and June 3, 2004.

Finding of No Significant Impact

Based on the above environmental assesment, the Commission has concluded that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, NRC has determined that a Finding of No Significant Impact is appropriate and preparation of an environmental impact statement is not warranted.

The licensee's letters are available for inspection, and/or copying for a fee, in the NRC Region I, Public Document Room, 475 Allendale Road, King of Prussia, PA 19406. The documents are available electronically for public inspection from the Publicly Available Records (PARS) component of NRC's Documents Access and Management System (ADAMS), accession numbers ML041190282 and ML041620397, respectively. ADAMS is accessible from the NRC Web site at: *http://www.nrc.gov/reading-rm/adams.html.*

Dated at Rockville, Maryland, this 24th day of September, 2004.

For the Nuclear Regulatory Commissinon.

Sandra Wastler,

Section Chief, Material Safety and Inspection Branch, Division of Industrial and Medical Nuclear Safety, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 04–22197 Filed 10–1–04; 8:45 am]

BILLING CODE 7590–01–M

NUCLEAR REGULATORY COMMISSION

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Nuclear Regulatory Commission.

DATE: Week of October 4, 2004.

PLACE: Commissioner's Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

ADDITIONAL MATTER TO BE CONSIDERED:

Week of October 4, 2004

Thursday, October 7, 2004

9:25 a.m. Affirmation Session (Public Meeting)(Tentative)

a. State of Alaska Department of Transportation and Public Facilities (Confirmatory Order Modifying License); appeals of LBP–04–16 by NRC Staff and Licensee (Tentative)

b. Private Fuel Storage (Independent Spent Fuel Storage Installation) Docket No. 72–22–ISFSI (Tentative)

c. USEC, Inc. (Tentative)

d. Citizen's Awareness Network's (CAN) Motion to Dismiss the Yankee Rowe License Termination Proceeding or to Re-Notice It (Tentative)

e. Duke Energy Corp. (Catawba Nuclear Station, Units 1 and 2); Licensing Board's certification of its ruling on "need to know" during discovery (Tentative)

f. Final Rulemaking to Add New Section 10 CFR 50.69, "Risk-Informed Categorization and Treatment of Structures, Systems, and Components for Nuclear Power

Reactors'' (Tentative)

The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings call (recording)—(301) 415–1292. Contact person for more information: Dave Gamberoni, (301) 415–1651.

The NRC Commission Meeting Schedule can be found on the Internet at: *www.nrc.gov/what-we-do/policy-making/schedule.html.*

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.* braille, large print), please notify the NRC's Disability Program Coordinator, August Spector, at 301–415–7080, TDD: 301–4152100, or by e-mail at *aks@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

This notice is distributed by mail to several hundred subscribers; if you no longer wish to receive it, or would like to be added to the distribution, please contact the Office of the Secretary, Washington, DC 20555 (301–415–1969). In addition, distribution of this meeting notice over the Internet system is available. If you are interested in receiving this Commission meeting schedule electronically, please send an electronic message to *dkw@nrc.gov.*

Dated: September 29, 2004.

Dave Gamberoni,

Office of the Secretary.

[FR Doc. 04–22308 Filed 9–30–04; 8:45 am]

BILLING CODE 7590–01–M

OVERSEAS PRIVATE INVESTMENT CORPORATION

Agency Report Form Under OMB Review

AGENCY: Overseas Private Investment Corporation.

ACTION: Request for comments.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35), agencies are required to publish a Notice in the **Federal Register** notifying the public that the Agency has prepared an information collection request for OMB review and approval and has requested public review and comment on the submission. OPIC published its first **Federal Register** Notice on this information collection request on July 15, 2004, in vol. 69 No. 135, FR 42470, at which time a 60-calendar day comment period was announced. This comment period ended September 15, 2004. No comments were received in response to this notice. This information collection submission has now been submitted to OMB for review. Comments are again being solicited on the need for the information; the accuracy of the Agency's burden estimate, the quality, practical utility, and clarity of the information to be collected; and on ways to minimize the reporting burden, including automated collection techniques and uses of other forms of technology. The proposed form under review, OMB control number 3420–0015, is summarized below.

DATES: Comments must be received within 30-calendar days of this Notice.

ADDRESSES: Copies of the subject form and the request for review submitted to OMB may be obtained from the Agency Submitting Officer. Comments on the form should be submitted to the OMB Reviewer.

FOR FURTHER INFORMATION CONTACT:

OPIC Agency Submitting Officer: Bruce I. Campbell, Records Management Officer, Overseas Private Investment Corporation, 1100 New York Avenue, NW., Washington, DC 20527; (202) 336–8563.

OMB Reviewer: David Rostker, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Docket Library, Room 10102, 725 17th Street, NW., Washington, DC 20503, (202) 395–3897.

Summary of Form Under Review

Type of Request: Form Renewal.
Title: Application for Financing.
Form Number: OPIC–115.
Frequency of Use: One per investor, per project.
Type of Respondents: Business or other institutions (except farms); individuals.
Standard Industrial Classification Codes: All.
Description of Affected Public: U.S. companies or citizens investing overseas.
Reporting Hours: 4 hours per project.
Number of Responses: 300 per year.
Federal Cost: $21,600 per year.
Authority for Information Collection: Sections 231 and 234 (b) and (c) of the Foreign Assistance Act of 1961, as amended.

Abstract (Needs and Uses): The OPIC 115 form is the principal document used by OPIC to determine the investor's and project's eligibility for dept financing, to assess the environmental impact and developmental effects of the project, to measure the economic effects for the United States and the host country economy, and to collect information for underwriting analysis.

Dated: September 29, 2004.

Eli Landy,

Senior Counsel, Administrative Affairs, Department of Legal Affairs.

[FR Doc. 04–22215 Filed 10–1–04; 8:45 am]

BILLING CODE 3210–03–M

OVERSEAS PRIVATE INVESTMENT CORPORATION

Privacy Act of 1974, as Amended; System of Records Notice

AGENCY: Overseas Private Investment Corporation.

ACTION: Notice to add new Privacy Act system of records.

SUMMARY: The Overseas Private Investment Corporation (OPIC) is giving notice that it proposes to add a new system of records, Staff Central (OPIC–4), to its existing inventory of systems subject to the privacy Act of 1974 (5 U.S.C. 552a), as amended. This system of records incorporates and replaces OPIC–4, Employee Exit Forms, which OPIC is deleting from its inventory of systems of records. Staff Central is an electronic workflow and information tracking system employed in connection with the administration and handling of OPIC personnel. The system automates administrative tasks associated with the processing of new employees, moving personnel between offices, and processing employees through OPIC's employment exit procedures. Staff Central also transfers staff in formation to various directories and applications, and provides a central location for other OPIC systems to link to and pull information from as needed.

DATES: The new system will be effective without further notice on November 15, 2004, unless comments on or before the date cause a contrary decision.

ADDRESSES: Written comments may be addressed and mailed or hand-delivered to Christopher Astriab, Overseas Private Investment Corporation, 1100 New York Avenue, NW., Washington, DC 20527. Faxes may be sent to Christopher Astriab at (202) 842–8413. Submit electronic comments to *cast@opic.gov.* If changes are made based on OPIC's review of comments received, a new final notice will be published.

FOR FURTHER INFORMATION CONTACT: Christopher Astriab, Overseas Private Investment Corporation, 1100 New York Avenue, NW., Washington, DC 20527, telephone (202) 336–8633.

SUPPLEMENTARY INFORMATION: OPIC last published a comprehensive set of Privacy Act system notices in the **Federal Register** on July 9, 1999 (64 FR 37152). OPIC published one additional system, OPIC–21, in the **Federal Register** on December 9, 1999 (64 FR 69033). OPIC is proposing to replace one of its existing systems of record, OPIC–4, Employee Exit Forms, with a new system of records, OPIC–4 Staff Central. OPIC's employee exit process is incorporated into Staff Central.

Section 552a(e)(4) and (11) of Title 5, United States Code, provides that the public be afforded a 30-day period in which to comment on this addition to OPIC's existing record systems. Additionally, a copy of this notice has been submitted to the Chair of the Committee on Government Reform and Oversight of the House of Representatives, the Chair of the Committee on Governmental Affairs of the Senate, and the Office of Management and Budget, pursuant to 5 U.S.C. 552a(r).

Staff Central, an electronic workflow and information tracking system, enables OPIC to automate the processes associated with the administration and handling of OPIC personnel. This includes such tasks as processing new employees, moving personnel between offices, and processing employees through OPIC's employment exit procedures. Staff Central also transfers staff information to various directories and applications, and provides a central location for other OPIC systems to link to and pull information from as needed. The system cross-references; indexes, and tracks a number of administrative work processes in a centralized, paperless environment. Records maintained in Staff Central are primarily accessed by employee name. In addition, records may be accessed by reference to any information entered into the system, including address, phone number, certification in CPR, etc.

OPIC–4

SYSTEM NAME:

Staff Central

SECURITY CLASSIFICATION:

Sensitive But Unclassified

SYSTEM LOCATION:

Overseas Private Investment Corporation, 1100 New York Avenue, NW., Washington, DC 20527.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Current and former employees of the Corporation (including personal services contractors) and industrial contractors.

CATEGORIES OF RECORDS IN THE SYSTEM:

(1) Security records, including records indicating level of building and network access, security badge number, and security clearance level and adjudication date; (ii) emergency contract information records, including home address, phone number and e-mail, emergency contact person information, and information on the individual's home computer operating system, home Internet access, and whether they possess first-aid or CPR certification; and (iii) employee exit process records, including signatures and date stamps reflecting whether department employees have been debriefed on the government's classified information program, the Corporation's security program, and the Corporation's records policies and procedures; have been advised if and fully understand provisions on post employment conflicts of interest; and certifying that all required clearances for release of the employee's final pay check have been obtained. Authority for maintenance of the system: General authority for agency records management is provided by 5 U.S.C. 301, Departmental Regulations, and 44 U.S.C. 3101, Records Management by Agency Heads. Additional authority to maintain security records is provided by 5 U.S.C. 3301, Examination, Selection and Placement, E.O. 10450, Clearance for Federal Employment, April 17, 1953, as amended; E.O. 12968, Access to Classified Information, August 4, 1995. Additional authority to maintain emergency contact information records is provided by Federal Preparedness Circular 65, Federal Executive Branch Continuity of Operations (COOP), July 26, 1999; E.O. 12656, Assignment of Emergency Preparedness Responsibilities, November 18, 1988, as amended; and Presidential Decision Directive 67, Enduring Constitutional Government and Continuity of Government Operations, October 21, 1998. Additional authority to maintain employee exit process records is provided by E.O. 12958, Classified National Security Information, April 17, 1995; 32 CFR 2003.20, Classified Information Non-Disclosure Agreement: SF–312; 5 CFR part 2637, Regulations Concerning Post Employment Conflicts of Interest; and Pub. L. 104–134, Debt Collection Improvement Act of 1996.

PURPOSE(S):

These records are used (i) as an easy-reference record to determine the suitability and/or eligibility of employees and contractors for access to facilities, information systems, and classified information; (iii) to account for and/or communicate with employees and contractors or their designees in the event of an emergency or disaster; (iii) to process existing employees and contractors when their tenure with OPIC ends; and (iv) to maintain a record of all debriefings and completed exit procedures for former employees.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES.

Security records are used (i) by OPIC human resources and security managers to check the status, level, and date received of security clearances, and (ii) by OPIC departmental security officers to confirm that employees who require access to classified information have the appropriate level of security clearance. Emergency contact information records are used (i) by OPIC human resources and security managers to notify an employee's designee of an emergency that affects the employee or to account for an employee's whereabouts, especially in the event of a disaster; (ii) by OPIC human resources managers to communicate with an employee's designee regarding survivor benefits or other benefits or employment information in the event an employee becomes incapacitated or dies; and (iii) by OPIC security managers for emergency management or continuity of operations purposes. Employee exist process records are used by OPIC agency managers (i) to verify that all departing employees have completed the checkout process and returned government property to OPIC, (ii) to ensure the security of OPIC-related information, (iii) to ensure that employees are briefed concerning post-employment restrictions; and (iv) to certify that all required clearances for release of the employee's final pay check have been obtained.

OPIC may disclose information contained in a record in this system of records under the routine uses listed in this notice without the consent of the individual if the disclosure is compatible with the purposes for which the record was collected. Disclosures may be made:

(i) In the event that information in this system of records indicates, either on its face or in connection with other information, a violation or potential violation of any applicable statute, regulation, or order of a competent authority, OPIC may disclose the relevant records to the appropriate agency, whether Federal, State, or local, charged with the responsibility of

investigating or prosecuting that violation and/or charged with enforcing or implementing the statute, executive order, rule, regulation, or order issued pursuant thereto.

(ii) In a proceeding before a court or adjudicative body before which OPIC is authorized to appear when any of the following is a party to litigation or has an interest in litigation and information in this system is determined by OPIC to be arguably relevant to the litigation: OPIC; any OPIC employee in his or her official capacity, or in his or her individual capacity where the Department of Justice agrees to represent the employee; or the United States where OPIC determines that the litigation is likely to affect it.

(iii) To a court, a magistrate, administrative tribunal, or other adjudicatory body in the course of presenting evidence or argument, including disclosure to opposing counsel or witnesses in the course of civil discovery, litigation, or settlement negotiations, or in connection with criminal law proceedings.

(iv) To a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of and at the written request of the individual who is the subject of the record.

(v) To another Federal agency or other public authority, in connection with the hiring or retention of an employee or other personnel action, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license, grant, or other benefit, to the extent that the record is relevant and necessary to the receiving entity's decision on the matter.

(vi) To the National Archives and Records Administration and to the General Services Administration in records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906.

(vii) To the employees of entities with which OPIC contracts for the purposes of performing any function that requires disclosure of records in this system. Before entering into such a contract, OPIC shall require the contractor to maintain Privacy Act safeguards as required under 5 U.S.C. 552a(m) with respect to the records in the system.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR RESTORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM

STORAGE:

Records are stored electronically on OPIC's computer network or on backup media such as tape and/or CD–ROM. Copies of records may be stored in hard copy format in file folders in secure file cabinets accessible only by authorized individuals either onsite at OPIC or at approved offsite locations.

RETRIEVABILITY:

Records are retrieved by the names of the individuals covered by the system and may be searched and indexed by any field within the record.

SAFEGUARDS:

Access to and use of each of the records in the system are limited to persons whose official duties require such access. Information contained in the system is safeguarded and protected through physical and system-based safeguards, including system access controls. Retention and disposal: Records related to post-employment conflict of interest debriefings are retained for six years following separation from employment. All other records are retained for two years following separation from employment or contractual relationship with OPIC. All records are destroyed pursuant to existing General Records Schedules and OPIC records disposition schedules.

SYSTEM MANAGER(S) AND ADDRESS:

Director of Operations, Overseas Private Investment Corporation, 1100 New York Avenue, NW., Washington, DC 20527.

NOTIFICATION PROCEDURE:

Requests by individuals concerning the existence of a record may be submitted in writing, addressed to the system manager above. The request must comply with the requirements of 22 CFR 707.21(b).

RECORD ACCESS PROCEDURES:

Same as notification procedure.

CONTESTING RECORD PROCEDURES:

Requests by individuals to amend their record must be submitted in writing, addressed to the system manager above. Requests for amendments to records and requests for review of a refusal to amend a record must comply with the requirements of 22 CFR 707.22.

RECORD SOURCE CATEGORIES:

Federal agencies conducting background investigations under agreements with OPIC or under agreements with contracting agencies with whom OPIC has a contractual relationship; individuals on whom the records are maintained; and OPIC staff involved in the employee exit process.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

Dated: September 29, 2004.

Connie M. Downs,

Corporate Secretary, Department of Legal Affairs.

[FR Doc. 04–22230 Filed 10–1–04; 8:45 am]

BILLING CODE 3210–01–M

POSTAL SERVICE

Change to the Retirement Plan for Manually Set Postage Meters

AGENCY: Postal Service.

ACTION: Notice of change to the Retirement Plan for Manually Set Postage Meters.

SUMMARY: By this notice, the Postal Service™ revises the Retirement Plan for Manually Set Postage Meters, published in the **Federal Register** on December 13, 2000, pages 77934–77938, for meters with lease expiration dates on or after October 1, 2004. The retirement date for these manually set electronic meters will be May 31, 2005. The Postal Service will no longer reset electronic manually set meters after February 28, 2005.

DATES: This notice is effective on October 4, 2004.

FOR FURTHER INFORMATION CONTACT: Wayne A. Wilkerson, manager of Postage Technology Management, at (703) 292–3691 or by fax at (703) 292–4073.

SUPPLEMENTARY INFORMATION: A notice was published in the **Federal Register** on June 15, 2004, pages 33429–33430, with comments due on or before July 15, 2004. Written comments were received from the vendor community. There was no opposition to the proposal to retire all manually set electronic meters from service by May 31, 2005.

An exception was taken to the proposed restriction on replacing a malfunctioning manually set meter with a functional meter of the same model. The Postal Service reconsidered its proposal and removed this restriction. Replacement meters will be permitted up to February 28, 2005.

You can review the comments received by submitting a request to the office of Postage Technology Management at (703) 292–3691 or by fax at (703) 292–4073.

The final plan follows.

The Revised Plan For Manually Set Postage Meters

The Postal Service retirement date for manually set electronic meters with lease expiration dates on or after October 1, 2004, will be May 31, 2005. The Postal Service will no longer reset electronic manually set meters after February 28, 2005. Anyone in possession of a manually set meter must return it to the meter provider on or before May 31, 2005. The meter provider will withdraw the meter from service.

Any manually set electronic postage meter that is capable of remote meter setting must be either converted to remote meter setting or retired from service and returned to the meter provider. The function that allows manual setting must be disabled.

The manager of Postage Technology Management, Postal Service Headquarters, will send official notification to those affected users with an explanation of this plan. Any other explanation received by users may not accurately represent the position of the Postal Service.

Stanley F. Mires,

Chief Counsel, Legislative.

[FR Doc. 04–22232 Filed 10–1–04; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 35–27897]

Filings Under the Public Utility Holding Company Act of 1935, as Amended (Act)

September 28, 2004.

Notice is hereby given that the following filing(s) has/have been made with the Commission pursuant to provisions of the Act and rules promulgated under the Act. All interested persons are referred to the application(s) and/or declaration(s) for complete statements of the proposed transaction(s) summarized below. The application(s) and/or declaration(s) and any amendment(s) is/are available for public inspection through the Commission's Branch of Public Reference.

Interested persons wishing to comment or request a hearing on the application(s) and/or declaration(s) should submit their views in writing by October 20, 2004, to the Secretary, Securities and Exchange Commission, Washington, DC 20549–0609, and serve a copy on the relevant applicant(s) and/or declarant(s) at the address(es) specified below. Proof of service (by affidavit or, in the case of an attorney at law, by certificate) should be filed with the request. Any request for hearing should identify specifically the issues of facts or law that are disputed. A person who so requests will be notified of any hearing, if ordered, and will receive a copy of any notice or order issued in the matter. After October 20, 2004, the application(s) and/or declaration(s), as filed or as amended, may be granted and/or permitted to become effective.

Allegheny Energy, Inc. (70–10247)

Allegheny Energy, Inc. ("Allegheny"), a registered holding company under the Act, 800 Cabin Hill Drive, Greensburg, Pennsylvania 15601, has filed a declaration ("Declaration") under section 12(d) and rule 44 of the Act.

Allegheny requests authorization to sell its nine percent ownership interest in Ohio Valley Electric Corporation ("OVEC") to Buckeye Power Generating, LLC ("Buckeye Power"), an affiliate of Buckeye Power Inc. OVEC is a public utility company under the Act.

OVEC was formed in the early 1950s by a group of holding companies and utilities located in the Ohio Valley region in response to the request of the United States Atomic Energy Commission ("AEC") to supply the electric power and energy necessary to meet the needs of a uranium enrichment plant being built by the AEC in Pike County, Ohio. The holding companies that directly or indirectly own 10 percent or more of OVEC's stock, each of which is a registered holding company, are: Allegheny (12.5%),[1] American Electric Power Company, Inc. ("AEP") (44.2%) and FirstEnergy Corp. ("FirstEnergy") (20.5%).[2]

OVEC owns two coal-fired generating stations: (1) The Kyger Creek Plant in Cheshire, Ohio, which has a generating capacity of 1,075 megawatts, and (2) the Clifty Creek Plant in Madison, Indiana, which has a generating capacity of 1,290 megawatts and is owned by OVEC's wholly-owned subsidiary, Indiana-Kentucky Electric Corporation. Originally, the Department of Energy ("DOE") purchased essentially all of the generating capacity of OVEC's generating facilities. However, DOE terminated its purchase agreement on April 30, 2003, and each of the Sponsoring Companies currently is entitled to its specified share of all net power and energy produced by OVEC's two generating stations.[3]

Buckeye Power, Inc., is a member-owned generation and transmission cooperative based in Columbus, Ohio that supplies power and energy to all the electric distribution cooperatives that serve customers in Ohio. The certified service territory of these distribution cooperatives covers nearly 40 percent of the land area in the State and encompasses 77 of Ohio's 88 counties.

On May 17, 2004, Allegheny signed a purchase agreement ("Purchase Agreement") under which Allegheny will sell a nine percent equity interest in OVEC, and Allegheny Energy Supply Company, LLC ("AE Supply"), will assign its rights to nine percent of the power generated by OVEC, to Buckeye Power for $102 million in cash and the assumption of approximately $37 million in debt by Buckeye Power ("Purchase Price"). Of the total cash component of the Purchase Price, $7,140,000 represents the price for the transfer of Allegheny's nine percent equity interest in OVEC, the transaction for which authority is being sought in this Application. The remainder represents the price for the assignment of AE Supply's rights under the OVEC Inter-Company Power Agreement ("OVEC Power Agreement") to nine percent of the power generated by OVEC.[4]

Allegheny maintains that the sale and assignment of these various interests is consistent with Allegheny's strategic goals of improving its financial strength

[1] In addition to the nine percent ownership interest in OVEC that is the subject of this Declaration, Allegheny owns another direct 3.5 percent interest in OVEC. Monongahela receives power from OVEC under an entitlement to power associated with this 3.5 percent interest. Allegheny is not proposing to transfer this 3.5 percent interest at this time.

[2] The following is a complete list of owners of OVEC's stock: Allegheny (12.5%); AEP (39.9%); Cincinnati Gas & Electric Company (9.0%); Columbus Southern Power Company, a subsidiary of AEP (4.3%); The Dayton Power and Light Company (4.9%); Kentucky Utilities Company (2.5%); Louisville Gas and Electric Company (4.9%); Ohio Edison Company, a subsidiary of FirstEnergy (16.5%); Southern Indiana Gas and Electric Company (1.5%); and The Toledo Edison Company, a subsidiary of FirstEnergy (4.0%). Each of these companies is either an original owner of OVEC's stock or a successor to an original owner. These companies are referred to in this Declaration as the "Sponsoring Companies."

[3] By letter dated September 29, 2000, the DOE notified OVEC that it had elected to terminate the power agreement as of April 30, 2003. Allegheny understands that the DOE currently maintains its uranium enrichment plant in "cold standby" status and is exploring various options for the plant and the Ohio site. OVEC currently provides retail service to DOE through an "arranged power" agreement under which OVEC procures power and energy for DOE at cost from third parties.

[4] AE Supply will retain the right to nine percent of the power from OVEC until March 12, 2006, at which time Buckeye Power will begin to receive the power. The time for receipt of power by Buckeye Power may be accelerated upon occurrence of certain events relating to the financial condition of Allegheny.

by reducing debt and of refocusing its attention on the generation assets it owns and operates within the PJM Interconnection ("PJM") territory. Allegheny will use the net proceeds from the OVEC sale to reduce outstanding debt and for general corporate purposes.

Allegheny states that the Purchase Price and other definitive terms for the sale of OVEC reflected in the Purchase Agreement—negotiated by representatives of the parties over a number of months—are the result of arm's-length bargaining, and the Purchase Price constitutes fair and adequate consideration for the sale and assignment of Allegheny's interests in OVEC.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E4–2463 Filed 10–1–04; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–50457; File No. SR–FICC–2004–11]

Self-Regulatory Organizations; Fixed Income Clearing Corporation; Notice of Filing of a Proposed Rule Change To Amend the Rules of the Government Securities Division To Modify the Penalty Assessment Process for Violations of Minimum Financial Standards and for Failures of Members To Submit Requisite Financial Reports on a Timely Basis

September 27, 2004.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1], notice is hereby given that on May 17, 2004, the Fixed Income Clearing Corporation ("FICC") filed with the Securities and Exchange Commission ("Commission") and on July 8, 2004, amended the proposed rule change described in Items I, II, and III below, which items have been prepared primarily by FICC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested parties.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FICC is seeking to amend the rules of its Government Securities Division ("GSD") to modify the penalty assessment process for violations of minimum financial standards and for failures to submit requisite financial reports on a timely basis.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FICC 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. FICC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.[2]

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The proposed rule change would amend the rules of the GSD by modifying the penalty assessment process for violations of minimum financial standards and failure to submit requisite financial reports on a timely basis.

(1) Violations of Minimum Financial Standards

The rules of the GSD require netting members and clearing members to meet and maintain certain minimum financial standards at all times. While the majority of GSD members consistently satisfy their minimum financial requirements, occasionally members do breach these requirements and create undue risk for FICC and its GSD members. FICC has decided that a more uniform system of enforcing minimum financial requirements within the GSD would enhance the ability of FICC to minimize risk to itself and its members in a fair and effective manner.

Currently, the GSD Rules provide clearing fund consequences for the various categories of netting members that fall out of compliance with minimum financial requirements as follows:

Netting membership category	Current clearing fund consequence for falling below minimum financial standard[3]
Bank Member	Treated as a Category 2 Dealer[4]
Category 1 Dealer Member	Treated as a Category 2 Dealer
Category 2 Dealer Netting Member	Impose Required Fund Deposit equal to 150 percent of the normal calculation of Required Fund Deposit.
Category 1 Futures Commission Merchant Member	Treated as a Category 2 Futures Commission Merchant.
Category 2 Futures Commission Merchant Member	Impose Required Fund Deposit equal to 150 percent of the normal calculation of Required Fund Deposit.
Category 1 Inter-Dealer Broker Member	Treated as a Category 1 Dealer as far as Required Fund Deposit exceeds $5 million.
Category 2 Inter-Dealer Broker Member	Treated as a Category 1 Inter-Dealer Broker, if it qualifies as such, or if it does not so qualify, impose Required Fund Deposit equal to 150 percent of the normal calculation of the Required Fund Deposit.

[1] 15 U.S.C. 78s(b)(1).

[2] The Commission has modified the text of the summaries prepared by FICC.

Netting membership category	Current clearing fund consequence for falling below minimum financial standard [3]
Government Securities Issuer Member	Treated as a Category 2 Dealer.

[3] Each consequence remains effective for a period beginning on the date on which the member fell below such level and continuing until the 90th calendar day after the date on which such member returned to compliance with the applicable standard. If the consequence consists of a reclassification and the member does not return to compliance with its original minimum financial requirement within 90 calendar days of falling out of compliance, then the reclassification becomes permanent.

[4] Treating a bank or other non-Inter-Dealer Broker Category 1 Member as a Category 2 non-Inter-Dealer Broker Member for clearing fund purposes results in a higher clearing fund requirement for such a member because higher margin rates are imposed on on-Inter-Dealer Broker Category 2 Dealer Members than are imposed on banks and non-Inter-Dealer Broker Category 1 Members.

Under the proposed rule change, a violation of a minimum financial requirement by a member [5] of the GSD would result in the imposition on such member of a margin premium equal to the greater of (a) 25 percent of the member's unadjusted [6] clearing fund requirement or (b) $1,000,000, to continue for ninety calendar days after the later to occur of (i) the member's return to compliance with applicable minimum financial standards or (ii) FICC's discovery of the applicable violation. This increase would not apply to Category 1 Dealer Netting Members, Category 1 Futures Commission Merchant Netting Members or Category 2 Inter-Dealer Broker Netting Members, where such members would continue to be reclassified as a different category netting member.[7] In addition, such violation would result in (1) a report of the violation to the FICC Membership and Risk Management Committee at its next regularly scheduled meeting or sooner if deemed appropriate by FICC and (2) the placement of such member on FICC's "watch list" subjecting it to more frequent and thorough monitoring. None of these consequences would preclude FICC from imposing any other margin consequences permitted by GSD's Rules.

(2) Failure To Submit Requisite Financial Reports on a Timely Basis

Certain members that are required to provide monthly or quarterly financial data to FICC at times have violated GSD's membership requirements by not timely providing such financial data. In such instances, management contacts each offending member and follows up with a letter.

Failure to timely receive required information creates risk to FICC and as a result hinders FICC's ability to appropriately assess the financial condition of such members. To encourage timely submission of required financial data, FICC has established a mechanism to fine delinquent members.[8] FICC is now proposing two additional measures to enforce timely filing of financial information.

First, FICC proposes to subject delinquent members to a more stringent clearing fund requirement. Specifically, under the proposed rule filing FICC would automatically impose a margin premium equal to the greater of (1) 25 percent of the member's unadjusted clearing fund requirement or (2) $1,000,000. The margin premium would be applied until appropriate financial data is submitted to FICC and is reviewed for compliance purposes. In addition, delinquent members would be precluded from taking back any excess clearing fund collateral to which they might ordinarily be entitled.

Second, members that fail to submit requisite financial reports on a timely basis would also automatically be placed on FICC's "watch list" and subject to more frequent and thorough monitoring.

FICC believes that the proposed rule change is consistent with the requirements of Section 17A of the Act [9] and the rules and regulations thereunder applicable to FICC because it assures the safeguarding of securities and funds which are in the custody or control of FICC by encouraging members to maintain their minimum financial standards and to submit their required financial reports on a timely basis. As a result, FICC's ability to maintain a financially sound membership base should be enhanced.

(B) Self-Regulatory Organization's Statement on Burden on Competition

FICC does not believe that the proposed rule change will have any impact or impose any burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed rule change have not yet been solicited or received. FICC will notify the Commission of any written comments received by FICC.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within thirty-five days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to ninety days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

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–FICC–2004–11 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–FICC–2004–11. This file

[5] The proposed rule change only applies to GSD members that have minimum financial requirements (*i.e.*, GSD netting members).

[6] "Unadjusted" means the standard calculation before any additional assessments.

[7] If GSD Category 1 Dealer Netting Members, GSD Category 1 Futures Commission Merchant Netting Members and GSD Category 2 Inter-Dealer Broker Netting Members do not meet the membership qualifications applicable to the new category of netting member, then they will be subject to the increased margin premium specified in clause (1) above.

[8] Securities Exchange Act Release No. 49947 (June 30, 2004), 69 FR 41316 [File No. SR–FICC–2003–01].

[9] 15 U.S.C. 78q–1.

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 Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing also will be available for inspection and copying at the principal office of FICC and on FICC's Web site at *http://www.ficc.com/gov/gov.docs.jsp?NS-query*. 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–FICC–2004–11 and should be submitted on or before October 22, 2004.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[10]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E4–2465 Filed 10–1–04; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–50456; File No. SR–NASD–2004–098]

Self-Regulatory Organizations; National Association of Securities Dealers, Inc.; Order Approving Proposed Rule Change and Amendment No. 1 Thereto Relating to Proposed Amendments to Eliminate Exemptions From the Continuing Education Regulatory Element Requirements

September 27, 2004.

On June 25, 2004, the National Association of Securities Dealers ("NASD") filed with the Securities and Exchange Commission ("Commission" or "SEC") a proposed rule change, pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and rule 19b–4 thereunder,[2] to eliminate all currently effective exemptions from the requirement to complete the Regulatory Element of the Continuing Education ("CE") Program. On July 23, 2004, NASD submitted Amendment No. 1 to the proposed rule change.[3] The proposed rule change, as amended, was published for comment in the **Federal Register** on August 23, 2004.[4] The Commission received no comments on the proposal. This order approves the proposed rule change, as amended.

NASD Rule 1120(a) currently provides, in part, that no member shall permit any registered person to continue to, and no registered person shall continue to, perform duties as a registered person, unless such person has complied with the Regulatory Element of the CE requirement set forth in this Rule.[5] The Regulatory Element component of NASD Rule 1120(a)(1) requires each registered person to complete a standardized, computer-based, interactive CE program within 120 days of their second registration anniversary date and every three years thereafter, or as otherwise prescribed by NASD. Registered persons who fail to complete the Regulatory Element are deemed inactive and may not perform in any capacity or be compensated in any way requiring registration.

Currently, two classes of persons are exempt from Regulatory Element requirements under NASD Rule 1120(a). The first class of persons come within the "grandfathered" exemption which applies to persons who were continuously registered, without serious disciplinary action,[6] for more than ten years as of the Rule's effective date (*i.e.*, July 1, 1995). The second class of persons come within the "graduated" exemption, which, although discontinued as of July 1998, continues to apply to registered persons who were "graduated" prior to the discontinuation of the exemption.[7]

However, in response to recommendations made by the Securities Industry/Regulatory Council on Continuing Education (the "Council"), NASD submitted a proposed rule change to eliminate all currently effective exemptions from required participation in Regulatory Element programs.[8] The Council believes that there is great value in exposing all registered industry participants to the full benefit of Regulatory Element programs.

NASD will announce the effective date of the proposed rule change in a Notice to Members to be published no later than 60 days following Commission approval. Proposed amendments are expected to become effective (1) not more than 30 days following publication of the Notice to Members announcing Commission approval, (2) not more than 30 days following the implementation of necessary changes to Web Central Registration Depository ("Web CRD"), or (3) April 4, 2005, whichever date is latest to occur.

The Commission finds that the proposed rule change, as amended, is consistent with the requirements of section 15A of the Act,[9] and the rules and regulations thereunder applicable to a national securities association.[10] In particular, the Commission finds that the proposed rule change is consistent with section 15A(b)(6) of the Act,[11] which requires, among other things, that the Association's rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. The Commission

[10] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* letter from Grace Yeh, Assistant General Counsel, NASD, to Katherine A. England, Assistant Director, Division of Market Regulation, Commission, dated July 22, 2004 ("Amendment No. 1"). In Amendment No. 1, NASD replaced in its entirety the original rule filing.

[4] *See* Securities Exchange Act Release No. 50204 (August 16, 2004), 69 FR 51873 (August 23, 2004).

[5] *See* NASD Rule 1120(a)(1).

[6] For purposes of NASD Rule 1120, a significant disciplinary action generally means a statutory disqualification as defined in section 3(a)(39) of the Act; a suspension or imposition of a fine of $5,000 or more; or being subject to an order from a securities regulator to re-enter the Regulatory Element. *See* Rule 1120(a)(3).

[7] When NASD Rule 1120 was first adopted in 1995, the Regulatory Element schedule required registered persons to satisfy the Regulatory Element on the second, fifth, and tenth anniversary of their initial securities registration. After satisfying the tenth anniversary requirement, a person was "graduated" from the Regulatory Element. A graduated principal re-entered the Regulatory Element if he or she incurred a significant disciplinary action. A graduated person who was not a principal re-entered if he or she acquired a principal registration or incurred a significant disciplinary action.

[8] The Council recommended at its December 2003 meeting that SRO Rules (*e.g.*, NASD Rule 1120(a)), be amended to eliminate existing exemptions from the Regulatory Element and to require all "grandfathered" and "graduated" persons to fully participate in future standardized CE programs, according to the Rule's prescribed schedule.

[9] 15 U.S.C. 78*o*–3.

[10] In approving the proposed rule change, the Commission has considered its impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[11] 15 U.S.C. 78*o*–3(b)(6).

believes that the proposed rule change should help to ensure that all registered persons are kept up-to-date on regulatory, compliance, and sales practice-related industry issues. Further, the Commission believes that the proposed rule change will reinforce the importance of compliance with just and equitable principles of trade by exposing all registered industry participants to the full benefits of the Regulatory Element programs, which include a new Regulatory Element module that focuses specifically on ethics.

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[12] that the proposed rule change (SR–NASD–2004–098), as amended, is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[13]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 04–22195 Filed 10–1–04; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–50458; File No. SR–NASD–2004–109]

Self-Regulatory Organizations; National Association of Securities Dealers, Inc.; Order Granting Approval to Proposed Rule Change To Increase the Initial Inclusion Requirements for Certain Foreign Securities Seeking To List on the Nasdaq SmallCap Market

September 28, 2004.

On July 15, 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"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] a proposed rule change to modify Rule 4320 to apply the same, heightened quantitative initial inclusion standards upon non-Canadian foreign issuers that currently apply to domestic and Canadian issuers seeking to list on the Nasdaq SmallCap Market ("SmallCap Market"). Specifically, Nasdaq has added to the initial inclusion requirements of Rule 4320 a minimum bid price requirement of $4 and a market value requirement for publicly held shares of $5,000,000.

The proposed rule change was published for comment in the **Federal Register** on August 18, 2004.[3] The Commission received no comments on the proposal.

The Commission finds that the proposed rule change is consistent with the provisions of Section 15A of the Act,[4] in general, and with Section 15A(b)(6) of the Act,[5] in particular, in that the proposal is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and, in general, to protect investors and the public interest. The Commission believes that applying the same quantitative initial inclusion standards upon non-Canadian foreign issuers seeking to list on the Nasdaq SmallCap market that currently apply to domestic and Canadian issuers is an appropriate change that raises the applicable standards and achieves consistent application of those standards among issuers.

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[6] that the proposed rule change (File No. SR–NASD–2004–109) be, and it hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[7]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E4–2468 Filed 10–1–04; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–50461; File No. SR–NFA–2004–01]

Self-Regulatory Organizations; National Futures Association; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change and Amendment No. 1 Thereto Adopting Bylaw 1508 Regarding Security Futures Agreements

September 28, 2004

Pursuant to Section 19(b)(7) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–7 thereunder,[2] notice is hereby given that on September 7, 2004, the National Futures Association ("NFA") 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 NFA. The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons. On September 3, 2004, the NFA filed the proposed rule change with the Commodity Futures Trading Commission ("CFTC") for approval and invoked the "ten-day" provision of Section 21(j) of the Commodity Exchange Act[3] ("CEA"). On September 17, 2004, the CFTC determined not to review the proposed rule change and permitted NFA to make the proposed rule change effective on September 17, 2004.[4] On September 27, 2004, NFA filed Amendment No. 1 to the proposed rule change.[5]

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

NFA proposes to adopt NFA Bylaw 1508 regarding securities futures agreements. The text of the proposed rule change appears below. New language is in italics.

* * * * *

Bylaws

* * * * *

Bylaw 1508. Security Futures Agreements.

Staff may, with the approval of the Executive Committee, enter into one or more agreements with one or more designated contract markets to provide regulatory services to NFA to assist NFA in discharging its obligations under Sections 15A(k) and 19(g) of the Securities Exchange Act of 1934. Any action taken by a designated contract market, or its employees or authorized agents, acting on behalf of NFA pursuant to a regulatory services agreement shall be deemed to be an action taken by NFA; provided, however, that nothing in this provision shall affect the oversight of the designated contract market by the Commodity Futures Trading

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[12] 15 U.S.C. 78s(b)(2).

[13] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Release No. 50183 (August 11, 2004), 69 FR 51341 (August 18, 2004).

[4] 15 U.S.C. 78o–3.

[5] 15 U.S.C. 78o–3(b)(6).

[6] 17 U.S.C. 78s(b)(2).

[7] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(7).

[2] 17 CFR 240.19b–7.

[3] 7 U.S.C. 21(j).

[4] *See* letter from Lawrence B. Patent, Deputy Director, Compliance and Registration Section, Division of Clearing and Intermediary Oversight, CFTC to Thomas W. Sexton, III, General Counsel, NFA, dated September 17, 2004.

[5] *See* letter from Kathryn Page Camp, Associate General Counsel, NFA, to John C. Roeser, Assistant Director, Division of Market Regulation ("Division"), Commission, dated September 27, 2004. Amendment No. 1 clarifies the proposal. Amendment No. 1 is incorporated into this notice.

Commission. Notwithstanding the fact that NFA may enter into one or more regulatory services agreements regarding security futures, NFA shall retain ultimate legal responsibility for, and control of, its self-regulatory responsibilities under the Securities Exchange Act of 1934, and any such regulatory services agreement shall so provide.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

NFA has prepared statements concerning the purpose of, and basis for, the proposed rule change, burdens on competition, and comments received from members, participants and others. The text of these statements may be examined at the places specified in Item IV below. NFA 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

Under the Act, NFA is required, as a limited purpose national securities association, to adopt and enforce SFP sales practice rules for notice-registered broker-dealers. Pursuant to CFTC Regulation 1.52(b),[6] NFA and the futures exchanges have entered into a plan that delegates auditing responsibilities for joint members to a designated futures self-regulatory organization ("DSRO"). NFA is not the DSRO for twenty-one exchange-member FCMs that are notice-registered as broker-dealers and, therefore, NFA is not responsible for auditing the futures activities of these firms.

NFA is, however, responsible under the Act for auditing the security futures activities of these notice-registered broker-dealers. In order to minimize the number of audits these firms are subject to, NFA Bylaw 1508 authorizes the NFA to enter into a regulatory services agreement with the futures exchanges that audit them. The bylaw also provides that NFA retains full responsibility for its obligations under the Exchange Act. If the futures exchanges do not conduct the appropriate audit steps or report potential violations to NFA, then NFA will be responsible to the Commission for those failures.

[6] 17 CFR 1.52(b).

2. Statutory Basis

The rule change is authorized by, and consistent with Section 15A(k) of the Act.[7]

B. Self-Regulatory Organization's Statement on Burden on Competition

NFA believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act and the CEA. In fact, NFA believes that the rule change will lessen the burdens on competition by avoiding duplicative examinations of notice-registered broker-dealers.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

NFA did not publish the rule change to the membership for comment. NFA did not receive comment letters concerning the rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The proposed rule change became effective on September 17, 2004. Within 60 days of the date of effectiveness of the proposed rule change, the Commission, after consultation with the CFTC, may summarily abrogate the proposed rule change and require that the proposed rule change be refiled in accordance with the provisions of Section 19(b)(1) of the Act.[8]

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)*;
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–NFA–2004–01 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.

[7] 15 U.S.C. 78*o*–3(k).

[8] 15 U.S.C. 78s(b)(1). For purposes of calculating the 60-day abrogation period, the Commission considers the period to commence on September 27, 2004, the date NFA filed Amendment No. 1.

All submissions should refer to File Number SR–NFA–2004–01. 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. Copies of such filing also will be available for inspection and copying at the principal office of NFA. 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–NFA–2004–01 and should be submitted on or before October 25, 2004.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[9]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E4–2467 Filed 10–1–04; 8:45 am]

BILLING CODE 8010–01–P

[9] 17 CFR 200.30–3(a)(75).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–50460; File No. SR-PCX–2004–77]

Self-Regulatory Organizations; Pacific Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change and Amendment No. 1 Thereto To Clarify Routing Away Practices

September 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 August 30, 2004, the Pacific Exchange, Inc. ("PCX" or "Exchange"), through its wholly owned subsidiary PCX Equities,

[1] 15 U.S.C. 78s(b)(1)

[2] 17 CFR 240.19b–4.

Inc. ("PCXE"), 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. The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(i) of the Act,[3] and Rule 19b–4(f)(6) thereunder,[4] which renders the proposal effective upon filing with the Commission. On September 1, 2004, the PCX filed Amendment No. 1 to the proposed rule change.[5] The Commission is publishing this notice, as amended, 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

The Exchange proposes to amend PCXE Rule 7.37 ("Order Execution"), which governs the Archipelago Exchange ("ArcaEx"), an equities trading facility of PCXE, to apply the restriction on the size of an order routed outside ArcaEx only to Intermarket Trading System "ITS" Eligible Listed securities, and not to over-the-counter "OTC" securities. The text of the proposed rule change appears below. New text is in italics. Deleted text is in brackets.

* * * * *

Rule 7

Equities Trading

Order Execution

* * * * *

Rule 7.37. (a)–(c) No change.

(d) Step 5: Routing Away.

(1)–(2)—No change.

(A)(i) The order shall be routed, either in its entirety or as component orders, to another market center or market participant as a limit order*:*

(a) for ITS Eligible Listed Securities—equal to the price and no greater than the size of the quote published by the market center or market participant[.]; *and*

(b) for OTC securities—equal to the price of the quote published by the market center or market participant.

The remaining portion of the order, if any, shall be ranked and displayed in the Arca Book in accordance with the terms of such order under Rule 7.36 and such order shall be eligible for execution under Rule 7.37.

(ii)—No change.

(B)—(E)—No change.

* * * * *

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 PCX 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 PCX 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

The Commission recently approved a rule change to PCXE Rule 7.37 that clarified ArcaEx's execution rules related to routing to away markets.[6] Specifically, the rule change amended PCXE Rule 7.37(d)(2)(A) to require that the size of orders routed outside of ArcaEx to another market center or market participant be no greater than the size of the quote published by that away market center or market participant. According to the PCX, this restriction is consistent with Section 6(b)(iii) of the ITS Plan and as a result, the Exchange proposes to clarify that the restriction only applies to ITS Eligible Securities. The Exchange does not believe that PCXE Rule 7.37 should apply to OTC securities as there is no intermarket linkage plan for OTC securities that places restrictions on the size of orders routed to an outside market center or market participant. The Exchange further believes this clarification is necessary in light of the prevalence of reserve orders in the OTC market in which the size available for execution is greater than the displayed quote size. By routing away an order of a size greater than the displayed quote on the outside market, ArcaEx may be able to fill larger orders.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b)[7] of the Act, in general, and further the objectives of Section 6(b)(5),[8] in particular, because it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanisms of a free and open market, and to protect investors and the public interest. In addition, the Exchange believes the proposed rule is consistent with provision of Section 11A(a)(1)(B) of the Act,[9] which states that new data processing and communications techniques create the opportunity for more efficient and effective market operations.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose 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

Written comments were neither solicited nor received 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[10] and Rule 19b–4(f)(6) thereunder[11]. At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate the 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 furtherance of the purposes of the Act.

The Exchange has requested that the Commission waive the 30-day operative

[3] 15 U.S.C. 78s(b)(3)(A)(i).

[4] 17 CFR 204.19b–4(f)(6).

[5] *See* letter from Mai S. Shiver, Director, Regulatory Policy, PCX, to Nancy J. Sanow, Assistant Director, Division of Market Regulation, Commission, dated August 31, 2004. Amendment No. 1 replaced the proposed rule change in its entirety. For purposes of calculating the 60-day abrogation period, the Commission considers the period to commence on September 1, 2004, the date the PCX filed Amendment No. 1.

[6] *See* Securities Exchange Act Release No. 48934 (December 16, 2003), 68 FR 74690 (December 24, 2003) (File No. SR–PCX–2003–54).

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] 9 15 U.S.C. 78k–1(a)(1)(B).

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6).

delay to implement the proposed rule change. The PCX contends that these proposed rules are non-controversial as the Exchange is seeking to clarify its rules to conform to current practices for OTC securities. As a result, the Exchange believes that the proposed rule change does not raise any new regulatory issues, significantly affect the protection of investors or the public interest, or impose any significant burden on competition for the proposed rule change to become immediately operative upon filing. The Commission believes that waiving the 30-day operative period is consistent with the protection of investors and the public interest and, therefore, has determined to allow the proposed rule change to become effective and operative as of the date of the filing with the Commission.[12]

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*);
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–PCX–2004–77 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–PCX–2004–77. 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 Room. Copies of the filing also will be available for inspection and copying at the principal office of the PCX. 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–PCX–2004–77 and should be submitted on or before October 25, 2004.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[13]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E4–2469 Filed 10–1–04; 8:45 am]

BILLING CODE 8010–01–P

[12] For purposes of waiving the operative period date of this proposal only, the Commission has considered the proposed rule's impact on efficiency, competition and capital formation. 15 U.S.C. 78c(f).

[13] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: Notice of reporting requirements submitted for OMB review.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35), agencies are required to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the **Federal Register** notifying the public that the agency has made such a submission.

DATES: Submit comments on or before November 3, 2004. If you intend to comment but cannot prepare comments promptly, please advise the OMB Reviewer and the Agency Clearance Officer before the deadline.

Copies: Request for clearance (OMB 83–1), supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer.

ADDRESSES: Address all comments concerning this notice to: *Agency Clearance Officer,* Jacqueline White, Small Business Administration, 409 3rd Street, SW., 5th Floor, Washington, DC 20416; and *David_Rostker@omb.eop.gov*, fax number 202–395–7285 Office of Information and Regulatory Affairs, Office of Management and Budget.

FOR FURTHER INFORMATION CONTACT: Jacqueline White, Agency Clearance Officer, (202) 205–7044.

SUPPLEMENTARY INFORMATION: *Title:* Notice of Award and Grant/Cooperative Agreement Cost Sharing Proposal.

Form No's: 1222 and 1224.

Frequency: On Occasion.

Description of Respondents: Participating Colleges.

Responses: 2,256.

Annual Burden: 202,080.

Jacqueline K. White,

Chief, Administrative Information Branch.

[FR Doc. 04–22200 Filed 10–1–04; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

Region II Buffalo District Advisory Council; Public Meeting

The U.S. Small Business Administration Region II Advisory Council located in the geographical area of Buffalo, New York, will hold a public meeting at 10 a.m. eastern time on Wednesday, October 20, 2004, at the Buffalo Club, 388 Delaware Avenue, Buffalo, New York, to discuss such matters that may be presented by members, and staff of the U.S. Small Business Administration, or others present. Anyone wishing to make an oral presentation to the Board must contact Franklin J. Sciortino, District Director, in writing by letter or fax no later than Friday, October 15, 2004, in order to be put on the agenda. Franklin J. Sciortino, District Director, U.S. Small Business Administration, 1311 Federal Building, 111 West Hurton Street, Buffalo, NY 14202. Telephone (716) 551–4301 or Fax (716) 551–4418.

Matthew K. Becker,

Committee Management Officer.

[FR Doc. 04–22201 Filed 10–1–04; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

National Environmental Policy Act Procedures

AGENCY: U.S. Small Business Administration (SBA).

ACTION: Notice of proposed change in procedures; notice of extension of comment period.

SUMMARY: SBA published a Notice of a proposed change in procedures on August 6, 2004 seeking comments on its proposed revisions to its procedures implementing the National Environmental Policy Act (NEPA) specifically relating to loans made

under its business loan assistance programs, as well as seeking comments on a proposed assessment of the effects of the Agency's 7(a) business loan program and 504 certified development company program upon the environment. The comment period closes on October 5, 2004. Due to a request from the public for an extension of time for comments and SBA's desire to have a meaningful dialogue on these issues, SBA is extending the time period for comments through December 15, 2004.

DATES: The comment period for the Notice of proposed change in procedures published August 6, 2004 (69 FR 47971) is extended through December 15, 2004.

ADDRESSES: You may submit comments, identified by a reference to "NEPA Procedures Public Comments," by any of the following methods: Through the Federal eRulemaking portal at *http://www.regulations.gov;* by mail to Eric S. Benderson, Associate General Counsel, Office of General Counsel, 7th Floor, U.S. Small Business Administration, 409 Third Street, SW., Washington, DC 20416; by e-mail (include reference to "NEPA Procedures Public Comments" in the subject line) to *eric.benderson@sba.gov;* or via facsimile to (202) 205–7154.

FOR FURTHER INFORMATION CONTACT: Eric S. Benderson, Associate General Counsel (202) 205–6636; *eric.benderson@sba.gov.*

Dated: September 28, 2004.

Ronald E. Bew,

Associate Deputy Administrator.

[FR Doc. 04–22187 Filed 10–1–04; 8:45 am]

BILLING CODE 8025–01–P

SOCIAL SECURITY ADMINISTRATION

Agency Information Collection Activities: Proposed Request and Comment Request

The Social Security Administration (SSA) publishes a list of information collection packages that will require clearance by the Office of Management and Budget (OMB) in compliance with Pub. L. 104–13, the Paperwork Reduction Act of 1995, effective October 1, 1995. The information collection packages that may be included in this Notice are for revisions to OMB-approved information collections and extensions (no change) of OMB-approved information collections.

SSA is soliciting comments on the accuracy of the agency's burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and on ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology. Written comments and recommendations regarding the information collection(s) should be submitted to the OMB Desk Officer and the SSA Reports Clearance Officer. The information can be mailed and/or faxed to the individuals at the addresses and fax numbers listed below:

(OMB), Office of Management and Budget, Attn: Desk Officer for SSA, New Executive Building, Room 10235, 725 17th St., NW., Washington, DC 20503, Fax: 202–395–6974.

(SSA), Social Security Administration, DCFAM, Attn: Reports Clearance Officer, 1338 Annex Building, 6401 Security Blvd., Baltimore, MD 21235, Fax: 410–965–6400.

I. The information collections listed below are pending at SSA and will be submitted to OMB within 60 days from the date of this notice. Therefore, your comments should be submitted to SSA within 60 days from the date of this publication. You can obtain copies of the collection instruments by calling the SSA Reports Clearance Officer at 410–965–0454 or by writing to the address listed above.

1. *Cessation or Continuance of Disability or Blindness Determination—20 CFR 404.1615, 20 CFR 404.1512, and 20 CFR 404.1588–1599—0960–0443.* The information on Form SSA–832-U3/C3 is used by SSA to document determinations as to whether an individual's disability benefits should be terminated or continued on the basis of his/her impairment. The respondents are State Disability Determination Service employees adjudicating Supplemental Security Income (SSI) disability claims.

Type of Request: Extension of an OMB-approved information collection.

Number of Respondents: 392,191.

Frequency of Response: 1.

Average Burden Per Response: 30 minutes.

Estimated Annual Burden: 196,096 hours.

2. *Work Activity Report (Self-Employed Person)—20 CFR 404.1520(b), 20 CFR 1571–.1576, 20 CFR 404.1584–.1593, and 20 CFR 416.971–.976—0960–0598.* The information on Form SSA–820–F4 is used by SSA to determine initial or continuing eligibility for SSI or Social Security disability benefits. Under titles II and XVI of the Act, applicants for disability benefits must prove an inability to perform any kind of Substantial Gainful Activity (SGA) generally available in the national economy for which they might be expected to qualify on the basis of age, education, and work experience. SSA needs to secure information about this work in order to ascertain whether the applicant was (or is) engaging in SGA. Work after a claimant becomes entitled can cause the cessation of disability benefits. The information obtained from form SSA–820–F4 is needed to determine if a cessation of benefits should occur. The respondents are applicants and claimants for SSI or Social Security benefits.

Type of Request: Extension of an OMB-approved information collection.

Number of Respondents: 100,000.

Frequency of Response: 1.

Average Burden Per Response: 30 minutes.

Estimated Annual Burden: 50,000 hours.

3. *Representative Payee Report—20 CFR 404.2035, 20 CFR 404.2065, 20 CFR 416.635, and 20 CFR 416.665—0960–0068.* The information on Forms SSA–623 and SSA–6230 is used by SSA to determine whether payments certified to the representative payee have been used for the beneficiary's current maintenance and personal needs, and to determine whether the representative payee continues to be concerned with the beneficiary's welfare. The respondents are representative payees.

Type of Request: Extension of an OMB-approved information collection.

Number of Respondents: 6,000,000.

Frequency of Response: 1.

Average Burden Per Response: 15 minutes.

Estimated Annual Burden: 1,500,000 hours.

4. *Modified Benefit Formula Questionnaire—0960–0395.* The Social Security Administration uses the information collected by the SSA–150 to determine the correct formula to be used in computing the Social Security benefit for someone who receives a pension from employment not covered by Social Security. The SSA–150 collects the information needed to make all the necessary benefit computations. The respondents are claimants for Social Security benefits who are entitled to both Social Security and a pension not covered by Social Security.

Type of Request: Extension of an OMB-approved information collection.

Number of Respondents: 90,000.

Frequency of Response: 1.

Average Burden Per Response: 8 minutes.

Estimated Average Burden: 12,000 hours.

5. *Modified Benefit Formula Questionnaire-Employer—0960–0477.* The information collected on Form SSA–58 is used by the SSA to verify the

claimant's allegations on Form SSA–150 (OMB No. 0960–0395). SSA must make a determination regarding whether the modified benefit formula is applicable and when to first apply it to a person's benefit. This form will be sent to an employer for pension-related information if the claimant is unable to provide it. The respondents are individuals who are eligible after 1985 for both Social Security benefits and a pension based on work not covered by Social Security.

Type of Request: Extension of an OMB-approved information collection.

Number of Respondents: 30,000.

Frequency of Response: 1.

Average Burden Per Response: 20 minutes.

Estimated Average Burden: 10,000 hours.

6. *Report by Former Representative Payee—20 CFR 404.2060 and 20 CFR 404.2065—0960–0112.* SSA collects the information on Form SSA–625 when a mental facility is terminating its payee services and a successor payee is to be named. The information is needed to determine the proper disposition of any conserved funds. The respondents are State institutions or agencies which are no longer serving as representative payee(s) for beneficiaries who are incapable of managing benefits.

Type of Request: Extension of an OMB-approved information collection.

Number of Respondents: 8,000.

Frequency of Response: 1.

Average Burden Per Response: 15 minutes.

Estimated Average Burden: 2,000 hours.

7. *State Death Match—20 CFR 404.301, 20 CFR 404.310–311, 20 CFR 404.316, 20 CFR 404.330–341, 20 CFR 404.350–352, 20 CFR 404.371, and 20 CFR 416.912—0960–NEW*

Background

Section 205(r) of the Social Security Act requires SSA to contract with the States to obtain death certificate information in order to compare it to SSA's payment files. This match ensures the accuracy of our payment files by detecting unreported or inaccurate deaths of beneficiaries.

Entitlement to retirement, disability, wife's, husband's or parent's benefits under the provisions of the Social Security Act terminates when the beneficiary dies. About 2.5 million people die in the United States each year. Approximately 2.0 million are SSA beneficiaries. Therefore, the information is instrumental in maintaining payment integrity.

SSA is seeking clearance of both the current state death match reporting process and the new Web-based Electronic Death Registration (EDR) process described below:

State Death Match—Current Process

The first participants in the death registration process, usually funeral directors, are charged by State law to complete the demographic information on the decedent and obtain necessary physicians' signatures to complete the death registration. Once the death registration information is completed, the first participant sends the information to the State's bureaus of vital statistics (SBVS). The SBVS officially registers the death and is the official keeper of the death record. Each State then furnishes this information to SSA, using current technology including Vital Information Systems Network (VISN), electronic Vital Information Systems Network (eVISN), and ConnectDirect. Under this process SSA must independently verify the State death data before taking a termination action. The respondents are the SBVS.

State Death Match— EDR Online Verification of the Social Security Number in State Death Registration Process

The States are now updating and further automating the death registration processes. This State reengineering effort is widely known as the Electronic Death Registration (EDR) initiative. The EDR system permits electronic transfer of the death certificate. Under EDR the first participant completes a portion and electronically sends the document to the next participant for completion and submission to the BVS.

An additional feature of EDR is the Online Verification System (OVS) developed by the National Association for Public Health Statistics and Information System (NAPHSIS) in conjunction with SSA. The process allows the first participants in the death registration process to enter the decedent's demographic information including the social security number (SSN) into the EDR system. The system will verify the SSN online in real time and creates an electronic death certificate as well as a fact of death report. The States have agreed that the on-line verification of the SSN at the first point of collection in the registration process will satisfy the requirement to independently verify the SSN.

EDR reduces the processing time needed to register deaths and greatly improves the business practices of the various participants in death registration process. EDR will result in the State's ability to send SSA the report with a verified SSN within 5 days of the date of death and within 24 hours of receipt in the State repository. SSA is using a phased-in approach to EDR. When fully implemented, SSA will save significant program dollars and work years annually. The respondents are the SBVS.

Type of Request: New information collection.

Estimated Annual Cost for all respondents:

Collection format	Number of respondents	Frequency of responses	Average cost per record request	Estimated annual cost burden
State death match—current registration process.	52	50,000 per state	.67	$1,742,000
State death match—electronic death registration (EDR).	3	50,000 per state	$2.48	$372,000

** Please note that both of these data matching processes are entirely electronic and there is no hourly burden for the respondent to provide this information.

II. The information collection listed below has been submitted to OMB for clearance.

Your comments on the information collection would be most useful if received by OMB and SSA within 30 days from the date of this publication. You can obtain a copy of the OMB clearance package by calling the SSA Reports Clearance Officer at 410–965–0454, or by writing to the address listed above.

Request for Waiver of Special Veterans Benefits (SVB) Overpayment Recovery or Change in Repayment Rate—0960—NEW

Background

Section 251 of the Foster Care Independence Act of 1999, Pub. L. 106–169, added Title VIII (Special Benefits for Certain World War II veterans) to the Social Security Act. Title VIII allows for the payments of monthly benefits to qualified World War II veterans who reside outside the United States. When an overpayment in SVB occurs, the beneficiary can request a waiver of recovery of the overpayment or a change in the overpayment rate.

The Information Collection

Form SSA–2032–BK will be used by SSA to obtain the information necessary to determine whether the provisions of the Act regarding waiver of recovery of the overpayment are met. The information on the form is needed to determine a repayment rate if repayment cannot be waived. The information will be collected by personnel in SSA field offices, U.S. Embassies or consulates, or the Veterans Affairs Regional Office in the Philippines. Respondents to the SSA–2032 are beneficiaries who have overpayments on their Title VIII record and wish to file a claim for waiver of recovery or change in repayment rate.

Type of Request: New Information Collection.

Number of Respondents: 39.

Frequency of Response: 1.

Average Burden Per Response: 120 minutes.

Estimated Annual Burden: 78 hours.

Dated: September 28, 2004.

Elizabeth A. Davidson,

Reports Clearance Officer, Social Security Administration.

[FR Doc. 04–22219 Filed 10–1–04; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF STATE

[Public Notice 4849]

Notice of Finding of No Significant Impact and Summary Environmental Assessment: Express Pipeline in Montana and Wyoming

AGENCY: Department of State, Office of International Energy and Commodities Policy.

ACTION: Notice.

The proposed action is to issue a Presidential Permit to Express Pipeline LLC ("Express") to authorize it to construct, connect, operate and maintain six new pump stations for an existing 24-inch outer diameter pipeline to convey crude petroleum from Hardisty, Alberta in Canada, to Casper, Wyoming. The Department of State (the "Department") issued a Presidential Permit on August 30, 1996 to construct, connect, operate, and maintain the 24-inch-diameter buried steel pipeline that is currently capable of transporting 172,000 bpd of petroleum from Hardisty, Alberta, Canada to Casper, Wyoming. On behalf of Express, Westech Environmental Services of Helena, Montana, prepared a draft environmental assessment ("EA") for the proposed action under the guidance and supervision of the Department. The Department placed a notice in the **Federal Register** (69 FR 33691 (June 16, 2004)) regarding the availability for inspection of the Express permit application and the draft environmental assessment, and initiating a 30-day public comment period. No public comments were submitted on the draft environmental assessment.

Numerous Federal and State agencies independently reviewed the Express Permit application and the draft environmental assessment. They include: the Environmental Protection Agency, the Department of Transportation, the Department of the Interior, the U.S. Fish and Wildlife Service, the U.S. Department of Homeland Security, the Department of Defense, the Department of Commerce and the Department of Energy.

Comments received from the Federal and State agencies were either responded to directly, or addressed directly by incorporation into the analysis contained in the draft environmental assessment. In addition to inclusion in the analyses of impacts and risks, Federal and State agency comments were used to develop measures to be undertaken by Express to prevent or mitigate potentially adverse environmental impacts, which were included as commitments by Express and its operator Terasen Pipelines, Inc., in the EA and are to be included in the permit to be issued.

The summary environmental assessment, comments submitted by the Federal and State agencies, responses to those comments, and the draft environmental assessment, as amended, together constitute the Final Environmental Assessment of the proposed action.

Introduction

The Express Pipeline is a 24-inch-diameter buried steel pipeline currently capable of transporting approximately 172,000 bpd of petroleum from Hardisty, Alberta, Canada to Casper, Wyoming. The U.S. portion of the Express Pipeline was authorized by a Presidential Permit issued by the Department on August 30, 1996 which permitted the operation of five pump stations, several mainline valves and other pipeline related facilities on the basis of an environmental impact statement that is an annex to this environmental assessment. The Express Pipeline was constructed in the fall and winter of 1996–1997, and became operational in early 1997.

The 1996 Presidential Permit was issued to Express Pipeline partnership, a Delaware partnership. On August 1, 2001, Express Pipeline partnership filed a certificate of conversion to a limited liability company with the Delaware Secretary of State, thereby automatically converting to a domestic limited liability company, Express Pipeline LLC. On January 9, 2003, Encana Corporation of British Columbia sold Express Pipeline LLC to a consortium comprised of Terasen, Inc., of British Columbia, the Ontario Municipal Employees Retirement System and the Ontario Teachers Pension Plan Board, each holding an equal one-third interest. Terasen Pipelines (USA) Inc., ("Terasen") operates and maintains the existing system on behalf of Express Pipeline LLC.

Express Pipeline LLC ("Express") owns the portion of the Express Pipeline system from the Canada/U.S. border to Casper, Wyoming. Express is now applying for a Presidential Permit from the U.S. Department of State to construct, operate and maintain six additional pump stations on the Express Pipeline in Montana and Wyoming and to transfer the existing Presidential Permit from Express Pipeline partnership to Express (the "Proposed Action"). This expansion of the capacity of the Express Pipeline in the United States would enable Express to respond to the market demand of Rocky Mountain and Midwest refiners for

increased access to a wider diversity and additional supply of Canadian petroleum.

Subsequent engineering and operational analysis demonstrated that, in conjunction with the Proposed Action, two new 150,000 barrel storage tanks would be needed at the existing Casper Station Tank Farm located in Casper, Wyoming to accommodate the additional volumes of petroleum. The Casper Station Tank Farm is owned by Platte Pipe Line Company ("Platte"), an affiliate of Express. Because, according to Express, these storage tanks would be located beyond the terminus of the Express Pipeline system (*i.e.*, they would be part of the Platte Pipeline system), they were not included within the scope of Express' proposal for which it seeks a Presidential Permit from the Department. After thoroughly considering all factors, the Department has concluded that the two additional storage tanks at the Casper Station Tank Farm are not within the scope of the Proposed Action and therefore will not be subject to the Presidential Permit, once issued. The environmental consequences of construction, operation and maintenance of the two storage tanks are evaluated in conjunction with the Proposed Action, however.

Purpose and Need

The Express Pipeline was constructed to meet the requirements of refiners in the U.S., particularly in the Rocky Mountain and Midwest regions, by providing new sources of Canadian petroleum to numerous markets including Montana, Wyoming, Utah, Colorado, Kansas and Illinois. The Express Pipeline system is consistently operating at or near its maximum capacity in its current configuration. Market demand for additional Canadian petroleum supplies continues to grow. The Express Pipeline cannot meet the increased demand in its current configuration. The construction of additional pump stations along the existing, permitted Express Pipeline right-of-way ("ROW"), along with construction of two new storage tanks at the Casper Station Tank Farm, would result in the expansion of capacity necessary to enable Express Pipeline to transport additional petroleum to these markets. Without greater supply diversity and reliability of access to additional supply, the potential that the consumer will enjoy the availability of more competitively priced refined products could be substantially reduced and the refiners' ability to comply with more rigorous refined product specifications could be hindered.

Project Background

The increased demand for Canadian petroleum was anticipated at the time the Express Pipeline was originally proposed in 1993. The entire Express Pipeline system from Hardisty, Alberta to Casper, Wyoming was originally designed for an ultimate capacity of approximately 280,000 barrels per day ("bpd"), depending on the characteristics of the petroleum being transported. Accordingly, the original design of the Express Pipeline system called for 11 pump stations to be located in the United States.

Although the Express Pipeline system was designed for an ultimate capacity of approximately 280,000 bpd, it was originally constructed to transport approximately 172,000 bpd, in response to the anticipated market demand in 1996. Consequently, only five of the 11 pump stations planned for location in the U.S. were needed when the pipeline was constructed.

Mainline valves were installed at the locations of the six remaining pump stations in order to allow the future addition of the remaining pump stations without requiring substantial alteration or reconstruction of the pipeline itself.

To maintain the hydraulic efficiency of the pipeline system as currently designed, the remaining six pump stations in the U.S. would need to be placed at the locations originally planned. Three of the six new pump stations will be located on public land administered by the U.S. Department of the Interior, Bureau of Land Management ("BLM"). The BLM evaluated the environmental consequences of constructing and operating pipeline facilities in the Express Crude Oil Draft Environmental Impact Statement. Since environmental conditions at the three BLM-administered sites have not materially changed from those reflected in the DEIS, BLM issued a "Notice to Proceed" with construction of these pump stations on October 14, 2003.

The three pump stations on non-federal land would all be constructed within the certified 500-foot-wide Express Pipeline corridor. Express owns or has obtained easements on the land at these three proposed pump stations. The general discussion of impacts and mitigation measures for the pump stations on non-federal land set forth below would also be relevant to the pump stations on Federal land.

Description of Alternatives

Alternatives Considered but Eliminated From Further Analysis

Three action alternatives were considered but eliminated from further analysis for the reasons discussed below.

(1) Looping the Express Pipeline

"Looping" allows an existing pipeline system to expand its capacity by constructing a second, generally parallel pipeline alongside the existing pipeline. Looping is utilized when the existing pipeline does not have the potential capacity to transport additional petroleum. The two pipelines could be located in the same ROW, although they would be offset far enough so that construction activities on the second pipeline would not disturb the existing pipeline. The two pipelines may share certain facilities, such as an operations center.

Looping is a major construction activity that has the potential for environmental impacts equal to those encountered during construction of the original pipeline. For example, if the Express Pipeline was looped only along the U.S. portion of the pipeline, approximately 515 miles of new pipeline along with pump stations, mainline valves and other facilities would have to be constructed. The pipeline would have to cross 137 named perennial, intermittent or ephemeral rivers and streams, as well as 354 named or unnamed drainages, irrigations canals or ditches. There could be potential impacts to land use activities along the pipeline, to wildlife and fisheries habitat (including endangered or threatened species), to soils and cultural resources, as well as socioeconomic burdens on the existing infrastructure, such as temporary housing and road systems. Looping would require a minimum of two years to design the new pipeline and facilities, conduct a thorough environmental impact analysis, obtain construction easements and other permits, acquire the pipe and other materials, hire pipeline contractors, construct the pipeline and rehabilitate disturbed areas after construction.

In the case of the Express Pipeline, looping would not be necessary because the Express Pipeline system was conceived and designed for an ultimate capacity of approximately 280,000 bpd, assuming 18 pump stations in Canada and the U.S. In other words, the Express Pipeline system could be expanded simply by adding nine pump stations (three in Canada and six in the U.S.) at sites where mainline valves were placed

during construction of the original pipeline. The potential environmental impacts associated with constructing an entire pipeline would be avoided, and additional petroleum supplies could reach U.S. refiners within a few months, rather than a minimum of two years. Consequently, looping was eliminated as a possible alternative from further analysis.

(2) A New Pipeline on an Alternative Route

The Express Pipeline system transports petroleum from Hardisty, Alberta, Canada to Casper, Wyoming, crossing the Canada/U.S. border near the Port of Wild Horse. As part of the pre-construction environmental impact analysis for the Express Pipeline, the Express Crude Oil Draft Environmental Impact Statement evaluated three alternative points of entry into the U.S.: one located approximately 120 miles west of Wild Horse, and the other two located approximately 65 and 120 miles east of Wild Horse respectively. The Express Crude Oil Draft Environmental Impact Statement concluded that these alternative routes would add additional length and cost to the Express Pipeline system without providing any environmental or engineering benefits.

These same three entry points are still potentially available for an alternative pipeline route. However, use of any of these entry points would require construction of a new pipeline on the Canada portion of the Express Pipeline system as well as a new pipeline on the U.S. portion (in effect, construction of an entirely new Express Pipeline system). Any such pipeline system would be longer than the existing pipeline, would require substantial engineering and environmental study and design in both Canada and the U.S. that would delay construction of the project for several years, and (as stated in the Express Crude Oil Draft Environmental Impact Statement) would not provide any environmental or engineering benefits on the U.S. portion of the project. In addition, as discussed previously, a new pipeline would not be necessary to obtain the additional petroleum supplies for U.S. refiners, since the existing Express Pipeline system could provide those supplies by the simple addition of nine pump stations (three in Canada and six in the U.S.). Therefore, a new pipeline on an alternative route was also eliminated as an alternative from further analysis.

(3) Alternative Pump Station Locations

The original Express Pipeline was designed for an ultimate capacity of approximately 280,000 bpd, which would require a total of 18 pump stations in Canada and the U.S. The location of each of the 18 pump stations was selected when the Express Pipeline was originally designed to minimize environmental impact and maximize both the capacity and efficiency of the system. To achieve the initial capacity of approximately 172,000 bpd, nine of the 18 pump stations were constructed in 1996, four pump stations in Canada and five pump stations in the United States. To maintain the hydraulic efficiency of the pipeline system as it was originally designed, the remaining nine pump stations (three in Canada, six in the U.S.) must be placed at the intervals as originally planned.

The proposed pump station sites addressed in the Proposed Action were selected not only for their hydraulic efficiency but to minimize environmental impacts. The pump stations locations were deliberately selected to avoid impacts to the following land uses:

- National Wilderness Area
- National Primitive Area
- Designated or Undesignated Roadless Areas Greater Than 5,000 Acres
- National Wild and Scenic Rivers ("WSR")
- Rivers Under Study for the WSR System
- National Wildlife Refuges or Ranges
- National or State Recreation Areas
- National Trails
- National Historic Landmarks/National Register Historic Districts or Sites
- State Historic Preservation Office ("SHPO") Historic Districts or Sites
- Designated Habitat for Federally Listed, Proposed or Candidate Endangered or Threatened Species
- Habitats Occupied Seasonally by Federally Listed, Proposed or Candidate Endangered or Threatened Species
- Habitats Critical to Species of Special Interest or Concern
- Unique Habitats or Natural Areas
- Wetlands
- Federal or State Waterfowl Production Areas
- Areas With High Waterfowl Density
- State Game Ranges and Game Management Areas
- Big Game Winter Ranges
- Big Game Summer Security Areas
- Grouse Leks or Severe Winter Concentration Areas
- Bird Nesting Colonies
- Riparian Forests
- Conservation Easements
- Sites Funded by the Land and Water Conservation Fund or Urban Park and Recreation Recovery Programs
- Water Bodies Larger Than 20 Acres
- Municipal Watersheds
- Surface Supplies of Potable Waters
- Active Faults Showing Evidence of Post-Micoene Movement
- Rugged Topography With Slopes Greater Than 15%
- Erodible Soils, Areas with Severe Reclamation Constraints
- Undeveloped Natural Features
- Avalanche Chutes
- Permitted Surface Mining Areas
- Geological Formations with High Probability of Paleontological Resources
- Sites of Religious or Heritage Significance to Native Americans
- Schools or Future School Sites
- Agricultural Experiment Stations
- Prime or Unique Farmland and Orchards
- Scenic Overlooks and Scenic Highways
- Areas of Conflict with Published Visual Management Plans
- Limited Access Areas

Because of the placement of the existing pump stations, any change in the locations of the proposed pump stations would interfere with the hydraulics and performance of the entire pipeline system. Changing the locations of the proposed pump stations would not provide any engineering or environmental benefits. Consequently, use of alternative pump station locations were eliminated as an alternative from further analysis.

In sum, there do not appear to be any alternatives other than the Proposed Action and a No Action alternative. The design of the pump stations as described in the Proposed Action represents the most efficient use of the available site lands and minimizes environmental impacts associated with construction, operation and maintenance of the pump stations. Other alternatives that would increase pipeline capacity are less desirable from an environmental standpoint. Putting the six pump stations at new locations would entail much more invasive construction than that required at the locations already identified and moving the pipeline would be even more environmentally disruptive. Accordingly, there are no other alternatives that would meet the requirements of the Proposed Action and therefore this EA considers only the Proposed Action and a No Action alternative.

Proposed Action

The physical design of the pump station facilities would be similar to the originally constructed stations, although the footprint of the new pump stations would be smaller than that of the

existing pump stations. Each proposed pump station would require about 5.74 acres of land during construction, while the post-construction area of each pump station would be about 1.24 acres. Each site has previously been entirely or partially disturbed by agricultural activities and the construction of the Express Pipeline.

The stations would be constructed adjacent to existing mainline valves, in fenced and graveled station yards. Electrical supply lines and substations would provide the power required for the pump stations and would be permitted, constructed and maintained by local electrical utility companies.

Each pump station would have two 5,000 horsepower electric motor-driven pumps located above ground on concrete pads, and coated at the factory with protective paint to prevent corrosion. Each pump would have a pump seal. Additional equipment at each station would include piping, a double-walled sump tank, electrical controls, process instrumentation, data collection and communication equipment. An electrical building would be constructed at each pump station to house electrical equipment including switchgear, motor controls and Supervisory Control and Data Acquisition ("SCADA") equipment. Each of the proposed pump stations would be equipped with a SCADA system to control and monitor the station. A satellite dish would be installed to maintain the communication link with the Edmonton Control Center. Collected data would be relayed to the Control Center in Edmonton, Alberta where Control Center Operators monitor the status of the stations and pipeline. The Edmonton Control Center is a 24-hour staffed facility, and has full control of all the station equipment including the capability to start and stop station pumps, and close and open station valves.

Express and Terasen have agreed to test each pump station hydrostatically to ensure system integrity prior to operation. The pump stations would be maintained and operated in accordance with the standards set forth in the General Operations Management Plan that are applicable to the existing stations. All manuals, including the Express/Platte Emergency Response Plan ("ERP") required by the U.S. Department of Transportation ("U.S. DOT"), would be updated to reflect the addition of these proposed stations.

In addition, the storage tanks would be constructed at the Casper Station Tank Farm. Other possible locations outside the Casper Tank Farm boundary would reduce the efficiency of the transfer of petroleum from the Express Pipeline system to the Platte Pipeline system because it would lengthen the distance to the refineries as well as increase costs and opportunities for system failure. In addition, locating the storage tanks within the Casper Tank Farm, which has been disturbed by past and on-going activities with the existing tanks, would minimize potential environmental impacts from construction and operation of the tanks while allowing quick response from Terasen personnel and equipment in the event of an emergency.

The project facilities would consist of two 150,000-barrel storage tanks, leak detection system, spill-containment dikes, impervious liners, piping, control valves, manifold piping and site lighting. Electrical service would be provided by an extension from the distribution center in Platte's station yard, or from an adjacent transmission line. Other facilities such as an access road, control and quality assurance buildings and satellite dish are already in place in the Casper Station Tank Farm. A secure 6-foot chain link fence surrounds the entire complex.

Like the pump stations, Express and Terasen have agreed to hydrostatically test the storage tank facilities prior to operation to ensure system integrity. According to Express and Terasen, the new storage tanks would be operated in accordance with appropriate manuals and procedures for the Casper Station Tank Farm. Further they state that all manuals, including the Express/Platte ERP required by the U.S. DOT, would be updated to reflect the addition of these additional storage tanks.

No Action Alternative

The No Action Alternative would mean that the additional pump stations and storage tanks would not be constructed. There would be no additional environmental impacts under the No Action alternative. However, there would be no beneficial economic effects because the pipeline capacity would remain unchanged.

Environmental Impacts and Mitigation Measures

Proposed Action

Construction and normal operation of the Proposed Action would have beneficial economic impacts. Temporary socioeconomic benefits would flow to the local economy during the construction period and would result in a temporary increase in local personal income. Local motels, restaurants, retail outlets and recreation providers would be the primary recipients of these benefits.

Over the long-term, the state of Montana and respective counties would receive additional tax benefits as a result of the ad valorem tax that would be assessed on the three proposed stations on private land. It is estimated that the ad valorem tax would be approximately $225,000 per station per year.

The construction of the proposed pump stations would increase the throughput capacity of the Express Pipeline, increasing the pipeline's ability to deliver high quality Canadian petroleum to refiners in PADD II and PADD IV including Montana, Wyoming, Utah, Colorado, Kansas and Illinois. This would enable these refiners to access additional quantities of specialized petroleum, enhancing their ability to meet increasingly stringent refined product quality requirements. The Proposed Action would also provide the refiners access to an increased number of potential suppliers, and potentially longer-term supply sources at tolls that would be competitive with alternative routes.

Based on the draft environmental assessment prepared by Westech Environmental Services on behalf of Express, normal operation of the Proposed Action would have no significant adverse impacts on climate, air quality noise, geology, wetlands and riparian areas, navigable waters, floodplains, plant species of special concern/sensitive communities, noxious weeds, threatened or endangered species, land use, transportation, socioeconomics, population and housing, recreation, and cultural and paleontological resources. This document lays out the minimal impacts that have been identified in the environmental assessment.

Water Resources: There may be short-term impacts from construction of the Proposed Action to water resources as a result of runoff and sedimentation during construction or hydrostatic testing. Express and Terasen have agreed to undertake the following measures to mitigate impacts to surface water for the proposed pump stations:

- During construction, drainage control structures (ditches, ponds, sediment fence) would be designed, built and maintained to transport surface runoff from the affected area but prevent discharge to drainages or areas outside the 5.74-acre site.
- A detailed hydrostatic test plan would be prepared before mechanical construction of the pump stations would begin.

• Any necessary permits or approvals would be obtained prior to hydrostatic testing.

Soil: There could be impacts to soil resources during the construction phase as a result of salvage and storage, clearing and grading, compaction, and wind or water erosion. Express and Terasen have agreed to undertake the following measures to mitigate impacts to upland soil resources for pump stations:

• During construction, drainage control structures (ditches, ponds, sediment fence) would be designed, built and maintained to transport surface runoff off the affected area but to prevent discharge to drainages or areas outside the 5.74-acre site.

• With the potential exception of the proposed Faulkners Coulee pump station, salvaged topsoil would be spread to blend with the landforms on undisturbed portions of the site.

• At the proposed Faulkners Coulee pump station, it may be necessary to retain a small topsoil stockpile for the life of the project, due to the active cultivation of portions of the site that would make it difficult to maintain (and eventually salvage) a uniform soil depth. Unless otherwise requested by the landowner, the topsoil would be seeded in the first appropriate season with "Sodar" streambank wheatgrass.

Vegetation: Because soils would be disturbed, there could be impacts to upland vegetation as a result of construction of the Proposed Action. Express and Terasen have agreed to undertake the following measures to mitigate any impacts to vegetation resources for the Proposed Action:

• After construction is completed, temporary workspace and other portions of the affected area where long-term disturbance is not required would be rehabilitated using the topsoil spreading and revegetation mixtures recommended in the applicable discussion for each pump station in the EA.

• Ultimate reclamation of the three pump stations would be addressed in the abandonment plan.

• Noxious weeds at each station would be monitored and controlled.

Wildlife and Fisheries: Similarly, there could be impacts to wildlife and fisheries from surface runoff, as a result of surface disturbance during construction, and from normal operation of the Proposed Action. Express and Terasen have agreed to undertake the following measures to mitigate impacts to wildlife and fisheries from the Proposed Action:

• Implement the surface runoff control mitigation measures recommended above to reduce the potential for surface runoff and sedimentation to reach drainages.

• Any transmission line poles erected on the site would provide raptor protection in accordance with Suggested Practices for Raptor Protection on Power Lines: the State of the Art in 1996 (APLIC 1996).

Visual Resources: The Proposed Action could impair or detract from the scenery surrounding the pipeline as a result of vegetation removal, grading and site development, the presence of construction workers and equipment, and the long-term presence of small buildings, the pumps and other facilities. Express and Terasen have agreed to undertake the following measures to mitigate impacts to visual resources from the Proposed Action:

• Facilities would be painted similar to the paint scheme used at the existing pump stations.

• As soon as practicable after construction, temporary workspace that is not needed for the life of the project would be revegetated.

Environmental Justice: Executive Order 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, provides that each Federal agency must identify and address, as appropriate, effects of its activities on minority populations and low-income populations. The Proposed Action would be located in rural areas of comparatively low population density. No residences are located less than 0.25 mile from any proposed pump station. There are no population centers at or proximal to the Proposed Action, and none are proposed for development. Consequently, it is not anticipated that the Proposed Action would have any significant adverse human health or environmental effects on any minority or low-income populations.

Historical and Cultural Resources: Pre-construction field surveys for cultural and paleontological resources along the 500-foot-wide permitted Express Pipeline route discovered no such resources at any of the Proposed Action locations. No historic, archaeological, architectural and/or traditional cultural properties on or eligible for inclusion on the National Register of Historic Places were found. No paleontological resources were documented. The proposed pump station sites are comprised of land that is or has been cultivated, and no undisturbed surface cultural or paleontological resources would be expected at any of the sites. In addition, all proposed pump station sites were previously affected by construction of the Express Pipeline. Because no cultural or paleontological resources are known to be present at any of the proposed pump stations, there would be no known significant impacts from construction and operation of the proposed pump stations on these resources. Any cultural or paleontological resources found during the construction of the proposed pump stations would be addressed in accordance with protocols established for the existing Express Pipeline.

Pipeline Safety and Reliability: The potential for an operational petroleum release from the Express Pipeline throughout its life would be very low. Because the pipeline and its facilities were designed for the ultimate capacity of approximately 280,000 bpd, it was constructed to accommodate the change in pressure profile that would be needed to transport that capacity, which is the Proposed Action. The SCADA system and its accompanying leak detection system were also designed for the ultimate capacity of about 280,000 bpd. Consequently, the addition of the six pump stations covered by this Proposed Action would not require any material changes in the overall design, engineering, or operational procedures currently employed by the Express Pipeline. None of the proposed additional pump stations is located in a "High Consequence Area" as defined by 49 CFR 195.450. Therefore the addition of the Proposed Action to the Express Pipeline system would not result in an increase in the pipeline integrity-related potential for an accidental petroleum release, compared to the existing conditions.

The potential for a petroleum release during normal operations would be driven by the age of the pipeline rather than its operating capacity. The Express Crude Oil Draft Environmental Impact Statement presented a risk analysis for petroleum release in or near riverbeds, based on pipeline industry statistics. That analysis concluded that, over a potential 25-year life of the project, two releases of 50 barrels or less and one release of over 50 barrels could statistically occur. If the life of the project were extended an additional 25 years (*i.e.*, a total of 50 years), there would be a statistical potential for nine more releases of less than 50 barrels and two releases of over 50 barrels. Since the Express Pipeline was placed in service in 1997, there has been only one release that occurred in 2003 when a backhoe excavating at a block valve hit a valve fitting. The entire release (approximately 70 barrels) was contained on site.

The statistical potential for a major release (*i.e.*, greater than 500 barrels) during the first 25 years of the Express Pipeline was calculated to be 0.31, and 0.62 during the second 25 years. This release potential would not be expected to change regardless of the operating capacity of the pipeline, because the maximum release in the event of a major rupture is comprised of the *volume* lost before the leak is recognized and the valves are closed, plus the volume that *drains down* due to topography. The *volume* lost prior to shut down is related to the amount of flow (*i.e.*, 280,000 bpd vs. 172,000 bpd), but this is small in relation to the amount of peak *drain down*, which is generally not affected by throughput (*i.e.*, amount of flow).

For example, a 15-minute recognition and shut down time of a major rupture of the Express Pipeline at 280,000 bpd (release volumes were calculated in accordance with 49 CFR 194.105(b)(1)), would result in a *volume* release of 2,917 barrels, which could be up to 1,125 barrels greater than would be expected under the current capacity.

In comparison, *drain down* volumes following shut down would vary as a function of topography, rather than throughput, and so would not be significantly increased by the Proposed Action (as compared to current capacity). Peak *drain down* volumes for the Express Pipeline would be in the order of 30,000 to 50,000 barrels, far greater than the volume lost as a result of the increased flow in the pipeline system.

Terasen has an Integrity Management Program, developed as a result of the requirements of 49 CFR 195.452. When constructed, the Express Pipeline employed "state-of-the-art" technology, including the most recent SCADA and leak detection systems.

The sensitivity of leak detection is a function of the uncertainty in the flow rate of fluid entering and delivered from the pipeline system, and the uncertainty in the line pack within the pipeline. These uncertainties are dependent on a number of parameters including instrumentation accuracy and repeatability, fluid properties and SCADA system characteristics. The proposed Action would not fundamentally change the type or level of instrumentation, the fluids being transported or the SCADA system. Therefore the leak detection system would continue to operate at the same sensitivity, as a percentage of flow rate, at the ultimate capacity of approximately 280,000 bpd as it does at the current rate of 172,000 bpd.

Upon regulatory approval of the Proposed Action, as required by the U.S. DOT, Terasen would update the Express/Platte ERP to consider the worst-case scenario based on the throughput under the Proposed Action. Although the worst-case scenario would not likely represent a "real world" occurrence, Terasen's response planning is based on this scenario. For example, additional manpower and spill response equipment might be needed as a result of these calculations; if so, Terasen would obtain these resources through local contractors and the Montana-Wyoming Spill Cooperative.

As discussed in the Express Crude Oil Draft Environmental Impact Statement, in the event of a release anywhere on the Express Pipeline, the magnitude and duration of environmental damage would be influenced by a number of factors. The kind, magnitude and duration of these effects would not be expected to materially change under the Proposed Action, although the released volume could be greater in some locations and smaller in others.

The U.S. Department of Transportation ("DOT") regulates all aspects of pipeline design, construction, operations, maintenance and emergency and spill response. Pipeline safety regulations are designed to protect the public, environmentally sensitive areas, cultural resources and economic resources. Emergency and spill response planning regulations require the identification of environmentally important areas, and require that operators have response capabilities in place to minimize a pipeline release and the impact of such a release on the environment, the public and other resources.

In the event of a release, the Federal regulatory programs define the notification requirements and required response actions. These programs include: The National Oil and Hazardous Substances Pollution Contingency Plan (NCP: 40 CFR part 300); the Clean Water Act; the Oil Pollution Act; and the Superfund Amendment and Reauthorization Act. U.S. DOT NEPA regulations allow for coordinated implementation of these federal requirements. The U.S. DOT requires Terasen to develop, maintain and update an approved ERP. The ERP defines notification and initiation of response actions in a timeframe and on a scale appropriate to the extent of the release. The ERP establishes a required endpoint for response actions, that being the mitigation of any unacceptable threat to human health or the environment. The ERP includes a mechanism for providing compensation for short- or long-term damages to any natural resources and for restoration costs. The cumulative result of these regulatory constraints is that the adverse impacts of a release will be temporary and that baseline conditions will be restored.

In summary, although the throughput of the Express Pipeline system would be greater under the Proposed Action than under the currently certificated capacity, the kind, magnitude, duration and result of environmental impacts are not expected to be significant under the Proposed Action because:

(1) The range of these impacts was identified and discussed in the Express Crude Oil Draft Environmental Impact Statement and would not be expected to change as a result of the Proposed Action;

(2) The Express Pipeline was designed and constructed to operate at the volumes contemplated by the Proposed Action, and can safely accommodate these volumes;

(3) The petroleum release detection system currently in place on the Express Pipeline would continue to work at the same efficiency as at the current certificated volume, and continues to be "state-of-the-art" technology; and

(4) Procedures for design, construction, operation and maintenance of the Express and Platte Pipeline systems are covered by a variety of Federal regulations under the oversight of the U.S.DOT. The ERP required by the U.S. DOT mandates the mechanisms of Terasen's response to a petroleum release and would be updated to reflect the pipeline capacities under the Proposed Action.

Accidental release of petroleum at any of the proposed pump stations would not affect most environmental disciplines. The disciplines most likely to be affected would be surface water, groundwater, wildlife and fish. The following measures are proposed to minimize the potential impacts as a result of a petroleum spill:

- Sump tanks will be constructed to incorporate a double wall with integrity monitoring instrumentation, to enable Terasen to know of any leak in either sump tank wall.
- In accordance with U.S. DOT requirements, Terasen has developed an ERP that is updated as necessary. In accordance with the ERP, sufficient petroleum spill response equipment and other resources, such as contractors and equipment, are provided to respond to any emergency along the Express pipeline within a specified timeframe. Therefore response times in the event of major petroleum spill at any of the

action alternative sites would be approximately two hours.

• In the event of a petroleum release, Terasen is committed to remediating impacted areas so that vegetation can be reestablished. Implementing the ERP and reestablishing vegetation will remediate impacts to surface water, groundwater, fish and wildlife.

As noted above, implementation of the Proposed Action would require the construction and normal operation of the two storage tanks at the Casper Station Tank Farm. Construction and operation of the storage tanks would contribute to the local and State (Wyoming) economic benefits described above.

Based on the draft environmental assessment prepared by Westech Environmental Services on behalf of Express, construction and normal operation of the storage tanks would have no significant adverse environmental impacts on climate, air quality noise, geology, wetlands and riparian areas, navigable waters, floodplains, plant species of special concern/sensitive communities, noxious weeds, threatened or endangered species, land use, transportation, socioeconomics, population and housing, recreation, and cultural and paleontological resources, given that they are additions to an existing tank farm.

Construction and operation of the storage tanks could affect surface water as a result of runoff and sedimentation during construction or hydrostatic testing. Express and Terasen have agreed to undertake the following measures to mitigate impacts to surface water from the two storage tanks:

• During construction, drainage control structures (ditches, ponds, sediment fence) would be designed, built and maintained to transport surface runoff from the affected area but prevent discharge to drainages or areas outside the Casper Station Tank Farm.

• Terasen would prepare a detailed hydrostatic test plan before mechanical construction of the storage tanks and piping would begin.

• Terasen would obtain any necessary permits or approvals prior to hydrostatic testing.

Groundwater at the Casper Station Tank Farm consists of shallow, fractured aquifers that could be affected by construction of the proposed storage tanks. Express and Terasen have agreed to undertake the following measures to mitigate impacts to groundwater at the storage tank site:

• An impervious liner would be installed beneath the storage tanks and berm.

• A leak detection system would be installed below the tanks.

There could be impacts to soil resources at the Casper Station Tank Farm as a result of salvage and storage, clearing and grading, compaction, and wind or water erosion. Express and Terasen have agreed to undertake the following measures to mitigate any such impacts to upland soil resources:

• During construction, drainage control structures (ditches, ponds, sediment fence) would be designed, built and maintained to transport surface runoff off the affected area but to prevent discharge outside the Casper Station Tank Farm.

• After construction, any remaining subsoil would be spread onto the 2–4 acres used for temporary workspace, and the salvaged topsoil would be placed over the subsoil. The topsoil would be seeded with "Ephraim" crested wheatgrass (*Agropyron cristatum*) and Sodar streambank wheatgrass (*Agropyron riparium*) at a rate of eight pounds each pure live seed (PLS) per acre if applied by drill seeding, and 16 pounds each PLS per acre if applied by broadcast seeding. These two perennial cultivars were selected because they are drought-tolerant, readily available, relatively low growing, and have a rhizomatous growth habit that would readily cover and stabilize topsoil. This vegetative cover would reduce fire hazards and maintenance concerns.

• Ultimate reclamation of the proposed storage tank site would be addressed in the abandonment plan to be submitted to the DOT Office of Pipeline Safety at least one year prior to abandonment.

Because soils would be disturbed, there could be impacts to upland vegetation as a result of construction and normal operation of the storage tanks. Express and Terasen have agreed to undertake the following measures to mitigate impacts to vegetation resources:

• After construction is completed, temporary workspace and other portions of the affected area where long-term disturbance is not required would be rehabilitated using the topsoil spreading and revegetation mixtures recommended above.

• Ultimate reclamation of the site would be addressed in the abandonment plan.

• Noxious weeds would be monitored and controlled.

Similarly, there could be impacts from construction and operation of the storage tanks to wildlife and fisheries. Express and Terasen have agreed to undertake the following measures to mitigate these impacts:

• Terasen would implement the surface runoff control mitigation measures recommended above to reduce the potential for surface runoff and sedimentation to reach drainages.

• Wildlife habitat would be considered in the abandonment plan.

• Terasen would prepare a detailed hydrostatic test plan before mechanical construction of the storage tanks and piping would begin.

• Terasen would obtain any necessary permits or approvals prior to hydrostatic testing.

Because the storage tanks would be constructed in the existing Casper Station Tank Farm, they would not detract from the visual impression of the site or surrounding area. However, Express and Terasen have agreed to undertake the following measures to minimize impacts to visual resources from the two storage tanks:

• Facilities would be painted similar to the paint scheme used at the existing Casper Station Tank Farm.

• As soon as practicable after construction, temporary work space that is not needed for the life of the project would be revegetated.

No Action Alternative

If no action were taken, there would be no environmental impacts from the Proposed Action or associated facilities. Any environmental impacts currently occurring at these sites would continue to occur.

Under the No Action Alternative, economic benefits to the U.S. from additional petroleum supplies via the Express Pipeline would not be realized. Economic benefits to the States of Montana and Wyoming from additional taxes, and construction and operation benefits to local power providers and communities, would not materialize.

If the Express Pipeline were not expanded, three potential scenarios would be reasonably foreseeable:

(1) Existing pipelines other than Express would expand by looping or building entirely new pipelines;

(2) Some smaller refineries could be forced to reduce throughput or close if they were unable to access specialized petroleum and maintain the quality of their petroleum via transportation on a batch pipeline system such as Express; and

(3) A refined products pipeline could be built that would serve the Rocky Mountain region thereby causing the closure of smaller refineries because of competing lower-priced refined products from larger refineries.

Under the first scenario, the market responses to the Express Pipeline's inability to deliver additional petroleum

supplies could encourage other pipelines to expand their systems. While no information is available at this time about the location or time frames of any such projects, expansion of these systems could result in more extensive environmental impacts than the Proposed Action because they would require the construction of additional pipelines, while the Proposed Action would not. Specific impacts from these other projects would be speculative, but would have to be identified and analyzed during the regulatory process for these other projects.

Under the second scenario, one or more Rocky Mountain refineries could close. These refineries are currently evaluating their ability to comply with new environmental requirements. To comply they must either invest in facility upgrades or obtain a source of higher quality petroleum that enables them to comply without major capital investment. The Proposed Action would expand access to a wide variety of high quality petroleum supply that complies with the new environmental objectives. The Express Pipeline also transports petroleum on a batched basis, which meets the smaller refiners' need for specialized petroleum. It is possible that one or more of these refineries could close under the No Action alternative.

Under the third scenario, an entirely new refined product pipeline could be constructed from Canada to the United States. The construction of an entirely new pipeline would likely result in more extensive environmental impacts than the installation of additional pump stations on the existing Express Pipeline. The specific impacts would be speculative and would have to be identified and evaluated during the regulatory process for these other projects.

Cummulative Effects

Cumulative effects are the impacts on the environment that result from an incremental impact of the Proposed Action when added to other past, present and reasonably foreseeable actions. Examples of such actions would include the past construction and operation of the Express Pipeline; other pipelines proposed for construction near the Express Pipeline; upgrades of existing highways in the vicinity of the proposed pump stations; and construction or upgrades of transmission lines in the vicinity of the proposed pump stations.

The Express Pipeline was constructed in 1996 and has been in operation since 1997. The Express Pipeline has provided positive economic benefits to local communities, local power providers, the States of Montana and Wyoming through ad valorem taxes, and improved petroleum supply to Montana refiners. Environmental impacts from construction of the pipeline have been largely mitigated, and there have been no major operational problems with the pipeline.

No other petroleum pipelines are known to be proposed for construction in the vicinity of the Express Pipeline. No substantial upgrades (*i.e.*, not including normal maintenance and resurface operations, which are short-term activities) are scheduled for any of the public highways in the vicinity of the proposed pump stations for the next two years. Thus there would be no conflicts with the Proposed Action in terms of use of temporary housing or short-term population increases. It is assumed that environmental impacts of any new highway construction projects would be addressed by separate analysis documents.

There are no known proposals to construct or upgrade electric transmission lines in the vicinity of the proposed pump stations, except for the transmission lines that would directly supply the proposed pump stations. It is assumed that environmental impacts of any transmission line projects would be addressed by separate analysis documents. If it assumed that the transmission lines that would supply electrical power to the proposed pump stations were constructed in the same time frame as the proposed pump stations, there could be increased short-term socioeconomic benefits to the States of Montana and Wyoming, as well as counties and local communities, but there could also be shortages of temporary housing for construction workers, depending on the number of workers employed for transmission line construction, and the season of construction.

Unavoidable Adverse Impacts

Construction of the Proposed Action would result in some short-term direct and indirect unavoidable impacts. Temporary impacts to wildlife and visual resources during construction could not be avoided. Soil and vegetation would be removed, and agricultural productivity would be lost, on a maximum of 1.24 acres at each proposed pump station over the life of the project, but restored per the mitigation measures described here-in. All such impacts would be mitigated as described above.

Conclusion

On the basis of the Final Environmental Assessment submitted by the sponsor, the Department's independent review of that assessment, information developed during the review of the application and Environmental Assessment, comments received by the Department from Federal and State agencies, and measures that Express and Terasen are prepared to undertake to prevent or mitigate potentially adverse environmental impacts, the Department has concluded that issuance of a Presidential Permit authorizing construction and operation of the proposed Express Pipeline capacity increase would not have a significant impact on the quality of the human environment within the United States. Accordingly, a Finding of No Significant Impact is adopted and an Environmental Impact Statement will not be prepared.

The Final Environmental Assessment addressing this action is incorporated by reference and is on file and may be reviewed by interested parties at the Department of State, 2201 C Street NW., Room 3535, Washington, DC 20520 (Attn: Mr. Pedro Erviti, Tel. 202–647–1291).

Dated: September 24, 2004.

Stephen J. Gallogly,

Director, Office of Energy & Commodity Policy, Bureau of Economic and Business Affairs, Department of State.

[FR Doc. 04–22241 Filed 10–1–04; 8:45 am]

BILLING CODE 4710–07–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Commercial Space Transportation Advisory Committee—Open Meeting

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Commercial Space Transportation Advisory Committee open meeting.

SUMMARY: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C. App. 2), notice is hereby given of a meeting of the Commercial Space Transportation Advisory Committee (COMSTAC). The meeting will take place on Wednesday, October 27, 2004, starting at 8 a.m. at the Federal Aviation Administration Headquarters Building, 800 Independence Avenue, SW., Washington, DC, in the Bessie Coleman Conference Center, 2nd Floor. This will be the fortieth meeting of the COMSTAC.

The proposed agenda for the meeting will include updates on current

commercial space transportation legislation, and an activities report from FAA's Associate Administrator for Commercial Space Transportation. An agenda will be posted on the FAA Web site at *http://ast.faa.gov*. Meetings of the COMSTAC Working Groups (Technology and Innovation, Reusable Launch Vehicle, Risk Management, and Launch Operations and Support) will be held on Tuesday, October 26, 2004. For specific information concerning the times and locations of the working group meetings, contact the Contact Person listed below.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should inform the Contact Person listed below in advance of the meeting.

FOR FURTHER INFORMATION CONTACT: Brenda Parker (AST–200), Office of the Associate Administrator for Commercial Space Transportation (AST), 800 Independence Avenue, SW., Room 331, Washington, DC 20591, telephone (202) 385–4713; e-mail *brenda.parker@faa.dot.gov*.

Issued in Washington, DC, September 28, 2004.

Patricia G. Smith,

Associate Administrator for Commercial Space Transportation.

[FR Doc. 04–22277 Filed 10–1–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Environmental Impact Statement: Etowah County, AL

AGENCY: Federal Highway Administration (FHWA), Department of Transportation.

ACTION: Notice of intent.

SUMMARY: The FHWA is issuing this notice to advise the public that an Environmental Impact Statement will be prepared for a proposed highway project in Etowah County, Alabama. This Notice of Intent (NOI) supersedes a NOI for this proposed project that was issued by the FHWA in the **Federal Register** dated May 29, 2001 (Volume 66, Number 103) Public involvement and coordination activities on the original proposal have resulted in a change in the scope of the project that should better meet the needs of local community and impacted neighborhoods.

FOR FURTHER INFORMATION CONTACT: Mr. Joe D. Wilkerson, Division Administrator, Federal Highway Administration, 500 Eastern Boulevard, Suite 200, Montgomery, Alabama 36117, Telephone: (334) 223–7370.

SUPPLEMENTARY INFORMATION: The FHWA, in cooperation with the State of Alabama Department of Transportation, will prepare an Environmental Impact Statement (EIS) for Alabama Project HPP–1602 (539), old project number NHF–PE 94 (2). The proposal is to construct a limited access facility from the eastern terminus of Interstate Highway 759 (I–759) near George Wallace Drive to an interchange with U.S. Highway 431 and U.S. Highway 278 in the city of Gadsden, Alabama. The project will be a multi-lane roadway on new location. The proposal will allow traffic from I–759 to flow through the city of Gadsden.

Alternatives under consideration include (1) alternate route locations, (2) a no-action alternative, and (3) postponing the action.

Letters describing the proposed action and soliciting comments will be sent to appropriate Federal, State, and local agencies and to private organizations and citizens that have previously expressed or are known to have an interest in this proposal. A public involvement meeting and a public hearing will be held in the city of Gadsden. Public notice with be given of the time and place for the meeting and hearing. A formal scoping meeting will not be held.

To ensure that the full range of issues related to this proposed action are addressed and all significant issues identified, comments and suggestions are invited from all interested parties. Comments or questions concerning this proposed action and the EIS should be directed to the FHWA at the address provided above.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Issued on: September 21, 2004.

Joe D. Wilkerson,

Division Administrator, Montgomery, Alabama.

[FR Doc. 04–22181 Filed 10–1–04; 8:45 am]

BILLING CODE 4910–22–M

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

Petition for Exemption from the Vehicle Theft Prevention Standard; Nissan North America, Inc.

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Grant of petition for exemption.

SUMMARY: This notice grants in full the petition of Nissan North America, Inc:, (Nissan) for an exemption of a high-theft vehicle line, [whose nameplate is confidential], from the parts-marking requirements of the Federal motor vehicle theft prevention standard. This petition is granted because the agency has determined that the antitheft device to be placed on the line as standard equipment is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the Theft Prevention Standard. Nissan requested confidential treatment for the information and attachments it submitted in support of its petition. In a letter dated July 23, 2004, the agency granted the petitioner's request for confidential treatment of most aspects of its petition.

DATES: The exemption granted by this notice is effective beginning with the [confidential] model year.

FOR FURTHER INFORMATION CONTACT: Ms. Rosalind Proctor, Office of International Policy, Fuel Economy and Consumer Programs, NHTSA, 400 Seventh Street, SW., Washington, DC 20590. Ms. Proctor's telephone number is (202) 366–0846. Her fax number is (202) 493–2290.

SUPPLEMENTARY INFORMATION: In a petition dated June 23, 2004, Nissan North America, Inc. (Nissan), requested exemption from the parts-marking requirements of the theft prevention standard (49 CFR Part 541) for a vehicle line. The nameplate of the line and the model year of introduction are confidential. The petition has been filed pursuant to 49 CFR Part 543, *Exemption from Vehicle Theft Prevention Standard*, based on the installation of an antitheft device as standard equipment for an entire vehicle line. Based on the evidence submitted by Nissan, the agency believes that the antitheft device for the vehicle line is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the theft prevention standard (49 CFR Part 541).

Section 33106(b)(2)(D) of Title 49, United States Code, gave the Secretary of Transportation the authority to grant a manufacturer *one* parts-marking exemption per model year for vehicle lines produced MYs' 1997–2000. However, it does not address the contingency of what to do after model year 2000 in the absence of a decision under Section 33103(d). 49 U.S.C. 33103(d)(3), states that the number of lines for which the agency can grant an exemption is to be decided after the Attorney General completes a review of the effectiveness of antitheft devices and finds that antitheft devices are an effective substitute for parts-marking. The Attorney General has not yet made a finding pursuant to 49 U.S.C. 33103(d)(3), *Long Range Review of Effectiveness*, and has not decided the number of lines, if any, for which the agency will be authorized to grant an exemption. Upon consultation with the Department of Justice, both agencies determined that the appropriate reading of Section 33103(d) is that the National Highway Traffic Safety Administration (NHTSA) may continue to grant parts-marking exemptions for no more than one additional model line each year, as specified for model years 1997–2000 by 49 U.S.C. 33106(b)(2)(C). This is the level contemplated by the Act for the period before the Attorney General's decision. The final decision on whether to continue granting exemptions will be made by the Attorney General at the conclusion of the review pursuant to Section 33103(d)(3).

Nissan's submittal is considered a complete petition, as required by 49 CFR 543.7, in that it meets the general requirements contained in "543.5 and the specific content requirements of "543.6. In its petition, Nissan provided a detailed description and diagram of the identity, design, and location of the components of the antitheft device for the new line. Nissan requested confidential treatment for the information it submitted in support of its petition. In a letter dated July 23, 2004, the agency granted the petitioner's request for confidential treatment of most aspects of its petition.

In order to ensure reliability and durability of the device, Nissan conducted tests based on its own specified standards. Nissan provided a detailed list of the tests conducted and believes that the device is reliable and durable since the device complied with its specified requirements for each test.

Nissan compared the device proposed for its vehicle line with devices which NHTSA has determined to be as effective in reducing and deterring motor vehicle theft as would compliance with the parts-marking requirements. Nissan stated that its proposed device, as well as other comparable devices that have received full exemptions from the parts-marking requirements, lack an audible and visible alarm. Therefore, these devices cannot perform one of the functions listed in 49 CFR 542.6(a)(3), that is, to call attention to unauthorized attempts to enter or move the vehicle. However, theft data have indicated a decline in theft rates for vehicle lines that have been equipped with antitheft devices similar to that which Nissan purposes. In these instances, the agency has concluded that the lack of a visual or audible alarm has not prevented these antitheft devices from being effective protection against theft.

On the basis of this comparison, Nissan has concluded that the antitheft device proposed for its vehicle line is no less effective than those devices in the lines for which NHTSA has already granted full exemption from the parts-marking requirements.

Based on the evidence submitted by Nissan, the agency believes that the antitheft device for the Nissan vehicle line is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the Theft Prevention Standard.

The agency concludes that the device will provide four of the five types of performance listed in § 543.6(a)(3): Promoting activation; preventing defeat or circumvention of the device by unauthorized persons; preventing operation of the vehicle by unauthorized entrants; and ensuring the reliability and durability of the device.

As required by 49 U.S.C. 33106 and 49 CFR 543.6 (a)(4) and (5), the agency finds that Nissan has provided adequate reasons for its belief that the antitheft device will reduce and deter theft. This conclusion is based on the information Nissan provided about its device, much of which is confidential. This confidential information included a description of reliability and functional tests conducted by Nissan for the antitheft device and its components.

For the foregoing reasons, the agency hereby grants in full Nissan's petition for exemption for the vehicle line from the parts-marking requirements of 49 CFR Part 541. The agency notes that 49 CFR Part 541, Appendix A–1, identifies those lines that are exempted from the Theft Prevention Standard for a given model year. Advanced listing, including the release of future product nameplates, is necessary in order to notify law enforcement agencies of new vehicle lines exempted from the parts marking requirements of the Theft Prevention Standard. Since Nissan has been granted confidential treatment for its vehicle line, the confidential status of its nameplate will be protected until the introduction of its vehicle line into the market place. At that time, Appendix A–1 will be revised to reflect the nameplate of Nissan's exempted vehicle line.

If Nissan decides not to use the exemption for this line, it must formally notify the agency, and, thereafter, the line must be fully marked as required by 49 CFR 541.5 and 541.6 (marking of major component parts and replacement parts).

NHTSA notes that if Nissan wishes in the future to modify the device on which this exemption is based, the company may have to submit a petition to modify the exemption. Part 543.7(d) states that a Part 543 exemption applies only to vehicles that belong to a line exempted under this part and equipped with the anti-theft device on which the line's exemption is based. Further, § 543.9(c)(2) provides for the submission of petitions to modify an exemption to permit the use of an antitheft device similar to but differing from the one specified in that exemption.

The agency wishes to minimize the administrative burden that § 543.9(c)(2) could place on exempted vehicle manufacturers and itself. The agency did not intend Part 543 to require the submission of a modification petition for every change to the components or design of an antitheft device. The significance of many such changes could be *de minimis*. Therefore, NHTSA suggests that if the manufacturer contemplates making any changes the effects of which might be characterized as *de minimis*, it should consult the agency before preparing and submitting a petition to modify.

Authority: 49 U.S.C. 33106; delegation of authority at 49 CFR 1.50.

Issued on: September 27, 2004.

Stephen R. Kratzke,

Associate Administrator for Rulemaking.

[FR Doc. 04–22281 Filed 10–1–04; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2004–18653; Notice 2]

Baby Trend, Inc., Grant of Petition for Decision of Inconsequential Noncompliance

Baby Trend, Inc. (Baby Trend) has determined that certain child restraint seats that it produced and sold between approximately June 2002 and June 2003 do not comply with S5.2.3.2(a) of 49 CFR 571.213, Federal Motor Vehicle Safety Standard (FMVSS) No. 213, "Child restraint systems." Pursuant to 49 U.S.C. 30118(d) and 30120(h), Baby Trend has petitioned for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential to motor vehicle safety. Notice of receipt of Baby Trend's petition was published, with a 30 day comment period, on July 29, 2004, in the **Federal Register** (69 FR 45372). NHTSA received no comments.

S5.2.3.2 of FMVSS No. 213 requires that:

> Each system surface * * * which is contactable by the dummy head when the system is tested in accordance with S6.1 shall be covered with slow recovery, energy absorbing material with the following characteristics: (a) A 25 percent compression-deflection resistance of not less than 0.5 and not more than 10 pounds per square inch when tested in accordance with S6.3.

Baby Trend produced a total of approximately 150,730 Latch-Loc infant car seats whose foam covering as molded onto the seat back of these seats has a compression-deflection resistance of 0.3 pounds per square inch, and therefore does not meet the compression-deflection resistance required by S5.2.3.2(a).

Baby Trend does not believe that the product presents any real world safety hazard as verified by highly sensitive testing with calibrated dummies on actual production product. In June 2003, FMVSS No. 213 underwent a number of revisions including amendments to incorporate advanced test dummies and updated test procedures (68 FR 37620, June 24, 2003). This included amending S5.2.3.1 to eliminate subjecting child restraint systems to the compression-deflection resistance requirements if they are tested to the revised standard using the advanced Part 572 Subpart R test dummy.

The revised S5.2.3.1 of FMVSS No. 213 states:

> Each child restraint system other than a child harness, manufactured before August 1, 2005, that is recommended under S5.5.2 for a child whose mass is less than 10 kg and that is not tested with the Part 572 Subpart R dummy, shall comply with S5.2.3.

Section S5.2.3 specifies the head impact protection requirements for the child restraint systems and includes the compression-deflection resistance requirements for the energy absorbing materials covering the child restraint system surfaces that are contactable by the dummy head when tested in accordance with S6.1.

As stated in its petition, Baby Trend conducted testing of the subject child restraint systems in accordance with the revised FMVSS No. 213. Its testing included dynamic sled testing with the 12-month-old size CRABI test dummy (Part 572 Subpart R dummy). The test results yielded head injury criterion (HIC36) values of approximately 500 to 600, which are well within the maximum HIC36 requirement of 1000.

NHTSA agrees that the noncompliance is inconsequential to motor vehicle safety. Based on the successful dynamic testing conducted by Baby Trend on the non-compliant child restraint systems using the Part 572 Subpart R dummy in accordance with the revised FMVSS No. 213, the head foam material appears to provide adequate head impact protection given the low HIC36 values measured.

In consideration of the foregoing, NHTSA has decided that the petitioner has met its burden of persuasion that the noncompliance described is inconsequential to motor vehicle safety. Accordingly, Baby Trend's petition is granted and the petitioner is exempted from the obligation of providing notification of, and a remedy for, the noncompliance.

(Authority: 49 U.S.C. 30118, 30120; delegations of authority at CFR 1.50 and 501.8)

Issued on: September 28, 2004.

Kenneth N. Weinstein,

Associate Administrator for Enforcement.

[FR Doc. 04–22280 Filed 10–1–04; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 34541]

Spokane County, WA, Division of Engineering and Roads—Acquisition Exemption—The Burlington Northern and Santa Fe Railway Company

Spokane County, Division of Engineering and Roads (Spokane), a Class III rail carrier, has filed a verified notice of exemption under 49 CFR 1150.41 to acquire from The Burlington Northern and Santa Fe Railway Company (BNSF), a line of railroad known as the Geiger Spur from milepost 1493.95, on its Columbia River Subdivision, to milepost 4.93, on the Geiger Spur, a total distance of 4.93 miles.

This transaction is related to a verified notice of exemption in STB Finance Docket No. 34546, *Western Rail Switching, Incorporated—Operation Exemption—Rail Line of Spokane County, WA*, wherein Western Rail Switching, Incorporated seeks to operate the line being acquired by Spokane.

Spokane certifies that its projected annual revenues as a result of this transaction will not exceed $5 million, and the transaction will not result in the creation of a Class I or Class II rail carrier.

The transaction was scheduled to be consummated on October 1, 2004.

If the notice contains false or misleading information, the exemption is void *ab initio*. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

An original and 10 copies of all pleadings, referring to STB Finance Docket No. 34541, must be filed with the Surface Transportation Board, 1925 K Street NW., Washington, DC 20423–0001. In addition, one copy of each pleading must be served on Martin Rollins, Spokane County Prosecuting Attorney's Office, Civil Division, 1115 West Broadway Avenue, Spokane, WA 99260.

Board decisions and notices are available on our Web site at *http://www.stb.dot.gov*.

Decided: September 24, 2004.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 04–22340 Filed 10–1–04; 8:45 am]

BILLING CODE 4915–01–P

Corrections

Federal Register
Vol. 69, No. 191
Monday, October 4, 2004

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR 744

[Docket No. 040713207–4207–01]

RIN 0694–AD13

India: removal of Indian Entity and Revision in License Review Policy for Certain Indian Entities; and a Clarification; Correction

Correction

In rule document 04–21837 beginning on page 58049 in the issue of September 29, 2004, make the following correction:

PART 744, Supplement 4—[Corrected]

1. On page 58050, under the table "SUPPLEMENT No. 4 TO PART 744–ENTITY LIST–Continued", in the first column "Country/Entity", in the first line "Dpeartment" should read "Department"

2. On the same page, under the same table, in the same column, in the 11th line "subjet" should read "subject ".

3. On the same page, under the same table, in the third column "License review policy", in the second paragraph, in the eighth line "(NPI)" should read "(NP1)".

[FR Doc. C4–21837 Filed 10–1–04; 8:45 am]
BILLING CODE 1505–01–D

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 300

[Docket No. 040209049–4117–02; I.D. 091404G]

Pacific Halibut Fisheries; Oregon Sport Fisheries

Correction

In rule document 04–21553 beginning on page 57651 in the issue of Monday, September 27, 2004, make the following correction:

On page 57652, in the first column, in the fourth line, the date "October 7, 2004" should read, "October 12, 2004."

[FR Doc. C4–21553 Filed 10–1–04; 8:45 am]
BILLING CODE 1505–01–D

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2004–18821; Airspace Docket No. 04–ACE–47]

Modification of Class E Airspace; St. Francis, KS

Correction

In rule document 04–21528 beginning on page 57170 in the issue of September 24, 2004, make the following correction:

§71.1 [Corrected]

On page 57171, in the third column, in § 71.1, under the heading "**ACE KS E5 St. Francis, KS**", in the third line, "(Lat. 39°40′40″ N.," should read "(Lat. 39°45′40″ N.,".

[FR Doc. C4–21528 Filed X–XX–04; 8:45 am]
BILLING CODE 1505–01–D

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2004–18822; Airspace Docket No. 04–ACE–48]

Modification of Class D Airspace; and Modification of Class E Airspace; Salina, KS

Correction

In rule document 04–21529 beginning on page 57169 in the issue of September 24, 2004, make the following correction:

§71.1 [Corrected]

On page 57170, in the second column, in § 71.1, under the heading "**ACE KS E5 Salina, KS**", in the second line, "(Lat. 38°47′127″ N.," should read "(Lat. 38°47′27″ N.,".

[FR Doc. C4–21529 Filed 10–1–04; 8:45 am]
BILLING CODE 1505–01–D

Federal Register

Monday,
October 4, 2004

Part II

Department of Labor

Occupational Safety and Health Administration

29 CFR Parts 1910, 1915, 1917, 1918, and 1926

Occupational Exposure to Hexavalent Chromium; Proposed Rule

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1910, 1915, 1917, 1918, and 1926

[Docket No. H054A]

RIN 1218–AB45

Occupational Exposure to Hexavalent Chromium

AGENCY: Occupational Safety and Health Administration (OSHA), Department of Labor.

ACTION: Proposed rule; request for comments and scheduling of informal public hearings.

SUMMARY: The Occupational Safety and Health Administration (OSHA) proposes to amend its existing standard for employee exposure to hexavalent chromium (Cr(VI)). The basis for issuance of this proposal is a preliminary determination by the Assistant Secretary that employees exposed to Cr(VI) face a significant risk to their health at the current permissible exposure limit and that promulgating this proposed standard will substantially reduce that risk. The information gathered so far in this rulemaking indicates that employees exposed to Cr(VI) well below the current permissible exposure limit are at increased risk of developing lung cancer. Occupational exposures to Cr(VI) may also result in asthma, and damage to the nasal epithelia and skin.

This document proposes an 8-hour time-weighted average permissible exposure limit of one microgram of Cr(VI) per cubic meter of air (1 mg/m^3) for all Cr(VI) compounds. OSHA also proposes other ancillary provisions for employee protection such as preferred methods for controlling exposure, respiratory protection, protective work clothing and equipment, hygiene areas and practices, medical surveillance, hazard communication, and recordkeeping. OSHA is proposing separate regulatory texts for general industry, construction, and shipyards in order to tailor requirements to the circumstances found in each of these sectors.

DATES: *Written comments.* The Agency invites interested persons to submit written comments regarding the proposed rule, including comments on the information collection determination described in Section X of the preamble (OMB Review under the Paperwork Reduction Act of 1995), by mail, facsimile, or electronically. All comments, whether submitted by mail, facsimile, or electronically through the Internet, must be sent by January 3, 2005.

Informal public hearings. The Agency plans to hold an informal public hearing in Washington, DC, beginning on February 1, 2005. OSHA expects the hearing to last from 9:30 a.m. to 5:30 p.m.; however, the exact daily schedule is at the discretion of the presiding administrative law judge.

Notice of intention to appear to provide testimony at the informal public hearing. Interested persons who intend to present testimony at the informal public hearing in Washington, DC, must notify OSHA of their intention to do so no later than December 3, 2004.

Hearing testimony and documentary evidence. Interested persons who request more than 10 minutes to present their testimony, or who will be submitting documentary evidence at the hearing, must provide the Agency with copies of their full testimony and all documentary evidence they plan to present by January 3, 2005. See Section XVI below for details on the format and how to file a notice of intention to appear, submit documentary evidence at the hearing, and request an appropriate amount of time to present testimony.

ADDRESSES: *Written comments.* Interested persons may submit three copies of written comments to the Docket Office, Docket H054A, Room N–2625, OSHA, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693–2350. If written comments are 10 pages or fewer, they may be faxed to the OSHA Docket Office, facsimile number (202) 693–1648. Comments may also be submitted electronically through the Internet at *http://ecomments.osha.gov*. Supplemental information such as studies and journal articles cannot be attached to electronic submissions. Instead, three copies of each study, article, or other supplemental document must be sent to the OSHA Docket Office at the address above. These materials must clearly identify the associated electronic comments to which they will be attached in the docket by the following information: Name of person submitting comments; date of comment submission; subject of comments; and docket number to which comments belong.

Informal public hearings. The informal public hearing to be held in Washington, DC, will be held in the Frances Perkins Building, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

Notice of intention to appear to provide testimony at the informal public hearing. Interested persons who intend to present testimony at the informal public hearing in Washington, DC, may submit three copies of their notice of intention to appear to the Docket Office, Docket H054A, Room N–2625, OSHA, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. Notices may also be submitted electronically through the Internet at *http://ecomments.osha.gov*. OSHA Docket Office and Department of Labor hours of operation are 8:15 a.m. to 4:45 p.m.

Hearing testimony and documentary evidence. Interested persons who request more than 10 minutes in which to present their testimony, or who will be submitting documentary evidence at the informal public hearing must submit three copies of the testimony and the documentary evidence to the Docket Office, Docket H054A, Room N–2625, OSHA, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. Written testimony may also be submitted electronically through the Internet at *http://ecomments.osha.gov*.

Please note that security-related problems may result in significant delays in receiving comments and other materials by regular mail. Telephone the OSHA Docket Office at (202) 693–2350 for information regarding security procedures concerning delivery of materials by express delivery, hand delivery, and messenger service.

All comments and submissions will be available for inspection and copying in the OSHA Docket Office at the address above. Most comments and submissions will be posted on OSHA's Web page (*http://www.osha.gov*). Contact the OSHA Docket Office at (202) 693–2350 for information about materials not available on the OSHA Web page and for assistance in using this Web page to locate docket submissions. Because comments sent to the docket or to OSHA's Web page are available for public inspection, the Agency cautions interested parties against including in these comments personal information such as social security numbers and birth dates.

FOR FURTHER INFORMATION CONTACT: For general information and press inquiries, contact Mr. George Shaw, Office of Communications, Room N–3647, OSHA, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693–1999. For technical inquiries, contact Ms. Amanda Edens, Directorate of Standards and Guidance, Room N–3718, OSHA, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693–2093 or

fax (202) 693–1678. For hearing information contact Ms. Veneta Chatmon, Office of Communications, Room N–3647, OSHA, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693–1999.

SUPPLEMENTARY INFORMATION: For additional copies of this **Federal Register** document, contact the Office of Publications, Room N–3101, OSHA, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693–1888. Electronic copies of this **Federal Register**, as well as news releases and other relevant documents, are available at OSHA's Home page at *http://www.osha.gov*.

I. General

The preamble to the proposed standard on occupational exposure to chromium (VI) discusses events leading to the proposal, health effects of exposure, the degree and significance of the risk presented, a summary of the analysis of technological and economic feasibility, regulatory impact, and regulatory flexibility, and the rationale behind the specific provisions set forth in the proposed standard. The discussion follows this outline:

II. Issues

OSHA requests comment on all relevant issues, including health effects, risk assessment, significance of risk determination, technological and economic feasibility, and the provisions of the proposed regulatory text. OSHA is especially interested in responses, supported by evidence and reasons, to the following questions:

Health Effects

1. OSHA has described a variety of studies addressing the major adverse health effects that have been associated with exposure to Cr(VI). Has OSHA adequately identified and documented all critical health impairments associated with occupational exposure to Cr(VI)? Are there any additional studies or other data that would controvert the information discussed or significantly enhance the determination of material health impairment or the assessment of exposure-response relationships? Submit any relevant information, and explain your reasoning for recommending the inclusion of any studies you suggest.

2. Using currently available epidemiologic and experimental studies, OSHA has made a preliminary determination that all Cr(VI) compounds (*e.g.*, water soluble, insoluble and slightly soluble) possess carcinogenic potential and thus present a lung cancer risk to exposed workers. Is this determination correct? Are there additional data OSHA should consider in evaluating the carcinogenicity or relative carcinogenic potencies of different Cr(VI) compounds?

Risk Assessment

3. In its preliminary assessment of risk, OSHA has relied primarily on two epidemiologic cohort studies of chromate production workers to estimate the lung cancer risk to workers exposed to Cr(VI) (Exs. 31–22–11; 33–10). Are there any other studies that you believe are better suited to estimating the risk to exposed workers; if so, please provide the studies and explain why you believe they are better.

4. OSHA is aware of two cohorts (i.e., Alexander cohort, Ex. 31–16–3, and Pastides cohort, Ex. 35–279) in which a sizable number of workers were probably exposed to low Cr(VI) air levels (*e.g.*, <10 $\mu g/m^3$) more consistent with concentrations found in the workplace today. However, OSHA believes the period of follow-up observation (median <10 yr), the young age (<45 yr at end of follow-up) and the low number of observed lung cancers (≤15 lung cancers) severely limits these cohorts as primary data sets for quantitative risk analysis. Other limitations to the Alexander study include a lack of data on workers who were employed between 1940 and 1974, but whose employment ended prior to 1974, and on exposures prior to 1974. Are there updated analyses available for the Alexander and Pastides cohorts? How many years do these cohorts need to be followed and how many lung cancers need to be observed in order for these data sets to provide insight into the shape of the exposure-response curve at lower levels of Cr(VI) exposure (*e.g.*, 0.5 to 5 $\mu g/m^3$)? In the case of the Alexander cohort, is there additional information on cohort members' exposures prior to 1974 or workers who left prior to 1974 that could improve the analysis? Are there other cohorts available to look at low exposures?

5. OSHA has relied upon a linear relative risk model and cumulative Cr(VI) exposure for estimating the lifetime occupational lung cancer risk among Cr(VI)-exposed workers. In particular, OSHA has made a preliminary determination that a threshold model is not appropriate for estimating the lung cancer risk associated with Cr(VI). However, there is some evidence that pathways (*e.g.*, extracellular reduction, DNA repair, cell apoptosis, etc.) may exist within the lung that protect against Cr(VI)-induced respiratory carcinogenesis, and may potentially introduce non-linearities into the Cr(VI) exposure-cancer response. Is there convincing scientific evidence of a non-linear exposure-response relationship in the range of occupational exposures of interest to OSHA? If so, are there sufficient data to define a non-linear approach that would provide more reliable predictions of risk than the linear relative risk model used by OSHA?

6. OSHA's estimates of lung cancer risk are based on workers primarily exposed to highly water-soluble sodium chromate and sodium dichromate. OSHA has preliminarily concluded that the risk for workers exposed to equivalent levels of other Cr(VI) compounds will be of a similar magnitude or, in the case of some Cr(VI) compounds, possibly greater than the risks projected in the OSHA quantitative risk assessment. Is this determination appropriate? Are there sufficient data to reliably quantify the risk from occupational exposure to specific Cr(VI) compounds? If so, explain how the risk could be estimated.

7. The preliminary quantitative risk assessment relies on two (Gibb and Luippold) cohort studies in which most workers were exposed higher Cr(VI) levels than the PEL proposed by OSHA, for shorter durations than a working lifetime exposure. The risks estimated by OSHA for lifetime exposure to the proposed PEL, therefore, carry the assumption that a cumulative exposure achieved by short duration exposure to higher Cr(VI) air levels (*e.g.*, exposed 3 years to 15 $\mu g/m^3$) leads to the same risk as an equivalent cumulative exposure achieved by longer duration exposure to

lower Cr(VI) exposure (e.g, exposed 45 years to 1 $\mu g/m^3$). OSHA preliminarily finds this assumed exposure equivalency to represent an uncertainty in the estimates of risk but does not have information that indicates this uncertainty introduces serious error in its predictions of risk. Does the OSHA exposure-response assessment based on the higher Cr(VI) air levels and/or shorter durations experienced by the Gibb and Luippold cohorts lead to a serious underprediction or overprediction in estimated risks for the occupational exposure scenarios of interest to OSHA? Please provide any data to support your rationale.

8. OSHA has made a preliminary determination that suitable data are not available for making quantitative risk estimates for the non-cancer adverse health effects associated with exposure to Cr(VI) (*e.g.*, nasal septum ulcerations and perforations, asthma, irritant and allergic contact dermatitis). Are there suitable data for a quantitative estimation of risk for non-cancer adverse effects that OSHA should include in its final quantitative risk assessment? If so, what models or approaches should be used?

9. Are there other factors OSHA should take into consideration in its final quantitative risk assessment to better characterize the risks associated with exposure to Cr(VI)?

Technologic and Economic Feasibility

10. In its Preliminary Economic Analysis of the proposed standard, OSHA presents a profile of the affected worker population. In that profile are estimates of the number of affected workers by application group and job category and the distribution of exposures by job category. Are there additional data that will enable the Agency to refine its profile of the worker population exposed to Cr(VI)? If so, how should OSHA use these data in making such revisions?

11. What are the job categories in which employees are potentially exposed to Cr(VI) in your company or industry? For each job category, provide a brief description of the operation and describe the job activities that may lead to Cr(VI) exposure. How many employees are exposed, or have the potential for exposure, to Cr(VI) in each job category in your company or industry? What are the frequency, duration and levels of exposures to Cr(VI) at each job category in your company or industry? Where commenters are able to provide exposure data, OSHA requests that, where possible, exposure data be personal samples with clear descriptions of the length of the sample and analytical method. Exposure data that provide information concerning the controls in place are more valuable than exposure data without such information.

12. Have there been technological changes within your industry that have influenced the magnitude, frequency, or duration of exposure to Cr(VI) or the means by which employers attempt to control exposures? Describe in detail these technological changes and their effects on Cr(VI) exposures and methods of control.

13. Has there been a trend within your industry to eliminate Cr(VI) from production processes, products and services? If so, comments are requested on the success of substitution efforts. Commenters should estimate the percentage reduction in Cr(VI), and the extent to which Cr(VI) is still necessary in their processes within product lines or production activities. OSHA also requests that commenters describe any technical, economic or other deterrents to substitution.

14. Does any job category or employee in your workplace have exposures to Cr(VI) that raw air monitoring data do not adequately portray due to the short duration, intermittent or non-routine nature, or other unique characteristics of the exposure? Please explain your response and indicate peak levels, duration and frequency of exposures for employees in these job categories.

15. OSHA requests the following information regarding engineering and work practice controls in your workplace or industry:

a. Describe the operations in which the proposed PEL is being achieved most of the time by means of engineering and work practice controls.

b. What engineering and work practice controls have been implemented in these operations?

c. For all operations in facilities where Cr(VI) is used, what engineering and work practice controls have been implemented? If you have installed engineering controls or adopted work practices to reduce exposure to Cr(VI), describe the exposure reduction achieved and the cost of these controls. Where current work practices include the use of regulated areas and hygiene facilities, provide data on the implementation of these controls, including data on the costs of installation, operation, and maintenance associated with these controls.

d. Describe additional engineering and work practice controls which could be implemented in each operation where exposure levels are currently above the proposed PEL to further reduce exposure levels.

e. When these additional controls are implemented, to what levels can exposure be expected to be reduced, or what per cent reduction is expected to be achieved?

f. What are the costs and amount of time needed to develop, install and implement these additional controls? Will the added controls affect productivity?

g. Are there any processes or operations for which it is not reasonably possible to implement engineering and work practice controls within two years to achieve the proposed PEL? If so, would allowing additional time for employers to implement engineering and work practice controls make compliance possible? How much additional time would be necessary?

16. OSHA requests information on whether there are any limited or unique conditions or job tasks in Cr(VI) manufacture or use where engineering and work practice controls are not available or are not capable of reducing exposure levels to or below the proposed PEL most of the time. Provide data and evidence to support your response.

17. In its Preliminary Economic Analysis, OSHA presents estimated baseline levels of use of personal protective equipment (PPE) and the incremental costs associated with the proposed standard. Are OSHA's estimated compliance rates reasonable? Are OSHA's estimates of PPE costs, and the assumptions underlying these estimates, consistent with current industry practice? Comments are solicited on OSHA's analysis of PPE costs.

18. In its Preliminary Economic Analysis, OSHA presents estimated baseline levels of communication of Cr(VI)-related hazards and the incremental costs associated with the additional requirements for communication in the proposed standard. OSHA requests information on hazard communication programs addressing Cr(VI) that are currently being implemented by employers and any necessary additions to those programs that are anticipated in response to the proposed standard. Are OSHA's baseline estimates and unit costs for training reasonable and consistent with current industry practice?

Effects on Small Entities

19. Will difficulties be encountered by small entities when attempting to comply with requirements of the proposed standard? Can any of the

proposal's requirements be deleted or simplified for small entities, while still protecting the health of employees? Would a longer time allowed for compliance for small entities make a difference to their ability to comply, and if so, why? (Information submitted in the SBREFA process is part of the record and need not be resubmitted).

Economic Impacts and Economic Feasibility

20. OSHA, in its Preliminary Economic Analysis, has estimated, by application group, compliance costs per affected entity and the likely impacts on revenues and profits under alternative market scenarios. OSHA requests that affected employers provide comment on OSHA's estimate of revenue, profit, and the impacts of costs for their industry or application group. Are there special circumstances—such as unique cost factors, foreign competition, or pricing constraints—that OSHA needs to consider when evaluating economic impacts for particular application groups? Comments are requested on OSHA's analysis of economic feasibility in the PEA.

Overlapping and Duplicative Regulations

21. Do any federal regulations duplicate, overlap, or conflict with the proposed Cr(VI) standard?

22. In some facilities, adjustments in ventilation systems to comply with the proposed PEL may require additional time and expense to retest these systems to ensure compliance with EPA requirements or state requirements. OSHA requests information and comment indicating how frequently retesting would be required, and the time and costs involved in such retesting.

Environmental Impacts

23. Submit any data, information, or comments pertaining to possible environmental impacts of adopting this proposal, such as the following:

a. Any positive or negative environmental effects that could result;

b. Any irreversible commitments of natural resources which could be involved; and

c. Estimates of the effect of the proposed standard on the levels of Cr(VI) in the environment.

In particular, consideration should be given to the potential direct or indirect impacts of the proposal on water and air pollution, energy use, solid waste disposal, or land use.

d. Some small entity representatives noted that OSHA PELs are sometimes used to set "fence line" standards for air pollutants. OSHA is unable to find evidence of states formally using this procedure, though some states may use such a procedure informally. Do any states or other air pollution authorities base standards on OSHA PELs? What effects might this have on the environment and on environmental compliance?

Provisions of the Standard

24. OSHA's safety and health advisory committees for Construction and Maritime advised the Agency to take into consideration the unique nature of their work environments by either settings separate standards or making accommodations for the differences in work environments in construction and maritime. To account for differences in the workplace environment for these different sectors OSHA has proposed separate standards for general industry, construction, and shipyards. Is this approach appropriate? What other approaches should the Agency consider? Please provide a rationale for your response.

25. OSHA has not proposed to cover agriculture, because the Agency is not aware of significant exposures to Cr(VI) in agriculture. Is this determination correct?

26. OSHA has proposed to regulate exposures to all Cr(VI) compounds. As discussed in the health effects section of this preamble, the Agency has made a preliminary determination that the existing data support coverage of all Cr(VI) compounds in the scope of the proposed standard. Is this an appropriate determination or are there additional data that support the exclusion of certain compounds from the scope of the final standard? If so, describe specifically how these data would support a decision to exclude certain compounds from the scope of the final rule.

27. OSHA has made a preliminary determination to exclude Cr(VI) exposures due to work with portland cement from the scope of the construction standard. OSHA believes that guidance efforts by the Agency may be more suitable for addressing the dermal hazards associated with portland cement use in construction settings. OSHA's Advisory Committee for Construction Safety and Health (ACCSH) advised OSHA to include construction cement work under the proposed standard because of the known hazards associated with wet cement and the large number of workers exposed to wet cement in construction work settings. In particular ACCSH advised OSHA that only certain provisions might be necessary for workers exposed to wet cement (*e.g.*, protective work clothing, hygiene areas and practices, medical surveillance for signs and symptoms of adverse health effects only, communication of hazards and recordkeeping for medical surveillance and training). Other provisions, ACCSH advised, might not be necessary (*e.g.*, permissible exposure levels, exposure assessment, methods of compliance and respiratory protection). Should OSHA expand the scope of the construction proposal to include Cr(VI) exposures from portland cement? If so, what would be the best approach for addressing the dermal hazards from Cr(VI) faced by these workers? If Cr(VI) exposure from portland cement work in construction is included in the final standard, should only certain provisions such as those outlined by ACCSH be considered?

28. OSHA has proposed to include exposure to Cr(VI) from portland cement in the scope of the standard for general industry. The Agency believes that the potential for airborne exposure to Cr(VI) in general industry due to work with portland cement, as indicated by the profile of exposed workers presented in Table IX–2 of this preamble, is higher than in the construction industry. OSHA acknowledges, however, that the exposure profile indicates that no workers are exposed to Cr(VI) at levels over the proposed action level. Given the low level of airborne exposure among cement workers in general industry, should OSHA exclude exposures to Cr(VI) from portland cement from the scope of the general industry standard? OSHA seeks data to help inform this issue, and solicits comments on particular provisions of the general industry and construction standards that may or may not be appropriate for cement workers.

29. OSHA has proposed to exempt from coverage Cr(VI) exposures occurring in the application of pesticides in general industry (such as the treatment of wood with chromium copper arsenate (CCA)) because pesticide application is regulated by EPA, and section 4(b)(1) of the OSH Act precludes OSHA from regulating where other Federal agencies exercise their statutory authority to do so. OSHA has proposed to cover exposures resulting from use of treated materials. Is this approach appropriate? Are there any instances where EPA-regulated pesticide application occurs in construction or shipyard workplaces?

30. Describe any additional industries, processes, or applications that should be exempted from the Cr(VI) standard and provide detailed reasons for any requested exemption. In

particular, are the epidemiologic and experimental studies sufficient to support OSHA's the inclusion of various industries or processes under the scope of the proposed standard? Please provide the rationale and supporting data for your response.

31. Can the proposed Cr(VI) standard for the construction industry be modified in any way to better account for the workplace conditions in that industry, while still providing appropriate protection to Cr(VI)-exposed workers in that industry? Would an alternative approach similar to that used in OSHA's asbestos standard, where the application of specified controls in certain situations would be considered adequate to meet the requirements of the standard, be useful? Is there enough information available to define such technology specifications?

32. Can the proposed Cr(VI) standard for shipyards be modified in any way to better account for the workplace conditions in that industry, while still providing appropriate protection to Cr(VI)-exposed workers in that industry?

33. OSHA has proposed a TWA PEL for Cr(VI) of 1.0 $\mu g/m^3$. The Agency has made a preliminary determination that this is the lowest level that is both technologically and economically feasible and is necessary to reduce significant risks of material health impairment from exposure to Cr(VI). Is this PEL appropriate and is it adequately supported by the existing data? If not, what PEL would be more appropriate or would more adequately protect employees from Cr(VI)-associated health risks? Provide evidence to support your response.

34. Should different PELs be established for different Cr(VI) compounds? If so, how should they be established? Where possible, provide specific detail about how different PELs could be established and how the Agency should apply those PELs in instances where workers may be exposed to more than one Cr(VI) compound.

35. OSHA has proposed an action level for Cr(VI) exposure in general industry, but not in construction or shipyards. Is this an appropriate approach? Should OSHA set an action level for exposure to Cr(VI) in construction and shipyards? Should the proposed action level in general industry be retained in the final rule?

36. If an action level is included in the final rule, is the proposed action level for general industry (0.5 $\mu g/m^3$) the appropriate level for the PEL under consideration? If not, at what level should the action level be set?

37. If an action level is included in the final rule, which provisions should be triggered by exposure above the action level? Indicate the basis for your position and include any supporting information.

38. If no action level is included in the final rule, which provisions should apply to all Cr(VI)-exposed workers? Which provisions should be triggered by the PEL? Are there any other appropriate triggers for the requirements of the standard?

39. Should OSHA set a short-term exposure limit (STEL) or ceiling for exposure to Cr(VI)? If so, please specify the appropriate air concentration and the rationale for its selection.

40. Do you conduct initial air monitoring or do you rely on objective data to determine Cr(VI) exposures? Describe any other approaches you have implemented for assessing an employee's initial exposure to Cr(VI).

41. Describe any follow-up or subsequent exposure assessments that you conduct. How often do you conduct such follow-up or subsequent exposure assessments? Please comment on OSHA's estimate of baseline industry practice and the projected costs for initial and periodic exposure assessment. Are OSHA's estimates consistent with current industry practice?

42. Do shipyard employers presently measure their employees' exposure to Cr(VI)? If not, do they use some alternative method of identifying which employees may be over-exposed to Cr(VI)?

43. OSHA has proposed specific requirements for exposure assessment in general industry, but has not proposed that these requirements apply to construction or shipyard employers. Should requirements for exposure assessment in construction or shipyards be included in the final Cr(VI) standard? Are there any advantages to requiring construction or shipyard employers to measure their employees' exposures to Cr(VI)? If so, would the exposure assessment requirements proposed for general industry be appropriate? Would construction or shipyard employers encounter situations where monitoring would be infeasible if they were required to follow the exposure assessment requirements proposed for employers in general industry? Indicate the basis for your position and include any supporting information. What types of exposure assessment strategies are effective for assessing worker exposures at construction and shipyard worksites?

44. Should requirements for exposure assessment in general industry be included in the final Cr(VI) standard, or would the performance-oriented requirement proposed for construction and shipyards be more appropriate? Indicate the basis for your position and include any supporting information.

45. OSHA has proposed that exposure monitoring in general industry be conducted at least every six months if exposures are above the action level but below the PEL, and at least every three months if exposures are at or above the PEL. Are these proposed frequencies appropriate? If not, what frequency of monitoring would be more appropriate, and why?

46. OSHA has proposed that regulated areas be established in general industry wherever an employee's exposure to airborne concentrations of Cr(VI) is, or can reasonably be expected to be, in excess of the PEL. OSHA seeks comments on this provision and in particular:

a. Describe any work settings where establishing regulated areas could be problematic or infeasible. If establishing regulated areas is problematic, what approaches might be used to warn employees in such work settings of high risk areas (i.e., areas where the airborne concentrations of Cr(VI) exceed the PEL?).

b. Should OSHA add hazards from eye or skin contact as a trigger for establishing regulated areas? Explain the basis for your position, and include any supporting information. c. Describe any methods currently used that have been found to be effective in establishing regulated areas.

47. OSHA has not proposed requirements for establishment of regulated areas in construction or shipyards. Should requirements for regulated areas for construction or shipyards be included in the final Cr(VI) standard? If so, would the requirements for regulated areas proposed for general industry be appropriate? Are there any particular problems in construction or shipyard settings that make regulated areas problematic or infeasible? If requirements for regulated areas for construction or shipyards are not included in the final Cr(VI) standard, should OSHA include requirements for warning signs or other measures to alert employees of the presence of Cr(VI)? If so, what practical means could be used to determine where and when such labeling would be required? What potential difficulties might be encountered by using such an approach? Indicate the basis for your position and include any supporting information.

48. Under the proposed standard, employers are required to use engineering and work practice controls

to reduce and maintain employee exposure to Cr(VI) to or below the PEL unless the employer can demonstrate that employees are not exposed above the PEL for 30 or more days per year, or the employer can demonstrate that such controls are not feasible. Is this approach appropriate for Cr(VI)? Indicate the basis for your position and include any supporting information.

49. In OSHA's Cadmium standard (29 CFR 1010.1027), the Agency established separate engineering control air limits (SECALs) for certain processes in selected industries. SECALs were established where compliance with the PEL by means of engineering and work practice controls was infeasible. For these industries, a SECAL was established at the lowest feasible level that could be achieved by engineering and work practice controls. The PEL was set at a lower level, and could be achieved by any allowable combination of controls. SECALs thus allowed OSHA to establish a lower PEL for cadmium than would otherwise have been possible, given technological feasibility constraints. Should OSHA establish SECALs for Cr(VI) in any industries or processes? If so, in what industries or processes, and at what levels? Provide rationale to support your position.

50. The proposed standard prohibits the use of job rotation for the sole purpose of lowering employee exposures to Cr(VI). Are there any circumstances where this practice should be allowed in order to meet the proposed PEL?

51. OSHA is proposing that employers provide appropriate protective clothing and equipment when a hazard is present or is likely to be present from skin or eye contact with Cr(VI). OSHA would expect an employer to exercise common sense and appropriate expertise to determine if a hazard is present or likely to be present. Is this approach appropriate? Are there other approaches that would be better for characterizing eye and skin contact with Cr(VI)? For example, are there methods to measure dermal exposure that could be used to routinely monitor worker exposure to Cr(VI) that OSHA should consider including in the final standard?

52. For employers whose employees are exposed to Cr(VI), what approaches do you currently use to assess potential hazards from eye or skin contact with Cr(VI)? What protective clothing and equipment do you use to protect employees from eye or skin contact with Cr(VI)? What does this protective clothing and equipment cost? Who pays for the protective clothing and equipment?

53. Should OSHA require the use of protective clothing and equipment for those employees who are exposed to airborne concentrations of Cr(VI) in excess of the PEL? If so, what type of protective clothing and equipment might be necessary?

54. OSHA has proposed to require that employers pay for protective clothing and equipment provided to employees. The Agency seeks comment on this provision, in particular:

a. Should OSHA refrain from requiring employer payment, and follow the outcome of the rulemaking addressing employer payment for personal protective equipment (64 FR 15401 (3/31/99))?

b. Are there circumstances where employers should not be required to pay for clothing and equipment used to protect employees from Cr(VI) hazards, such as situations where it is customary for employees to provide their own protective clothing and equipment (i.e., "tools of the trade")?

c. OSHA realizes that there is frequent turnover in the construction industry, where employees frequently move from jobsite to jobsite. This is an important factor because an employer with a high-turnover workplace would have to buy protective clothing and equipment for more employees if the protective clothing and equipment could only be used by one employee. The Agency requests comment on whether this proposal's requirement for employer payment for protective clothing and equipment is appropriate in the construction industry. Are there any alternative approaches that would be responsive to the turnover situation and would also be protective of construction workers? Are there any other issues specific to the construction industry that OSHA should be consider in this rulemaking?

d. At some ports, employees are hired for jobs in shipyards, longshoring, and marine terminals through a labor pool, and a single employee may work for five different employers in the same week. How do these factors affect who is required to pay for protective clothing and equipment? Are there any other issues specific to shipyards, longshoring, or marine terminals that OSHA should consider in this rulemaking?

55. OSHA is proposing that washing facilities capable of removing Cr(VI) from the skin be provided to affected employees, but does not propose that showers be required. Should OSHA include requirements to provide showers to employees exposed to Cr(VI)? If so, under what circumstances should showers be required? Describe work situations where showers are either unnecessary for employee protection or that present obstacles to their implementation and describe any such obstacles.

56. OSHA has not included housekeeping provisions in the proposed Cr(VI) standard for construction or shipyards. The Agency has made a preliminary determination that the housekeeping requirements proposed for general industry are likely to be difficult to implement in the construction and shipyard environments. Is this an appropriate determination? If not, what practicable housekeeping measures can construction and shipyard employers take to reduce employee exposure to Cr(VI) at the work site? What housekeeping activities are currently being performed?

57. Is medical surveillance being provided to Cr(VI)-exposed employees at your worksite? If so,

a. What exposure levels or other factors trigger medical surveillance?

b. What tests or evaluations are included in the medical surveillance program?

c. What benefits have been achieved from the medical surveillance program?

d. What are the costs of the medical surveillance program? How do your current costs compare with OSHA's estimated unit costs for the physical examination and employee time involved in the medical surveillance program? Please comment on OSHA's baseline assumptions and cost estimates for medical surveillance.

e. How many employees are included in your medical surveillance program?

f. In what North American Industry Classification System (NAICS) code does your workplace fall?

58. OSHA has proposed that medical surveillance be triggered in general industry in the following circumstances: (1) When exposure to Cr(VI) is above the PEL for 30 days or more per year; (2) after an employee experiences signs or symptoms of the adverse health effects associated with Cr(VI) exposure (*e.g.*, dermatitis, asthma); or (3) after exposure in an emergency. OSHA seeks comments as to whether or not these are appropriate triggers for offering medical surveillance and whether there are additional triggers that should be included. Should OSHA require that medical surveillance be triggered in general industry only upon an employee experiencing signs and symptoms of disease or after exposure in an emergency, as in the construction and maritime standards? OSHA also solicits comment on the optimal frequency of medical surveillance.

59. OSHA has proposed that medical surveillance be triggered in construction and shipyards in the following circumstances: (1) after an employee experiences signs or symptoms of the adverse health effects associated with Cr(VI) exposure (*e.g.*, dermatitis, asthma); or (2) after exposure in an emergency. Should medical surveillance in construction or shipyards be triggered by exposure to Cr(VI) above the PEL for 30 days or more per year, as proposed for general industry? OSHA seeks comments as to whether or not the proposed triggers are appropriate for offering medical surveillance and whether there are additional triggers that should be included.

60. OSHA has not included certain biological tests (*e.g.*, blood or urine monitoring, skin patch testing for sensitization, expiratory flow measurements for airway restriction) as a part of the medical evaluations required to be provided to employees offered medical surveillance under the proposed standard. OSHA has preliminarily determined that the general application of these tests is of uncertain value as an early indicator of potential Cr(VI)-related health effects. However, the proposed standard does allow for the provision of any tests (which could include urine or blood tests) that are deemed necessary by the physician or other licensed health care professional. Are there any tests (*e.g.*, urine tests, blood tests, skin patch tests, airway flow measurements, or others) that should be included under the proposed standard's medical surveillance provisions? If there are any that should be included, explain the rationale for their inclusion, including the benefit to worker health they might provide, their utility and ease of use in an occupational health surveillance program, and associated costs.

61. OSHA has not included requirements for medical removal protection (MRP) in the proposed standard. OSHA has made a preliminary determination that there are few instances where temporary worker removal and MRP will be useful. The Agency seeks comment as to whether the final Cr(VI) standard should include provisions for the temporary removal and extension of MRP benefits to employees with certain Cr(VI)-related health conditions. In particular, what endpoints should be considered for temporary removal and for what maximum amount of time should MRP benefits be extended? OSHA also seeks information on whether or not MRP is currently being used by employers with Cr(VI)-exposed workers, and the costs of such programs.

62. OSHA has proposed that employers provide hazard information to employees in accordance with the Agency's Hazard Communication standard (29 CFR 1910.1200), and has also proposed additional requirements regarding signs, labels, and additional training specific to work with Cr(VI). Should OSHA include these additional requirements in the final rule, or are the requirements of the Hazard Communication standard sufficient?

63. OSHA has proposed that bags or containers of laundry contaminated with Cr(VI) bear warning labels. Will this cause you to alter your current laundry practices? Are there laundries in your area that would accept such laundry? Would laundering costs increase? If so, by how much?

64. OSHA requests comment on the time allowed for compliance with the provisions of the proposed standard. Is the time proposed sufficient, or is a longer or shorter phase-in of requirements appropriate? Identify any industries, processes, or operations that have special needs for additional time, the additional time required and the reasons for the request.

65. Some other OSHA health standards have included appendices that address topics such as the hazards associated with the regulated substance, health screening considerations, occupational disease questionnaires, and PLHCP obligations. OSHA has not proposed to include any appendices with the Cr(VI) rule because the Agency has made a preliminary determination that such topics would be best addressed with guidance materials. What would be the advantage of including such appendices in the final rule? If you believe they should be included, what information should be included? What would be the disadvantage of including these appendices in the final rule?

III. Pertinent Legal Authority

The purpose of the Occupational Safety and Health Act, 29 U.S.C. 651 et seq. ("the Act") is to "assure so far as possible every working man and woman in the nation safe and healthful working conditions and to preserve our human resources." 29 U.S.C. 651(b). To achieve this goal Congress authorized the Secretary of Labor to promulgate and enforce occupational safety and health standards. 29 U.S.C. 655(a)(authorizing summary adoption of existing consensus and federal standards within two years of Act's enactment), 655(b)(authorizing promulgation of standards pursuant to notice and comment), 654(b)(requiring employers to comply with OSHA standards).

A safety or health standard is a standard "which requires conditions or the adoption of or use of one or more practices, means, methods, operations or processes, reasonably necessary or appropriate to provide safe or healthful employment or places of employment 29 U.S.C. 652(8).

A standard is reasonably necessary or appropriate within the meaning of Section 652(8) if it substantially reduces or eliminates significant risk, and is economically feasible, technologically feasible, cost effective, consistent with prior Agency action or supported by a reasoned justification for departing from prior Agency actions, supported by substantial evidence, and is better able to effectuate the Act's purpose than any national consensus standard it supersedes. See 58 Fed. Reg. 16612–16616 (March 30, 1993).

OSHA has generally considered, at minimum, fatality risk of 1/1000 over a 45-year working lifetime to be a significant health risk. *See* the Benzene standard, *Industrial Union Dep't* v. *American Petroleum Institute,* 448 U.S. 607, 646 ((1980); the Asbestos standard, *International Union, UAW* v. *Pendergrass,* 878 F.2d 389, 393 (D.C. Cir. 1989).

A standard is technologically feasible if the protective measures it requires already exist, can be brought into existence with available technology, or can be created with technology that can reasonably be expected to be developed. *American Textile Mfrs. Institute* v. *OSHA,* 452 U.S. 490, 513 (1981)("ATMI") American Iron and Steel Institute v. OSHA, 939 F.2d 975, 980 (D.C. Cir. 1991)("AISI").

A standard is economically feasible if industry can absorb or pass on the costs of compliance without threatening its long-term profitability or competitive structure. *See* ATMI, 452 U.S. at 530 n. 55; AISI, 939 F. 2d at 980.

A standard is cost effective if the protective measures it requires are the least costly of the available alternatives that achieve the same level of protection. ATMI, 453, U.S, at 514 n. 32; International *Union, UAW* v. *OSHA,* 37 F.3d 665, 668 (D.C., Cir 1994)("LOTO III").

All standards must be highly protective. See 58 FR 16614–16615; LOTO III, 37 F. 3d at 669. However, health standards must also meet the "feasibility mandate" of Section 6(b)(7) of the Act, 29 U.S.C. 655(b)(5). Section 6(b)(5) requires OSHA to select "The most protective standard consistent with feasibility" that is needed to reduce significant risk when regulating health standards. ATMI, 452 U.S. at 509.

Section 6(b)(5) also directs OSHA to base health standard on "the best available evidence," including research, demonstrations, and experiments. 29 U.S.C. 655(b)(5). OSHA shall consider "in addition to the attainment of the highest degree of health and safety protection * * * feasibility and experience gained under this and other health and safety laws." *Id.*

Section 6(b)(7) authorizes OSHA to include among a standard's requirements labeling, monitoring, medical testing and other information gathering and transmittal provisions. 29 U.S.C. 655(b)(7).

Finally, whenever practical, standards shall "be expressed in terms of objective criteria and of the performance desired." *Id.*

IV. Events Leading to the Proposed Standards

OSHA's present standards for workplace exposure to Cr(VI) were adopted in 1971, pursuant to section 6(a) of the OSH Act, from a 1943 American National Standards Institute (ANSI) recommendation originally established to control irritation and damage to nasal tissues (Ex. 20–3). OSHA's general industry standard set a permissible exposure limit (PEL) of 1 mg chromium trioxide per 10 m^3 air in the workplace (1 mg/10 m^3 CrO_3) as a ceiling concentration, which corresponds to a concentration of 52 µg/m^3 Cr(VI). A separate rule promulgated for the construction industry set an eight-hour time-weighted-average PEL of 1 mg/10 m^3 CrO_3, also equivalent to 52 µg/m^3 Cr(VI), adopted from the American Conference of Governmental Industrial Hygienists (ACGIH) 1970 Threshold Limit Value (TLV) (36 FR 7340 (4/17/71)).

Following the ANSI standard of 1943, other occupational and public health organizations evaluated Cr(VI) as a workplace and environmental hazard and formulated recommendations to control exposure. The ACGIH first recommended control of workplace exposures to chromium in 1946, recommending a time-weighted average Maximum Allowable Concentration (later called a Threshold Limit Value) of 100 µg/m^3 for chromic acid and chromates as Cr_2O^3 (Ex. 5–37), and classified certain Cr(VI) compounds as class A1 (confirmed human) carcinogens in 1974. In 1975, the NIOSH Criteria for a Recommended Standard recommended that occupational exposure to Cr(VI) compounds should be limited to a 10-hour TWA of 1 µg/m^3, except for some forms of Cr(VI) then believed to be noncarcinogenic (Ex. 3–92). The National Toxicology Program's First Annual Report on Carcinogens identified calcium chromate, chromium chromate, strontium chromate, and zinc chromate as carcinogens in 1980 (Ex. 35–157).

During the 1980s, regulatory and standards organizations came to recognize Cr(VI) compounds in general as carcinogens. The Environmental Protection Agency (EPA) Health Assessment Document of 1984 stated that "using the IARC [International Agency for Research on Cancer] classification scheme, the level of evidence available for the combined animal and human data would place hexavalent chromium Cr(VI) compounds into Group 1, meaning that there is decisive evidence for the carcinogenicity of those compounds in humans" (Ex. 19–1, p. 7–107). In 1988 IARC evaluated the available evidence regarding Cr(VI) carcinogenicity, concluding in 1990 that "There is sufficient evidence in humans for the carcinogenicity of chromium[VI] compounds as encountered in the chromate production, chromate pigment production and chromium plating industries", and "sufficient evidence in experimental animals for the carcinogenicity of calcium chromate, zinc chromates, strontium chromate and lead chromates'(Ex. 18–3, p. 213). In September 1988, NIOSH advised OSHA to consider all Cr(VI) compounds as potential occupational carcinogens (Ex. 31–22–22, p. 8). ACGIH now classifies water-insoluble and water-soluble Cr(IV) compounds as class A1 carcinogens (Ex. 35–207). Current ACGIH standards include specific 8-hour time-weighted average TLVs for calcium chromate (1 µg/m^3), lead chromate (12 µg/m^3), strontium chromate (0.5 µg/m^3), and zinc chromates (10 µg/m^3), and generic TLVs for water soluble (50 µg/m^3) and insoluble (10 µg/m^3) forms of hexavalent chromium not otherwise classified, all measured as chromium (Ex. 35–207).

In July 1993, OSHA was petitioned for an emergency temporary standard to reduce occupational exposures to Cr(VI) compounds (Ex. 1). The Oil, Chemical, and Atomic Workers International Union (OCAW) and Public Citizen's Health Research Group (HRG), citing evidence that occupational exposure to Cr(VI) increases workers' risk of lung cancer, petitioned OSHA to promulgate an emergency temporary standard to lower the PEL for Cr(VI) compounds to 0.5 µg/m^3 as an eight-hour, time-weighted average (TWA). Upon review of the petition, OSHA agreed that there was evidence of increased cancer risk from exposure to Cr(VI) at the existing PEL, but found that the available data did not show the "grave danger" required to support an emergency temporary standard (Ex. 1–C). The Agency therefore denied the request for an emergency temporary standard, but initiated section 6(b)(5) rulemaking and began performing preliminary analyses relevant to the rule. In 1997, OSHA was sued by HRG for unreasonable delay in issuing a Cr(VI) standard. The U.S. Court of Appeals for the Third Court ruled in OSHA's favor and the Agency continued its data collection and analytic efforts on Cr(VI) (Ex. 35–208, p. 3). OSHA was sued again in 2002 by HRG for continued unreasonable delay in issuing a Cr(VI) standard (Ex. 31–24–1). In August 2002, OSHA published a Request for Information on Cr(VI) to solicit additional information on key issues related to controlling exposures to Cr(VI)(67 FR 54389 (8/22/02)), and on December 4, 2002 announced its intent to proceed with developing a proposed standard (Ex. 307). The Court ruled in favor of HRG on December 24, 2002, ordering the Agency to proceed expeditiously with a Cr(VI) standard (Ex. 35–208). On April 2, 2003 the Court set deadlines of October 4, 2004 for publication of a proposed standard and January 18, 2006 for publication of a final standard (Ex. 35–306).

OSHA initiated Small Business Regulatory Enforcement Act (SBREFA) proceedings in 2003, seeking the advice of small business representatives on the proposed rule. The SBREFA panel, including representatives from OSHA, the Small Business Administration (SBA), and the Office of Management and Budget (OMB), was convened on December 23, 2003. The panel conferred with representatives from small entities in chemical, alloy, and pigment manufacturing, electroplating, welding, aerospace, concrete, shipbuilding, masonry, and construction on March 16–17, 2004, and delivered its final report to OSHA on April 20, 2004. The Panel's report, including comments from the small entity representatives (SERS) and recommendations to OSHA for the proposed rule, is available in the Cr(VI) rulemaking docket (Ex. 34).

OSHA provided the Advisory Committee on Construction Safety and Health (ACCSH) and the Maritime Advisory Committee on Occupational Safety and Health (MACOSH) with copies of the draft proposed rule for review in early 2004. OSHA representatives met with ACCSH in February 2004 and May 2004 to discuss the rulemaking and receive their comments and recommendations. On February 13, ACCSH recommended that portland cement should be included

within the scope of the proposed standard (Ex. 35–308, pp. 288–293) and that identical PELs should be set for the construction, maritime, and general industries (Ex. 35–308, pp. 293–297). The Committee recommended on May 18 that the construction industry should be included in the current rulemaking, and affirmed its earlier recommendation regarding portland cement. OSHA representatives met with MACOSH in March 2004. On March 3, MACOSH decided to collect and forward additional exposure monitoring data to OSHA to help the Agency better evaluate exposures to Cr(VI) in shipyards (Ex. 310, p. 208). MACOSH also recommended a separate Cr(VI) standard for the maritime industry, arguing that maritime involves different exposures and requires different means of exposure control than general industry and construction (Ex. 310, p. 227).

V. Chemical Properties and Industrial Uses

Chromium is a metal that exists in several oxidation or valence states, ranging from chromium (−II) to chromium (+VI). The elemental valence state, chromium (0), does not occur in nature. Chromium compounds are very stable in the trivalent state and occur naturally in this state in ores such as ferrochromite, or chromite ore ($FeCr_2O_4$). The hexavalent, Cr(VI) or chromate, is the second most stable state. It rarely occurs naturally; most Cr(VI) compounds are man made.

Chromium compounds in higher valence states are able to undergo "reduction" to lower valence states; chromium compounds in lower valence states are able to undergo "oxidation" to higher valence states. Thus, Cr(VI) compounds can be reduced to Cr(III) in the presence of oxidizable organic matter. Chromium can also be reduced in the presence of inorganic chemicals such as iron.

Chromium does exist in less stable oxidation (valence) states such as Cr(II), Cr(IV), and Cr(V). Anhydrous Cr(II) salts are relatively stable, but the divalent state (II, or chromous) is generally relatively unstable and is readily oxidized to the trivalent (III or chromic) state. Compounds in valence states such as (IV) and (V) usually require special handling procedures as a result of their instability. Cr(IV) oxide (CrO_2) is used in magnetic recording and storage devices, but very few other Cr(IV) compounds have industrial use. Evidence exists that both Cr(IV) and Cr(V) are formed as transient intermediates in the reduction of Cr(VI) to Cr(III) in the body.

Chromium (III) is also an essential nutrient that plays a role in glucose, fat, and protein metabolism by causing the action of insulin to be more effective. Chromium picolinate, a trivalent form of chromium combined with picolinic acid, is used as a dietary supplement, because it is claimed to speed metabolism.

Elemental chromium and the chromium compounds in their different valence states have various physical and chemical properties, including differing solubilities. Most chromium species are solid. Elemental chromium is a steel gray solid, with high melting and boiling points (1857 °C and 2672 °C, respectively), and is insoluble in water and common organic solvents. Chromium (III) chloride is a violet or purple solid, with high melting and sublimation points (1150 °C and 1300 °C, respectively), and is slightly soluble in hot water and insoluble in common organic solvents. Ferrochromite is a brown-black solid; chromium (III) oxide is a green solid; and chromium (III) sulfate is a violet or red solid, insoluble in water and slightly soluble in ethanol. Chromium (III) picolinate is a ruby red crystal soluble in water (1 part per million at 25 °C). Chromium (IV) oxide is a brown-black solid that decomposes at 300 °C and is insoluble in water.

Cr(VI) compounds have mostly lemon yellow to orange to dark red hues. They are typically crystalline, granular, or powdery although one compound (chromyl chloride) exists in liquid form. They range from very soluble to insoluble in water. For example, chromyl chloride is a dark red liquid that decomposes into chromate ion and hydrochloric acid in water. Chromic acids are dark red crystals that are very soluble in water. Other examples of soluble chromates are potassium chromate (lemon yellow crystals), sodium chromate (yellow crystals), and sodium dichromate (reddish to bright orange crystals). Nickel chromate, lead chromate oxide, and zinc chromate are completely insoluble in water. The nickel chromate (black crystals) dissolves in nitric acid and hydrogen peroxide. Lead chromate oxide is a red crystalline powder. The zinc chromate (lemon yellow crystals) decomposes in hot water and is soluble in acids and liquid ammonia. Examples of slightly soluble Cr(VI) compounds are barium (light yellow), calcium (yellow), lead (yellow to orange-yellow), and strontium (yellow) chromates, and zinc chromate hydroxide (yellow). They all exist in solid form as crystals or powder. Potassium zinc chromate hydroxide (greenish-yellow crystals) is also slightly soluble in water.

Some major users of chromium are the metallurgical, refractory, and chemical industries. Chromium is used by the metallurgical industry to produce stainless steel, alloy steel, and nonferrous alloys. Chromium is alloyed with other metals and plated on metal and plastic substrates to improve corrosion resistance and provide protective coatings for automotive and equipment accessories. Welders use stainless steel welding rods when joining metal parts.

Cr(VI) compounds are widely used in the chemical industry in pigments, metal plating, and chemical synthesis as ingredients and catalysts. Chromates are used as high quality pigments for textile dyes, paints, inks, glass, and plastics. Cr(VI) can be produced during welding operations even if the chromium was originally present in another valence state. While Cr(VI) is not intentionally added to portland cement, it is often present as an impurity.

Occupational exposures to Cr(VI) can occur from inhalation of mists (*e.g.*, chrome plating, painting), dusts (*e.g.*, inorganic pigments), or fumes (*e.g.*, stainless steel welding), and from dermal contact (cement workers).

There are about thirty major industries and processes where Cr(VI) is used. These include producers of chromates and related chemicals from chromite ore, electroplating, welding, painting, chromate pigment production and use, steel mills, and iron and steel foundries. A detailed discussion of the uses of Cr(VI) in industry is found in Section IX of this preamble.

VI. Health Effects

The studies of adverse health effects resulting from exposure to hexavalent chromium (Cr(VI)) in humans and experimental animals are summarized in the section below. Section VI includes information on the fate of Cr(VI) in the body and laboratory research that relates to its toxic mode of action. The primary health impairments from workplace exposure to Cr(VI) are lung cancer, asthma, and damage to the nasal epithelia and skin. This chapter on health effects will not attempt to describe every study ever conducted on Cr(VI) toxicity. Instead, only the most important articles and reviews of studies will be evaluated.

A. Absorption, Distribution, Metabolic Reduction and Elimination

Chromium can exist in a number of valence states from −2 to +6 valence. The most common forms are the elemental metal Cr(0), trivalent Cr(III), and hexavalent Cr(VI). Chromium exists naturally in the environment in

chromite ore as Cr(III). Cr(0) and Cr(VI), as well as Cr(III) are produced during industrial processes. Cr(VI) is the form considered to be the greatest health risk. A small amount of Cr(III) is needed for optimal insulin receptor function in human tissues but much larger amounts may be harmful. Much less is known about the toxicity of Cr(0), but it is believed to be converted to Cr(III) in the body and is not considered to be a serious health risk. Cr(VI) enters the body by inhalation, ingestion, or absorption through the skin. For occupational exposure, the airways and skin are the primary routes of uptake.

1. Deposition and Clearance of Inhaled Cr(VI) From the Respiratory Tract

Various anatomical, physical and physiological factors determine both the fractional and regional deposition of inhaled particulate matter. Due to the airflow patterns in the lung more particles tend to deposit at certain preferred regions in the lung. Schlesinger and Lippman have shown a high degree of correlation between sites of greatest particle deposition in the tracheobronchial airways and increased incidence of bronchial tumors (Ex. 35–102). It is possible to have a buildup of chromium at certain sites in the bronchial tree that could create areas of very high chromium concentration. This would especially be true for occupational environments that are particularly dusty or contain other irritating aerosols.

Large inhaled particles (>5 μm) are efficiently removed from the air-stream in the extrathoracic region (Ex. 35–175). Particles greater than 2.5 μm are generally deposited in the tracheobronchial regions, whereas particles less than 2.5 μm are generally deposited in the pulmonary region. Some larger particles (>2.5 μm) can reach the pulmonary region. The mucociliary escalator predominantly clears particles that deposit in the extrathoracic and the tracheobronchial region of the lung. Individuals exposed to high particulate levels of Cr(VI) may also have altered respiratory mucociliary clearance. Particulates that reach the alveoli can be absorbed into the bloodstream cleared by phagocytosis.

2. Absorption of Inhaled Cr(VI) Into the Bloodstream

The absorption of inhaled chromium compounds depends on a number of factors, including physical and chemical properties of the particles (oxidation state, size, solubility) and the activity of alveolar macrophages (Ex. 35–41). The hexavalent chromate anion $(CrO_4)^{2-}$ enter cells via facilitated diffusion through non-specific anion channels (similar to phosphate and sulfate anions). Suzuki *et al.* have demonstrated that Cr(VI) is rapidly and extensively transported to the bloodstream in rats (Ex. 35–97). They exposed rats to 7.3–15.9 mg Cr(VI)/m^3 as potassium dichromate for 2–6 hours. Following exposure to Cr(VI), the ratio of blood chromium/lung chromium was 1.44±0.30 at 0.5 hours, 0.81±0.10 at 18 hours, 0.85±0.20 at 48 hours, and 0.96±0.22 at 168 hours after exposure.

Once the Cr(VI) particles reach the alveoli, absorption into the bloodstream is greatly dependent on solubility. Bragt and van Dura demonstrated that more soluble chromates are absorbed faster than less soluble chromates (Ex. 35–56). Insoluble chromates are poorly absorbed and therefore have longer resident time in the lungs. They studied the kinetics of three Cr(VI) compounds: Sodium chromate, zinc chromate and lead chromate. They instilled ^{51}chromium-labeled compounds (0.38 mg Cr(VI)/kg as sodium chromate, 0.36 mg Cr(VI)/kg as zinc chromate, or 0.21 mg Cr(VI)/kg as lead chromate) intratracheally in rats. Peak blood levels of ^{51}chromium were reached after 30 minutes for sodium chromate (0.35 μg chromium/ml), and after 24 hours for zinc chromate (0.60 μg chromium/ml) and lead chromate (0.007 μg chromium/ml). At 30 minutes after administration, the lungs contained 36, 25, and 81% of the respective dose of the sodium, zinc, and lead chromate. On day six, >80% of the dose of all three compounds had been cleared from the lungs, during which time the disappearance from lungs followed linear first-order kinetics. The residual amount left in the lungs on day 50 or 51 was 3.0, 3.9, and 13.9%, respectively. From these results authors concluded that zinc chromate, which is less soluble than sodium chromate, is more slowly absorbed from the lungs. Lead chromate was more poorly and slowly absorbed, as indicated by very low levels in blood and greater retention in the lungs. The authors also noted that the kinetics of sodium and zinc chromates were very similar. Zinc chromate, which is less soluble than sodium chromate, was slowly absorbed from the lung, but the maximal blood levels were higher than those resulting from an equivalent dose of sodium chromate. The authors believe that this was probably due to irritative properties of the zinc chromate used, as it caused hemorrhages in the lungs which were macroscopically visible as early as 24 hours after intratracheal administration.

The studies by Langard *et al.* and Adachi *et al.* provide further evidence of absorption of chromates from the lungs (Exs. 35–93; 189). Rats exposed to 2.1 mg Cr(VI)/m^3 as zinc chromate for 6 hours/day achieved steady state concentrations in the blood after 4 days of exposure (Ex. 35–93). Adachi *et al.* studied rats that were subject to a single inhalation exposure to chromic acid mist generated from electroplating at a concentration of 3.18 mg Cr(VI)/m^3 for 30 minutes which was then rapidly absorbed from the lungs (Ex. 189). The amount of chromium in the lungs of these rats declined from 13.0 mg immediately after exposure to 1.1 mg after 4 weeks, with an overall half-life of five days.

Several other studies have reported absorption of chromium from the lungs after intratracheal instillation (Exs. 7–9; 9–81; Visek *et al.* 1953 as cited in Ex. 35–41). These studies indicated that 53–85% of Cr(VI) compounds (particle size <5 μm) were cleared from the lungs by absorption into the bloodstream or by mucociliary clearance in the pharynx; the rest remained in the lungs. Absorption of Cr(VI) from the respiratory tract of workers has been shown in several studies that identified chromium in the urine, serum and red blood cells following occupational exposure (Exs. 5–12; 35–294; 35–84).

Evidence indicates that even chromates that are encapsulated in a paint matrix may be released in the lungs (Ex. 31–15, p. 2). LaPuma *et al.* measured the mass of Cr(VI) released from particles into water originating from three types of paint particles: solvent-borne expoxy (25% strontium chromate ($SrCrO_4$)), water-borne expoxy (30% $SrCrO_4$) and polyurethane (20% $SrCrO_4$) (Ex. 31–2–1). The mean fraction of Cr(VI) released into the water after one and 24 hours for each primer averaged: 70% and 85% (solvent epoxy), 74% and 84% (water epoxy), and 94% and 95% (polyurethane). Correlations between particle size and the fraction of Cr(VI) released indicated that smaller particles (<5 m) release a larger fraction of Cr(VI) versus larger particles (>5 μm). This study demonstrates that the paint matrix only modestly hinders Cr(VI) release into a fluid, especially with smaller particles. Larger particles, which contain the majority of Cr(VI) due to their size, appear to release proportionally less Cr(VI) (as a percent of total Cr(VI)) than smaller particles.

A number of questions remain unanswered regarding encapsulated Cr(VI) and bioavailability from the lung. There is a lack of detailed information on the encapsulation process. The efficiency of encapsulation and whether all of the chromate molecules are

encapsulated is not known. The stability of the encapsulated product in physiological and environmental conditions has not been demonstrated. It would be useful to know if any processes can break the encapsulation during its use. Finally, the fate of inhaled encapsulated and unencapsulated Cr(VI) in the respiratory tract as well as the systemic tissues needs to be more thoroughly studied.

3. Dermal Absorption of Cr(VI)

Both human and animal studies demonstrate that Cr(VI) compounds are absorbed after dermal exposure. Dermal absorption depends on the oxidation state of chromium, the vehicle and the integrity of the skin. Cr(VI) readily traverses the epidermis to the dermis (Exs. 9–49; 309). The histological distribution of Cr(VI) within intact human skin was studied by Liden and Lundberg (Ex. 35–80). They applied test solutions of potassium dichromate in petrolatum or in water as occluded circular patches of filter paper to the skin. Results with potassium dichromate in water revealed that Cr(VI) penetrated beyond the dermis and penetration reached steady state with resorption by the lymph and blood vessels by 5 hours. About 10 times more chromium penetrated when potassium dichromate was applied in petrolatum than when applied in water, indicating that organic solvents facilitate the absorption of Cr(VI) from the skin. Baranowska-Dutkiewicz also demonstrated that the absorption rates of sodium chromate solutions from the occluded forearm skin of volunteers increase with increasing concentration (Ex. 35–75). The rates were 1.1 μg Cr(VI)/cm²/hour for a 0.01 molar solution, 6.4 μg Cr(VI)/cm²/hour for a 0.1 molar solution, and 10 μg Cr(VI)/cm²/hour for a 0.2 molar solution.

Using volunteers, Mali found that potassium dichromate penetrates the intact epidermis (Exs. 9–49; 35–41). Wahlberg and Skog demonstrated the presence of chromium in the blood, spleen, bone marrow, lymph glands, urine and kidneys of guinea pigs exposed to ^{51}chromium labeled Cr(VI) compounds (Ex. 35–81). In this study radiolabeled sodium chromate solution was dermally applied to guinea pigs and ^{51}Cr was monitored by scintillation counting in tissues. These studies demonstrate that the absorption of Cr(VI) compounds can take place through the dermal route. Also, the absorption of Cr(VI) can be facilitated by organic solvents.

4. Absorption of Cr(VI) by the Oral Route

Inhaled Cr(VI) can enter the digestive tract as a result of mucocilliary clearance and swallowing. Studies indicate Cr(VI) is absorbed from the gastrointestinal tract. The six-day fecal and 24-hour urinary excretion patterns of radioactivity in groups of six volunteers given Cr(VI) as sodium chromate labeled with ^{51}chromium indicated that at least 2.1% of the Cr(VI) was absorbed. After intraduodenal administration at least 10% of the Cr(VI) compound was absorbed. These studies also demonstrated that Cr(VI) compounds are reduced to Cr(III) compounds in the stomach, thereby accounting for the relatively poor gastrointestinal absorption of orally administered Cr(VI) compounds (Exs. 35–96; 35–41).

In the gastrointestinal tract, Cr(VI) can be reduced to Cr(III) by gastric juices, which is then poorly absorbed (Underwood, 1971 as cited in Ex. 19–1; Ex. 35–85). The mechanism by which Cr(VI) is carried across the intestinal wall and the site of absorption are not known and may well depend upon the efficiency of defense mechanisms (Mertz, 1969 as cited in Ex. 19–1).

Kuykendall *et al.* studied the absorption of Cr(VI) in human volunteers after oral administration of potassium dichromate (Ex. 35–77). They reported the bioavailability based on 14-day urinary excretion to be 6.9% (range 1.2–18%) for Cr(VI). Other investigators have also reported absorption of Cr(VI) compounds after oral administration (Exs. 35–76; 31–22–13; 35–91).

Studies with ^{51}chromium in animals also indicate that chromium and its compounds are poorly absorbed from the gastrointestinal tract after oral exposure. When radioactive sodium chromate (Cr(VI)) was given orally to rats, the amount of chromium in the feces was greater than that found when sodium chromate was injected directly into the small intestine. These results are consistent with evidence that the gastric environment has a capacity to reduce Cr(VI) to Cr(III) and therefore decrease the amount of Cr(VI) absorbed from the GI tract.

Treatment of rats by gavage with an unencapsulated lead chromate pigment or with a silica-encapsulated lead chromate pigment resulted in no measurable blood levels of chromium (measured as Cr(III), detection limit=10 μg/L) after two or four weeks of treatment or after a two-week recovery period. However, kidney levels of chromium (measured as Cr(III)) were significantly higher in the rats that received the unencapsulated pigment when compared to the rats that received the encapsulated pigment, indicating that silica encapsulation may reduce the gastrointestinal bioavailability of chromium from lead chromate pigments (Ex. 11–5). This study does not address the bioavailability of encapsulated chromate pigments from the lung where residence time could be different.

5. Distribution of Cr(VI) in the Body

Once in the bloodstream, Cr(VI) is taken up into erythrocytes, where it is reduced to lower oxidation states and forms chromium protein complexes during reduction (Ex. 35–41). Once complexed with protein, chromium cannot leave the cell. The binding of chromium compounds by proteins in the blood has been studied in some detail (Exs. 5–24; 35–41; 35–52). It was found that intravenously injected anionic Cr(VI) passes through the membrane of red blood cells and binds to the globin fraction of hemoglobin. It has been hypothesized that before Cr(VI) is bound by hemoglobin, it is reduced to Cr(III) by an enzymatic reaction within red blood cells. Once inside the blood cell, chromium ions are unable to repenetrate the membrane and move back into the plasma (Exs. 7–6; 7–7; 19–1; 35–41; 35–52). According to Aaseth *et al.*, the intracellular Cr(VI) reduction depletes Cr(VI) concentration in the red blood cell (Ex. 35–89). This serves to enhance diffusion of Cr(VI) from the plasma into the erythrocyte resulting in very low plasma levels of Cr(VI). It is also believed that the rate of uptake of Cr(VI) by red blood cells may not exceed the rate at which they reduce Cr(VI) to Cr(III) (Ex. 35–99). The higher tissue levels of chromium after administration of Cr(VI) than after administration of Cr(III) reflect the greater tendency of Cr(VI) to traverse plasma membranes and bind to intracellular proteins in the various tissues, which may explain the greater degree of toxicity associated with Cr(VI) (MacKenzie *et al.* 1958 as cited in 35–52; Maruyama 1982 as cited in 35–41; Ex. 35–71).

Examination of autopsy tissues from chromate workers who were occupationally exposed to Cr(VI) showed that the highest chromium levels were in the lungs. The liver, bladder, and bone also had chromium levels above background. Mancuso examined tissues from three individuals with lung cancer who were exposed to chromium in the workplace (Ex. 124). One was employed for 15 years as a welder, the second and third worked for 10.2 years and 31.8 years, respectively, in ore milling and preparations and boiler operations. The cumulative

chromium exposures for the three workers were estimated to be 3.45, 4.59, and 11.38 mg/m ^{3}–years, respectively. Tissues from the first worker were analyzed 3.5 years after last exposure, the second worker 18 years after last exposure, and the third worker 0.6 years after last exposure. All tissues from the three workers had elevated levels of chromium, with the possible exception of neural tissues. Levels were orders of magnitude higher in the lungs when compared to other tissues. The highest lung level reported was 456 mg/10 g tissue in the first worker, 178 in the second worker, and 1,920 for the third worker. There were significant chromium levels in the tissue of the second worker even though he had not been exposed to chromium for 18 years. Similar results were also reported in autopsy studies of people who may have been exposed to chromium in the workplace as well as chrome platers and chromate refining workers (Exs. 35–92; 21–1; 35–74; 35–88).

Animal studies have shown similar distribution patterns after inhalation exposure. The distribution of Cr(VI) compared with Cr(III) was investigated in guinea pigs after intratracheal instillation of potassium dichromate or chromium trichloride (Ex. 7–8). At 24 hours after instillation, 11% of the original dose of chromium from potassium dichromate remained in the lungs, 8% in the erythrocytes, 1% in plasma, 3% in the kidney, and 4% in the liver. The muscle, skin, and adrenal glands contained only a trace. All tissue concentrations of chromium declined to low or nondetectable levels in 140 days, with the exception of the lungs and spleen. After chromium trichloride instillation, 69% of the dose remained in the lungs at 20 minutes, while only 4% was found in the blood and other tissues, with the remaining 27% cleared from the lungs and swallowed. The only tissue that contained a significant amount of chromium two days after instillation of chromium trichloride was the spleen. After 30 and 60 days, 30 and 12%, respectively, of the Cr(III) was retained in the lungs, while only 2.6 and 1.6%, respectively, of the Cr(VI) dose was retained in the lungs.

6. Metabolic Reduction of Cr(VI)

Cr(VI) is reduced to Cr(III) in the lungs by a variety of reducing agents. This serves to limit uptake into lung cells and absorption into the bloodstream. Cr(V) and Cr(IV) are transient intermediates in this process. The genotoxic effects produced by the Cr(VI) are related to the reduction process and are further discussed in the section on Mechanistic Considerations.

In vivo and *in vitro* experiments in rats indicated that, in the lungs, Cr(VI) can be reduced to Cr(III) by ascorbate and glutathione. The reduction of Cr(VI) by glutathione is slower than the reduction by ascorbate (Ex. 35–65). Other studies have reported the reduction of Cr(VI) to Cr(III) by epithelial lining fluid (ELF) obtained from the lungs of 15 individuals by bronchial lavage. The average overall reduction capacity was 0.6 µg Cr(VI)/mg of ELF protein. In addition, cell extracts made from pulmonary alveolar macrophages derived from five healthy male volunteers were able to reduce an average of 4.8 µg Cr(VI)/10 ^{6} cells or 14.4 µg Cr(VI)/mg protein (Ex. 35–83). Postmitochondrial (S12) preparations of human lung cells (peripheral lung parenchyma and bronchial preparations) were also able to reduce Cr(VI) to Cr(III) (De Flora *et al.* 1984 as cited in Ex. 35–41). As discussed earlier, Cr(VI) is also reduced to Cr(III) in the gastric environment by the gastric juice (Ex. 35–85) and ascorbate after oral exposure (Ex. 35–82).

7. Elimination of Cr(VI) From the Body

Excretion of chromium from Cr(VI) compounds is predominantly in the urine, although there is some biliary excretion into the feces. In both urine and feces, the chromium is present as low molecular weight Cr(III) complexes. Absorbed chromium is excreted from the body in a rapid phase representing clearance from the blood and at least two slower phases representing clearance from tissues. Urinary excretion accounts for over 50% of eliminated chromium (Ex. 35–41). Although chromium is excreted in urine and feces, the intestine plays only a minor part in chromium elimination, representing only about 5% of elimination from the blood (Ex. 19–1). Normal urinary levels of chromium in humans have been reported to range from 0.24–1.8 µg/L with a median level of 0.4 µg/L (Ex. 35–79). Humans exposed to 0.05–1.7 mg Cr(III)/m ^{3} as chromium sulfate and 0.01–0.1 mg Cr(VI)/m ^{3} as potassium dichromate (8-hour time-weighted average) had urinary excretion levels from 0.0247 to 0.037 mg Cr(III)/L. Workers exposed mainly to Cr(VI) compounds had higher urinary chromium levels than workers exposed primarily to Cr(III) compounds. An analysis of the urine did not detect Cr(VI), indicating that Cr(VI) was rapidly reduced before excretion (Exs. 35–294; 5–48).

A half-life of 15–41 hours has been estimated for chromium in urine for four welders using a linear one-compartment kinetic model (Exs. 35–73; 5–52; 5–53). Limited work on modeling the absorption and deposition of chromium indicates that adipose and muscle tissue retain chromium at a moderate level for about two weeks, while the liver and spleen store chromium for up to 12 months. The estimated half-life for whole body chromium retention is 22 days for Cr(VI) and 92 days for Cr(III) (Ex. 19–1). The half-life of chromium in the human lung is 616 days, which is similar to the half-life in rats (Ex. 7–5).

Elimination of chromium was shown to be very slow in rats exposed to 2.1 mg Cr(VI)/m ^{3} as zinc chromate six hours/day for four days. Urinary levels of chromium remained almost constant for four days after exposure and then decreased (Ex. 35–93). After intratracheal administration of sodium dichromate to rats, peak urinary chromium concentrations were observed at six hours, after which the urinary concentrations declined rapidly (Ex. 35–94). The more prolonged elimination of the less soluble zinc chromate as compared to the more soluble sodium dichromate is consistent with the influence of Cr(VI) solubility on absorption from the respiratory tract discussed earlier.

Information regarding the excretion of chromium in humans after dermal exposure to chromium or its compounds is limited. Fourteen days after application of a salve containing potassium chromate, which resulted in skin necrosis and sloughing at the application site, chromium was found at 8 mg/L in the urine and 0.61 mg/100 g in the feces of one individual (Brieger 1920 as cited in Ex. 19–1). A slight increase over background levels of urinary chromium was observed in four subjects submersed in a tub of chlorinated water containing 22 mg Cr(VI)/L as potassium dichromate for three hours (Ex. 31–22–6). For three of the four subjects, the increase in urinary chromium excretion was less than 1 µg/day over the five-day collection period. Chromium was detected in the urine of guinea pigs after radiolabeled sodium chromate solution was applied to the skin (Ex. 35–81).

8. Physiologically-based Pharmacokinetic Modeling

O'Flaherty developed physiologically-based pharmacokinetic (PBPK) models that simulate absorption, distribution, metabolism, and excretion of Cr(VI) and Cr(III) compounds in humans (Ex. 35–95) and rats (Exs. 35–86; 35–70). The original model (Ex. 35–86) evolved from a similar model for lead, and contained compartments for the lung, GI tract, skin, blood, liver, kidney, bone, well-

perfused tissues, and slowly perfused tissues. The model was refined to include two lung subcompartments for chromium, one of which allowed inhaled chromium to enter the blood and GI tract and the other only allowed chromium to enter the GI tract (Ex. 35–70). Reduction of Cr(VI) to Cr(III) was considered to occur in every tissue compartment except bone.

The model was developed from several data sets in which rats were dosed with Cr(VI) or Cr(III) intravenously, orally or by intratracheal instillation, because different distribution and excretion patterns occur depending on the route of administration. In most cases, the model parameters (*e.g.*, tissue partitioning, absorption, reduction rates) were estimated by fitting model simulations to experimental data. The optimized rat model was validated against the 1978 Langard inhalation study (Ex. 35–93). Chromium blood levels were overpredicted during the four-day inhalation exposure period, but blood levels during the post-exposure period were well predicted by the model. The model-predicted levels of liver chromium were high, but other tissue levels were closely estimated.

A human PBPK model recently developed by O'Flaherty *et al.* is able to predict tissue levels from ingestion of Cr(VI) (Ex. 35–95). The model incorporates differential oral absorption of Cr(VI) and Cr(III), rapid reduction of Cr(VI) to Cr(III) in major body fluids and tissues, and concentration-dependent urinary clearance. The model does not include a physiologic lung compartment, but can be used to estimate an upper limit on pulmonary absorption of inhaled chromium. The model was calibrated against blood and urine chromium concentration data from a group of controlled studies in which adult human volunteers drank solutions of soluble Cr(III) or Cr(VI).

PBPK models are increasingly used in risk assessments, primarily to predict the concentration of a potentially toxic chemical that will be delivered to any given target tissue following various combinations of route, dose level, and test species. Further development of the respiratory tract portion of the model, specific Cr(VI) rate data on extracellular reduction and uptake into lung cells, and more precise understanding of critical pathways inside target cells would improve the model value for risk assessment purposes.

9. Summary

Based on the studies presented above, evidence exists in the literature that shows Cr(VI) can be systemically absorbed by the respiratory tract. The absorption of inhaled chromium compounds depends on a number of factors, including physical and chemical properties of the particles (oxidation state, size, and solubility), the reduction capacity of the ELF and alveolar macrophages and clearance by the mucociliary escalator and phagocytosis. Soluble Cr(VI) compounds enter the bloodstream more readily than highly insoluble Cr(VI) compounds. However, insoluble compounds may have longer residence time in lung. Absorption of Cr(VI) can also take place after oral and dermal exposure, particularly if the exposures are high.

The chromate $(CrO_4)^{2-}$ enters cells via facilitated diffusion through non-specific anion channels (similar to phosphate and sulfate anions). Following absorption of Cr(VI) compounds from various exposure routes, chromium is taken up by the blood cells and is widely distributed in tissues as Cr(VI). Inside blood cells and tissues, Cr(VI) is rapidly reduced to lower oxidation states and bound to macromolecules which may result in genotoxic or cytotoxic effects. However, in the blood a substantial proportion of Cr(VI) is taken up into erythrocytes, where it is reduced to Cr(III) and becomes bound to hemoglobin and other proteins.

Inhaled Cr(VI) is reduced to Cr(III) *in vivo* by a variety of reducing agents. Ascorbate and glutathione in the ELF and macrophages have been shown to reduce Cr(VI) to Cr(III) in the lungs. After oral exposure, gastric juices are also responsible for reducing Cr(VI) to Cr(III). This serves to limit the amount of Cr(VI) systemically absorbed.

Absorbed chromium is excreted from the body in a rapid phase representing clearance from the blood and at least two slower phases representing clearance from tissues. Urinary excretion is the primary route of elimination, accounting for over 50% of eliminated chromium. Although chromium is excreted in urine and feces, the intestine plays only a minor part in chromium elimination representing only about 5% of elimination from the blood.

B. Carcinogenic Effects

There has been extensive study on the potential for Cr(VI) to cause carcinogenic effects, particularly cancer of the lung. OSHA reviewed epidemiologic data from several industry sectors including chromate production, chromate pigment production, chromium plating, stainless steel welding, and ferrochromium production. Supporting evidence from animal studies and mechanistic considerations are also evaluated in this section.

1. Evidence from Chromate Production Workers

The epidemiologic literature of workers in the chromate production industry represents the earliest and best-documented relationship between exposure to chromium and lung cancer. The earliest study of chromate production workers in the United States was reported by Machle and Gregorius in 1948 (Ex.7–2). In the United States, two chromate production plants, one in Baltimore, Maryland and one in Painesville, Ohio have been the subject of multiple studies. Both plants were included in the 1948 Machle and Gregorius study and again in the study conducted by the Public Health Service and published in 1953 (Ex. 7–3). Both of these studies reported the results in aggregate. The Baltimore chromate production plant was studied by Hayes *et al.* (Ex. 7–14) and more recently by Gibb *et al.* (Ex. 31–22–11). The chromate production plant in Painesville, Ohio has been followed since the 1950s by Mancuso with his most recent follow-up published in 1997. The most recent study of the Painesville plant was published by Luippold *et al.* (Ex. 31–18–4). The studies by Gibb and Luippold present historical exposure data for the time periods covered by their respective studies. The Gibb exposure data are especially interesting since the industrial hygiene data were collected on a routine basis and not for compliance purposes. These routine air measurements may be more representative of those typically encountered by the exposed workers. In Great Britain, three plants have been studied repeatedly, with reports published between 1952 and 1991. Other studies of cohorts in the United States, Germany, Italy and Japan are also reported. The consistently elevated lung cancer mortality reported in these cohorts and the significant upward trends with duration of employment and cumulative exposure provide some of the strongest evidence that Cr(VI) be regarded as carcinogenic to workers. A summary of selected human epidemiologic studies in chromate production workers is presented in Table VI–1.

TABLE VI–1.—SUMMARY OF SELECTED EPIDEMIOLOGIC STUDIES OF LUNG CANCER IN WORKERS EXPOSED TO HEXAVALENT CHROMIUM—CHROMATE PRODUCTION

Reference/exhibit number	Study population	Reference population	Chromium (VI) exposure	Lung Cancer Risk
Hayes *et al.* (1979, Ex. 7–14) Braver *et al.* (1985, Ex. 7–17).	1803 male workers initially employed 3 or more months 1945–1974 at old and new Baltimore MD production facility; follow-up through 1977.	Baltimore City mortality	Primarily sodium chromate and dichromate production. Avg Cr(VI) of 21 to 413 $\mu g/m^3$ and avg duration 1.6 yr to 13 yr depending on subcohort, plant, and year employed.	—O/E of 2.0 ($p<0.01$) based on 59 lung cancer deaths. —Increased risk with duration of employment.
Gibb *et al.* (2000, Ex. 31–22–11).	2357 male workers initially employed 1950–1974 only at new Baltimore MD production facility; follow-up through 1992.	U.S. mortality	Primarily sodium chromate and dichromate. Mean cumulative Cr(VI) of 0.070 mg/m^3 – yr and work duration of 3.1 yr.	—O/E of 1.86 ($p<0.01$) based on 71 lung cancer deaths. —Significant upward mortality trend with cumulative Cr(VI) exposure.
Mancuso (1997, Ex. 23) ..... Mancuso (1975, Ex. 7–11). Mancuso and Heuper (1951, Ex. 7–13). Bourne and Yee (1950, Ex. 7–98).	332 male workers employed at Painesville OH facility 1931–1937; follow-up through 1993.	Mortality rate directly calculated using the distribution of person years by age group for the entire exposed population as the standard.	Primarily sodium chromate and dichromate production with some calcium chromate as a result of using high lime process. Most cumulative soluble Cr(VI) between 0.25 and 4.0 mg/m^3 – yr based on 1949 survey.	O/E not calculated but significant increase in age-adjusted lung cancer death rate with cumulative chromium exposure based on 66 deaths.
Luippold *et al.* (2003, Ex. 31–18–4).	492 male workers employed one year between 1940 and 1972 at Painesville OH facility; follow-up through 1997.	U.S. and Ohio Mortality Rates	Primarily sodium chromate and dichromate production with minor calcium chromate. Mean cumulative soluble Cr(VI) of 1.58 mg/m^3 – yr.	—O/E of 2.41($p<0.01$) based on Ohio rates and 51 deaths. —Significant upward mortality trend with cumulative Cr(VI) exposure
Davies *et al.* (1991, Ex. 7–99) Alderson *et al.* (1981, Ex. 7–22). Bistrup and Case (1956, Ex. 7–20).	2298 male chromate production workers employed for one year between 1950 and 1976 at three different UK plants; follow-up through 1989.	Cancer mortality of England, Wales and Scotland and unexposed local workers.	Principally sodium chromate and dichromate production with some calcium chromate before switch from high lime to no lime process. Avg soluble Cr(VI) in early 1950s from 2 to 880 $\mu g/m^3$ depending on job.	—O/E of 1.97 ($p<0.01$) pre-process change based on 175 deaths. —SMR of 1.02 (NS) post-process change based on 14 deaths. —Increased risk for high exposed compared with less exposed.
Korallus *et al.* (1993, Ex. 7–91).. Korallus *et al.* (1982, Ex. 7–26).	1417 chromate production workers employed for one year between 1948 and 1987 at two different German plants; follow-up through 1988.	Mortality rates for North Rhine-Westphalia region of Germany where plants located.	Principally sodium chromate and dichromate production with some calcium chromate before switch from high lime to no lime process. Annual mean Cr(VI) between 6.2 and 38 $\mu g/m^3$ after 1977. Cr(VI) exposure not reported before 1977.	—O/E of 2.27 ($p<0.01$) pre-process change based on 66 deaths. —O/E of 1.25 (NS) post-process change based on 9 deaths.

Observed/Expected (O/E)
Relative Risk (RR)
Not Statistically Significant (NS)
Odds Ratio (OR)

The basic hexavalent chromate production process involves milling and mixing trivalent chromite ore with soda ash, sometimes in the presence of lime (Exs. 7–103; 35–61). The mixture is "roasted" at a high temperature, which oxidizes much of the chromite to hexavalent sodium chromate. Depending on the lime content used in the process, the roast also contains other chromate species, especially calcium chromate under high lime conditions. The highly water-soluble sodium chromate is water-extracted from the water-insoluble trivalent chromite and the less water-soluble chromates (*e.g.*, calcium chromate) in the "leaching" process. The sodium chromate leachate is reacted with sulfuric acid and sodium bisulfate to form sodium dichromate. The sodium dichromate is prepared and packaged as a crystalline powder to be sold as final product or sometimes used as the starting material to make other chromates such as chromic acid and potassium dichromate.

a. *Cohort Studies of the Baltimore Facility.* The Hayes *et al.* study of the Baltimore, Maryland chromate production plant was designed to determine whether changes in the industrial process at one chromium chemical production facility were associated with a decreased risk of cancer, particularly cancer of the respiratory system (Ex. 7–14). Four thousand two hundred and seventeen (4,217) employees were identified as newly employed between January 1, 1945 and December 31, 1974. Excluded from this initial enumeration were employees who: (1) were working as of 1945, but had been hired prior to 1945 and (2) had been hired since 1945 but who had previously been employed at the plant. Excluded from the final cohort were those employed less than 90 days; women; those with unknown length of employment; those with no work history; and those of unknown age. The final cohort included 2,101 employees (1,803 hourly and 298 salaried).

Hayes divided the production process into three departments: (1) The mill and roast or "dry end" department which consists of grinding, roasting and leaching processes; (2) the bichromate department which consists of the acidification and crystallization processes; and (3) the special products department which produces secondary products including chromic acid. The bichromate and special products departments are referred to as the "wet end".

The construction of a new mill and roast and bichromate plant that opened during 1950 and 1951 and a new chromic acid and special products plant that opened in 1960 were cited by Hayes as "notable production changes" (Ex. 7–

14). The new facilities were designed to "obtain improvements in process technique and in environmental control of exposure to chromium bearing dusts * * *" (Ex. 7–14).

Plant-related work and health histories were abstracted for each employee from plant records. Each job on the employee's work history was characterized according to whether the job exposure occurred in (1) a newly constructed facility, (2) an old facility, or (3) could not be classified as having occurred in the new or the old facility. Those who ever worked in an old facility or whose work location(s) could not be distinguished based upon job title were considered as having a high or questionable exposure. Only those who worked exclusively in the new facility were defined for study purposes as "low exposure". Data on cigarette smoking was abstracted from plant records, but was not utilized in any analyses since the investigators thought it "not to be of sufficient quality to allow analysis."

One thousand one hundred and sixty nine (1,169) cohort members were identified as alive, 494 not individually identified as alive and 438 as deceased. Death certificates could not be located for 35 reported decedents. Deaths were coded to the 8th revision of the *International Classification of Diseases*.

Mortality analysis was limited to the 1,803 hourly employees calculating the standardized mortality ratios (SMRs) for specific causes of death. The SMR is a ratio of the number of deaths observed in the study population to the number that would be expected if that study population had the same specific mortality rate as a standard reference population (*e.g.*, age-, gender-, calendar year adjusted U.S. population). The SMR is typically multiplied by 100, so a SMR greater than 100 represents an elevated mortality in the study cohort relative to the reference group. In the Hayes study, the expected number of deaths was based upon Baltimore, Maryland male mortality rates standardized for age, race and time period. For those where race was unknown, the expected numbers were derived from mortality rates for whites. Cancer of the trachea, bronchus and lung accounted for 69% of the 86 cancer deaths identified and was statistically significantly elevated (O = 59; E = 29.16; SMR = 202; 95% CI: 155–263).

Analysis of lung cancer deaths among hourly workers by year of initial employment (1945–1949; 1950–1959 and 1960–1974), exposure category (low exposure or questionable/high exposure) and duration of employment (short term defined as 90 days–2 years; long term defined as 3 years +) was also conducted. For those workers characterized as having questionable/high exposure, the SMRs were significantly elevated for the 1945–1949 and the 1950–1959 hire periods and for both short- and long-term workers (not statistically significant for the short-term workers initially hired 1945–1949). For those characterized as low exposure, there was an elevated SMR for the long-term workers hired between 1950 and 1959, but based only on three deaths (not statistically significant). No lung cancer cases were observed for workers hired 1960–1974.

Case-control analyses of (1) a history of ever having been employed in selected jobs or combinations of jobs or (2) a history of specified morbid conditions and combinations of conditions reported on plant medical records were conducted. Cases were defined as decedents (both hourly and salaried were included in the analyses) whose underlying or contributing cause of death was lung cancer. Controls were defined as deaths from causes other than malignant or benign tumors. Cases and controls were matched on race (white/non-white), year of initial employment (+/− 3 years), age at time of initial employment (+/− 5 years) and total duration of employment (90 days–2 years; 3–4 years and 5 years +). An odds ratio (OR) was determined where the ratio is the odds of employment in a job involving Cr(VI) exposure for the cases relative to the controls.

Based upon matched pairs, analysis by job position showed significantly elevated odds ratios for special products (OR = 2.6) and bichromate and special products (OR = 3.3). The relative risk for bichromate alone was also elevated (OR = 2.1, not statistically significant).

The possible association of lung cancer and three health conditions (skin ulcers, nasal perforation and dermatitis) as recorded in the plant medical records was also assessed. Of the three medical conditions, only the odds ratio for dermatitis was statistically significant (OR = 3.0). When various combinations of the three conditions were examined, the odds ratio for having all three conditions was statistically significantly elevated (OR = 6.0).

Braver *et al.* used data from the Hayes study discussed above and the results of 555 air samples taken during the period 1945–1950 by the Baltimore City Health Department, the U.S. Public Health Service, and the companies that owned the plant, in an attempt to examine the relationship between exposure to Cr(VI) and the occurrence of lung cancer (Ex. 7–17). According to the authors, methods for determining the air concentrations of Cr(VI) have changed since the industrial hygiene data were collected at the Baltimore plant between 1945 and 1959. The authors asked the National Institute for Occupational Safety and Health (NIOSH) and the Occupational Safety and Health Administration (OSHA) to review the available documents on the methods of collecting air samples, stability of Cr(VI) in the sampling media after collection and the methods of analyzing Cr(VI) that were used to collect the samples during that period.

Air samples were collected by both midget impingers and high volume samplers. According to the NIOSH/OSHA review, high volume samplers could have led to a "significant" loss of Cr(VI) due to the reduction of Cr(VI) to Cr(III) by glass or cellulose ester filters, acid extraction of the chromate from the filter, or improper storage of samples. The midget impinger was "less subject" to loss of Cr(VI) according to the panel since neither filters nor acid extraction from filters was employed. However, if iron was present or if the samples were stored for too long, conversion from Cr(VI) to Cr(III) may have occurred. The midget impinger can only detect water soluble Cr(VI). The authors noted that, according to a 1949 industrial hygiene survey by the U.S. Public Health Service, very little water insoluble Cr(VI) was found at the Baltimore plant. One NIOSH/OSHA panel member characterized midget impinger results as "reproducible" and "accuracy * * * fairly solid unless substantial reducing agents (*e.g.*, iron) are present" (Ex. 7–17, p. 370). Based upon the panel's recommendations, the authors used the midget impinger results to develop their exposure estimates even though the panel concluded that the midget impinger methods "tend toward underestimation" of Cr(VI).

The authors also cite other factors related to the industrial hygiene data that could have potentially influenced the accuracy of their exposure estimates (either overestimating or underestimating the exposure). These include: measurements may have been taken primarily in "problem" areas of the plant; the plants may have been cleaned or certain processes shut down prior to industrial hygiene monitoring by outside groups; respirator use; and periodic high exposures (due to infrequent maintenance operations or failure of exposure control equipment) which were not measured and therefore not reflected in the available data.

The authors estimated exposure indices for cohorts rather than for specific individuals using hire period (1945–1949 or 1950–1959) and duration

of exposure, defined as short (at least 90 days but less than three years) and long (three years or more). The usual exposure to Cr(VI) for both the short- and long-term workers hired 1945–1949 was calculated as the average of the mean annual air concentration for 1945–1947 and 1949 (data were missing for 1948). This was estimated to be 413 μg/m^3. The usual exposure to Cr(VI) was estimated to be 218 μg/m^3 for the short and long employees hired between 1950 and 1959 based on air measurements in the older facility in the early 1950s.

Cumulative exposure was calculated as the usual exposure level × average duration. Short-term workers, regardless of length of employment, were assumed to have received 1.6 years of exposure regardless of hire period. For long-term workers, the average length of exposure was 12.3 years. Those hired 1945–1949 were assigned five years at an exposure of 413 μg/m^3 and 7.3 years at an exposure of 218 μg/m^3. For the long-term workers hired 1950–1959, the average length of exposure was estimated to be 13.4 years. The authors estimated that the cumulative exposures at which "significant increases in lung cancer mortality" were observed in the Hayes study were 0.35, 0.67, 2.93 and 3.65 μg/m^3-years. The association seen by the authors appears more likely to be the result of duration of employment rather than the magnitude of exposure since the variation in the latter was small.

Gibb *et al.* relied upon the Hayes study to investigate mortality in a second cohort of the Baltimore plant (Ex. 31–22–11). The Hayes cohort was composed of 1,803 hourly and 298 salaried workers newly employed between January 1, 1945 and December 31, 1974. Gibb excluded 734 workers who began work prior to August 1, 1950 and included 990 workers employed after August 1, 1950 who worked less than 90 days, resulting in a cohort of 2,357 males followed for the period August 1, 1950 through December 31, 1992. Fifty-one percent (1,205) of the cohort was white; 36% (848) nonwhite. Race was unknown for 13% (304) of the cohort. The plant closed in 1985.

Deaths were coded according to the 8th revision of the *International Classification of Diseases*. Person years of observation were calculated from the beginning of employment until death or December 31, 1992, whichever came earlier. Smoking data (yes/no) were available for 2,137 (93.3%) of the cohort from company records.

Between 1950 and 1985, approximately 70,000 measurements of airborne Cr(VI) were collected utilizing several different sampling methods. The program of routine air sampling for Cr(VI) was initiated to "characterize 'typical/usual exposures' of workers" (Ex. 31–22–11, p.117). Area samples were collected during the earlier time periods, while both area and personal samples were collected starting in 1977. Exposure estimates were derived from the area sampling systems and were adjusted to "an equivalent personal exposure estimate using job-specific ratios of the mean area and personal sampling exposure estimates for the period 1978–1985 * * *." (Ex. 31–22–11, p.117). According to the author, comparison of the area and personal samples showed "no significant differences" for about two-thirds of the job titles. For several job titles with a "significant point source of contamination" the area sampling methods "significantly underestimated" personal exposure estimates and were adjusted "by the ratio of the two" (Ex. 31–22–11, p.118).

A job exposure matrix (JEM) was constructed, where air sampling data were available, containing annual average exposure for each job title. Data could not be located for the periods 1950–1956 and 1960–1961. Exposures were modeled for the missing data using the ratio of the measured exposure for a job title to the average of all measured job titles in the same department. For the time periods where "extensive" data were missing, a simple straight line interpolation between years with known exposures was employed.

In an attempt to estimate airborne Cr(III) concentrations, 72 composite dust samples were collected at or near the fixed site air monitoring stations about three years after the facility closed. The dust samples were analyzed for Cr(VI) content using ion chromatography. Cr(III) content was determined through inductively coupled plasma spectroscopic analysis of the residue. The Cr(III):Cr(VI) ratio was calculated for each area corresponding to the air sampling zones and the measured Cr(VI) air concentration adjusted based on this ratio. Worker exposures were calculated for each job title and weighted by the fraction of time spent in each air-monitoring zone. The Cr(III):Cr(VI) ratio was derived in this manner for each job title based on the distribution of time spent in exposure zones in 1978. Cr(VI) exposures in the JEM were multiplied by this ratio to estimate Cr(III) exposures.

A total of 855 observed deaths (472 white; 323 nonwhite and 60 race unknown) were reported. SMRs were calculated using U.S. rates for overall mortality. Maryland rates (the state in which the plant was located) were used to analyze lung cancer mortality in order to better account for regional differences in disease fatality.

A statistically significant lung cancer SMR, based on the national rate, was found for whites (O=71; SMR=186; 95% CI: 145–234); nonwhites (O=47; SMR=188; 95% CI: 138–251) and the total cohort (O=122; SMR=180; 95% CI: 149–214). Of the 122 lung cancer cases, 116 were smokers and four were non smokers at the time of hire. Smoking status was unknown for two lung cancer cases. SMRs were not adjusted for smoking.

The ratio of observed to expected lung cancer deaths (O/E) for the entire cohort stratified by race and cumulative exposure quartile were computed. Cumulative exposure was lagged five years (only exposure occurring five years before a given age was counted). The cut point for the quartiles divided the cohort into four equal groups based upon their cumulative exposure at the end of their working history (0–0.00149 mgCrO_3/m^3-yr; 0.0015–0.0089 mgCrO_3/m^3-yr; 0.009–0.0769 mgCrO_3/m^3-yr; and 0.077–5.25 mgCrO_3/m^3-yr). For whites, the relative risk of lung cancer was significantly elevated for the second through fourth exposure quartiles with O/E values of 0.8, 2.1, 2.1 and 1.7 for the four quartiles, respectively. For nonwhites, the O/E values by exposure quartiles were 1.1, 0.9, 1.2 and 2.9, respectively. Only the highest exposure quartile was significantly elevated. For the total cohort, a significant exposure-response trend was observed such that lung cancer mortality increased with increasing cumulative Cr(VI) exposure.

Proportional hazards models were used to assess the relationship between chromium exposure and the risk of lung cancer. The lowest exposure quartile was used as the reference group. The median exposure in each quartile was used as the measure of cumulative Cr(VI) exposure. When smoking status was included in the model, relative lung cancer risks of 1.83, 2.48 and 3.32 for the second, third and fourth exposure quartiles respectively were estimated. Smoking, Cr(III) exposure, and work duration were also significant predictors of lung cancer risk in the model.

The analysis attempted to separate the effects into two multivariate proportionate hazards models (one model incorporated the log of cumulative Cr(VI) exposure, the log of cumulative Cr(III) exposure and smoking; the second incorporated the log of cumulative Cr(VI), work duration and smoking). In either regression model, lung cancer mortality remained significantly associated ($p < .05$) with

cumulative Cr(VI) exposure even after controlling for the combination of smoking and Cr(III) exposure or the combination of smoking and work duration. On the other hand, lung cancer mortality was not significantly associated with cumulative Cr(III) or work duration in the multivariate analysis indicating lung cancer risk was more strongly correlated with cumulative Cr(VI) exposure than the other variables.

Exponent, as part of a larger submission from the Chrome Coalition, submitted comments on the Gibb paper asking that OSHA review methodological issues believed by Exponent to impact upon the usefulness of the Gibb data in a risk assessment analysis. While Exponent states that the Gibb study offers data that "are substantially better for cancer risk than the Mancuso study* * *" they believe that further scrutiny of some of the methods and analytical procedures are necessary (Ex. 31–18–15–1, p. 5).

The issues raised by Exponent and the Chrome Coalition (Ex. 31–18–14) concerning the Gibb paper are: selection of the appropriate reference population for compilation of expected numbers for use in the SMR analysis; inclusion of short term workers (<1 year); expansion of the number of exposure groupings to evaluate dose response trends; analyzing dose response by peak JEM exposure levels; analyzing dose-response at exposures above and below the current PEL and calculating smoking-adjusted SMRs for use in dose-response assessments. Exponent obtained the original data from the Gibb study. The data were reanalyzed to address the issues cited above. Exponent's findings are presented in Exhibit 31–18–15–1 and are discussed below.

Exponent suggests that Gibb's use of U.S. and Maryland mortality rates for developing expectations for the SMR analysis was inappropriate and suggested that Baltimore city mortality rates would have been the appropriate standard to select since those mortality rates would more accurately reflect the mortality experience of those who worked at the plant. Exponent reran the SMR analysis to compare the SMR values reported by Gibb (U.S. mortality rates for SMR analysis) with the results of an SMR analysis using Maryland mortality rates and Baltimore mortality rates. Gibb reported a lung cancer SMR of 1.86 (95% CI: 1.45–2.34) for white males based upon 71 lung cancer deaths using U.S. mortality rates. Reanalysis of the data produced a lung cancer SMR of 1.85 (95% CI: 1.44–2.33) for white males based on U.S. mortality rates, roughly the same value obtained by Gibb. When Maryland and Baltimore rates are used, the SMR drops to 1.70 and 1.25 respectively.

Exponent suggested conducting sensitivity analysis that excludes short-term workers (defined as those with one year of employment) since the epidemiologic literature suggests that the mortality of short-term workers is different than long-term workers. Short-term workers in the Gibb study comprise 65% of the cohort and 54% of the lung cancers. The Coalition also suggested that data pertaining to short-term employee's information are of "questionable usefulness for assessing the increased cancer risk from chronic occupational exposure to Cr(VI)" (Ex. 31–18–15–1, p. 5).

Lung cancer SMRs were calculated for those who worked <1 year and for those who worked one year or more. Exponent defined short-term workers as those who worked a minimum of one year "because it is consistent with the inclusion criteria used by others studying chromate chemical production worker cohorts" (Ex. 31–18–15–1, p. 12). Exponent also suggested that Gibb's breakdown of exposure by quartile was not the most "appropriate" way of assessing dose-response since cumulative Cr(VI) exposures remained near zero until the 50th to 60th percentile, "so there was no real distinction between the first two quartiles * * *" (Ex. 31–18–15–1, p. 24). They also suggested that combining "all workers together at the 75th quartile * * * does not properly account for the heterogeneity of exposure in this group" (Ex. 31–18–15–1, p. 24). The Exponent reanalysis used six cumulative exposure levels of Cr(VI) compared with the four cumulative exposure levels of Cr(VI) in the Gibb analysis. The lower levels of exposure were combined and "more homogeneous" categories were developed for the higher exposure levels.

Using these re-groupings and excluding workers with less than one year of employment, Exponent reported that the highest SMRs are seen in the highest exposure group (1.5<5.25 mg CrO_3/m^3-years) for both white and nonwhite, based on either the Maryland or the Baltimore mortality rates. The authors did not find "that the inclusion of short-term workers had a significant impact on the results, especially if Baltimore rates are used in the SMR calculations" (Ex. 31–18–15–1, p. 28).

Analysis of length of employment and "peak" (i.e., highest recorded mean annual) exposure level to Cr(VI) was conducted. Exponent reported that approximately 50% of the cohort had "only very low" peak exposure levels (<07.2 μg CrO_3/m^3 or approximately 3.6 μg/m^3 of Cr(VI)). The "majority" of the short-term workers had peak exposures of <100 μg CrO_3/m^3. There were five peak Cr(VI) exposure levels (<7.2 μg CrO_3/m^3; 7.2<19.3 μg CrO_3/m^3; 19.3<48.0 μg CrO_3/m^3; 48.0<105 μg CrO_3/m^3; 105<182 μg CrO_3/m^3; and 182<806 μg CrO_3/m^3) included in the analyses. Overall, the lung cancer SMRs for the entire cohort grouped according to the six "peak" exposure categories were slightly higher using Maryland reference rates compared to Baltimore reference rates.

The Exponent analysis of workers who were ever exposed above the current PEL versus those never exposed above the current PEL produced slightly higher SMRs for those ever exposed, with the SMRs higher using the Maryland standard rather than the Baltimore standard. The only statistically significant result was for all lung cancer deaths combined.

Assessment was made of the potential impact of smoking on the lung cancer SMRs since Gibb did not adjust the SMRs for smoking. Exponent stated that the smoking-adjusted SMRs are more appropriate for use in the risk assessment than the unadjusted SMRs. It should be noted that smoking adjusted SMRs could not be calculated using Baltimore reference rates. As noted by the authors, the smoking adjusted SMRs produced using Maryland reference rates are, by exposure, "reasonably consistent with the Baltimore-referenced SMRs" (Ex. 31–18–15–1, p. 41).

Gibb *et al.* included workers regardless of duration of employment, and the cohort was heavily weighted by those individuals who worked less than 90 days. In an attempt to clarify this issue, Exponent produced analyses of short-term workers, particularly with respect to exposures. Exponent redefined short-term workers as those who worked less than one year, to be consistent with the definition used in other studies of chromate producers. OSHA finds this reanalysis excluding short-term workers to be useful. It suggests that including cohort workers employed less than one year did not substantively alter the conclusions of Gibb *et al.* with regard to the association between Cr(VI) exposure and lung cancer mortality. It should be noted that in the Hayes study of the Baltimore plant, the cohort is defined as anyone who worked 90 days or more.

Hayes *et al.* used Baltimore mortality rates while Gibb *et al.* used U.S. mortality rates to calculate expectations for overall SMRs. To calculate

expectations for the analysis of lung cancer mortality and exposure, Gibb *et al.* used Maryland state mortality rates. The SMR analyses provided by Exponent using both Maryland and Baltimore rates are useful. The data showed that using Baltimore rates raised the expected number lung cancer deaths and, thus, lowered the SMRs. However, there remained a statistically significant increase in lung cancer risk among the exposed workers and a significant upward trend with cumulative Cr(VI) exposure. The comparison group should be as similar as possible with respect to all other factors that may be related to the disease except the determinant under study. Since the largest portion of the cohort (45%) died in the city of Baltimore, and even those whose deaths occurred outside of Baltimore (16%) most likely lived in proximity to the city, the use of Baltimore mortality rates as an external reference population is preferable.

Gibb's selection of the cut points for the exposure quartiles is accomplished by dividing the workers in the cohort into four equal groups based on their cumulative exposure at the end of their working history. Using the same method but excluding the short-term workers would have resulted in slightly different cumulative exposure quartiles. Exponent expressed a preference for a six-tiered exposure grouping. The impact of using different exposure groupings is further discussed in preamble section VII.C of the preliminary quantitative risk assessment.

The exposure matrix of Gibb *et al.* does utilize a unique set of industrial hygiene data. Over 70,000 samples taken to characterize the "typical/usual" working environment is more extensive industrial hygiene data then is commonly available for most exposure assessments. However, there are several unresolved issues regarding the exposure assessment, including the impact of the different industrial hygiene sampling techniques used over the sampling time frame, how the use of different sampling techniques was taken into account in developing the exposure assessment and the use of area vs. personal samples.

Exponent and the Chrome Coalition also suggested that the SMRs should have been adjusted for smoking. According to Exponent, smoking adjusted SMRs based upon the Maryland mortality rates produced SMRs similar to the SMRs obtained using Baltimore mortality rates (Ex. 31–18–15–1). The accuracy of the smoking data is still questionable since it represents information obtained at the time of hire. Hayes abstracted the smoking data from the plant medical records, but "found it not to be of sufficient quality to allow analysis." One advantage to using the Baltimore mortality data may be to better control for the potential confounding of smoking.

Despite the potential methodological limitations of the Gibb study, this is one of the better cohort mortality studies of workers in the chromium production industry. The quality of the available industrial hygiene data and its characterization as "typical/usual" makes the Gibb study useful for risk assessment.

b. *Cohort Studies of the Painesville Facility.* The Ohio Department of Health conducted epidemiological and environmental studies at a plant in Painesville that manufactured sodium bichromate from chromite ore. Mancuso and Hueper (Ex. 7–12) reported an excess of respiratory cancer among chromate workers when compared to the county in which the plant was located. Among the 33 deaths in males who had worked at the plant for a minimum of one year, 18.2% were from respiratory cancer. In contrast, the expected frequency of respiratory cancer among males in the county in which the plant was located was 1.2%. Although the authors did not include a formal statistical comparison, the lung cancer mortality rate among the exposed workers would be significantly greater than the county rate.

Mancuso (Ex. 7–11) updated his 1951 study of 332 chromate production workers employed during the period 1931–1937. Age adjusted mortality rates were calculated by the direct method using the distribution of person years by age group for the total chromate population as the standard. Vital status follow-up through 1974 found 173 deaths. Of the 66 cancer deaths, 41 (62.1%) were lung cancers. A cluster of lung cancer deaths was observed in workers with 27–36 years since first employment.

Mancuso used industrial hygiene data collected in 1949 to calculate weighted average exposures to water-soluble (presumed to be Cr(VI)), insoluble (presumed to be principally Cr(III)) and total chromium (Ex. 7–98). The age-adjusted lung cancer death rate increased from 144.6 (based upon two deaths) to 649.6 (based upon 14 deaths) per 100,000 in five exposure categories ranging from a low of 0.25–0.49 to a high of 4.0+ mg/m^3 – years for the insoluble Cr(III) exposures. For exposure to soluble Cr(VI), the age adjusted lung cancer rates ranged from 80.2 (based upon three deaths) to 998.7 (based upon 12 deaths) in five exposure categories ranging from <0.25 to 2.0+ mg/m^3 – years. For total chromium, the age-adjusted death rates ranged from 225.7 (based upon three deaths) to 741.5 (based upon 16 deaths) for exposures ranging from 0.50–0.99 mg/m^3 – years to 6.0+ mg/m^3 – years.

Age-adjusted lung cancer death rates also were calculated by classifying workers by the levels of insoluble Cr(III) and total chromium exposure. From the data presented, it appears that for a fixed level of insoluble Cr(III), the lung cancer risk appears to increase as the total chromium increases (Ex. 7–11).

Mancuso (Ex. 23) updated the 1975 study. As of December 31, 1993, 283 (85%) cohort members had died and 49 could not be found. Of the 102 cancer deaths, 66 were lung cancers. The age-adjusted lung cancer death rate per 100,000 ranged from 187.9 (based upon four deaths) to 1,254.1 (based upon 15 deaths) for insoluble Cr(III) exposure categories ranging from 0.25–0.49 to 4.00–5.00 mg/m^3 years. For the highest exposure to insoluble Cr(III) (6.00+ mg/m^3 years) the age-adjusted lung cancer death rate per 100,000 fell slightly to 1,045.5 based upon seven deaths.

The age-adjusted lung cancer death rate per 100,000 ranged from 99.7 (based upon five deaths) to 2,848.3 (based upon two deaths) for soluble Cr(VI) exposure categories ranging from <0.25 to 4.00+ mg/m^3 years. For total chromium, the age-adjusted lung cancer death rate per 100,000 ranged from 64.7 (based upon two deaths) to 1,106.7 (based upon 21 deaths) for exposure categories ranging from <0.50 to 6.00+ mg/m^3 years.

To investigate whether the increase in the lung cancer death rate was due to one form of chromium compound (presumed insoluble Cr(III) or soluble Cr(VI)), age-adjusted lung cancer mortality rates were calculated by classifying workers by the levels of exposure to insoluble Cr(III) and total chromium. For a fixed level of insoluble Cr(III), the lung cancer rate appears to increase as the total chromium increases for each of the six total chromium exposure categories, except for the 1.00–1.99 mg/m^3 – years category. For the fixed exposure categories for total chromium, increasing exposures to levels of insoluble Cr(III) showed an increased age-adjusted death rate from lung cancer in three of the six total chromium exposure categories.

For a fixed level of soluble Cr(VI), the lung cancer death rate increased as total chromium categories of exposure increased for three of the six gradients of soluble Cr(VI). For the fixed exposure categories of total chromium, the increasing exposure to specific levels of

soluble Cr(VI) led to an increase in two of the six total chromium exposure categories. Mancuso concluded that the relationship of lung cancer is not confined solely to either soluble or insoluble chromium. Unfortunately, it is difficult to attribute these findings specifically to Cr(III) [as insoluble chromium] and Cr(VI) [as soluble chromium] since it is likely that some slightly soluble and insoluble Cr(VI) as well as Cr(III) contributed to the insoluble chromium measurement.

Luippold *et al.* conducted a retrospective cohort study of 493 former employees of the chromate production plant in Painesville, Ohio (Ex. 31–18–4). This Painesville cohort does not overlap with the Mancuso cohort and is defined as employees hired beginning in 1940 who worked for a minimum of one year at Painesville and did not work at any other facility owned by the same company that used or produced Cr(VI). An exception to the last criterion was the inclusion of workers who subsequently were employed at a company plant in North Carolina (number not provided). Four cohort members were identified as female. The cohort was followed for the period January 1, 1941 through December 31, 1997. Thirty-two percent of the cohort worked for 10 or more years.

Information on potential confounders was limited. Smoking status (yes/no) was available for only 35% of the cohort from surveys administered between 1960 and 1965 or from employee medical files. For those employees where smoking data were available, 78% were smokers (responded yes on at least one survey or were identified as smokers from the medical file). Information on race also was limited, the death certificate being the primary source of information.

Results of the vital status follow-up were: 303 deaths; 132 presumed alive and 47 vital status unknown. Deaths were coded to the 9th revision of the *International Classification of Diseases*. Cause of death could not be located for two decedents. For five decedents the cause of death was only available from data collected by Mancuso and was recoded from the 7th to the 9th revision of the ICD. There were no lung cancer deaths among the five recoded deaths.

SMRs were calculated based upon two reference populations: the U.S. (white males) and the state of Ohio (white males). Lung cancer SMRs stratified by year of hire, duration of exposure, time since first employment and cumulative exposure group also were calculated.

Proctor *et al.* analyzed airborne Cr(VI) levels throughout the facility for the years 1943 to 1971 (the plant closed April 1972) from 800 area air sampling measurements from 21 industrial hygiene surveys (Ex. 35–61). A job exposure matrix (JEM) was constructed for 22 exposure areas for each month of plant operation. Gaps in the matrix were completed by computing the arithmetic mean concentration from area sampling data, averaged by exposure area over three time periods (1940–1949; 1950–1959 and 1960–1971) which coincided with process changes at the plant (Ex. 31–18–1).

The production of water-soluble sodium chromate was the primary operation at the Painesville plant. It involved a high lime roasting process that produced a water insoluble Cr(VI) residue (calcium chromate) as byproduct that was transported in open conveyors and likely contributed to worker exposure until the conveyors were covered during plant renovations in 1949. The average airborne *soluble* Cr(VI) from industrial hygiene surveys in 1943 and 1948 was 0.72 mg/m ^{3} with considerable variability among departments. During these surveys, the authors believe the reported levels may have underestimated total Cr(VI) exposure by 20 percent or less for some workers due to the presence of *insoluble* Cr(VI) dust.

Reductions in Cr(VI) levels over time coincided with improvements in the chromate production process. Industrial hygiene surveys over the period from 1957 to 1964 revealed average Cr(VI) levels of 270 μg/m^3. Another series of plant renovations in the early 1960s lowered average Cr(VI) levels to 39 μg/m^3 over the period from 1965 to 1972. The highest Cr(VI) concentrations generally occurred in the shipping, lime and ash, and filtering operations while the locker rooms, laboratory, maintenance shop and outdoor raw liquor storage areas had the lowest Cr(VI) levels.

The average cumulative Cr(VI) exposure (mg/m ^{3} – yrs) for the cohort was 1.58 mg/m ^{3} – yrs and ranged from 0.006 to 27.8 mg/m ^{3} – yrs. For those who died from lung cancer, the average Cr(VI) exposure was 3.28 mg/m ^{3} – yrs and ranged from 0.06 to 27.8 mg/m ^{3} – yrs. According to the authors, 60% of the cohort accumulated an estimated Cr(VI) exposure of 1.00 mg/m ^{3} – yrs or less.

Sixty-three per cent of the study cohort was reported as deceased at the end of the follow-up period (December 31, 1997). There was a statistically significant increase for the all causes of death category based on both the national and Ohio state standard mortality rates (national: O=303; E=225.6; SMR=134; 95% CI: 120–150; state: O=303; E=235; SMR=129; 95% CI: 115–144). Fifty-three of the 90 cancer deaths were cancers of the respiratory system with 51 coded as lung cancer. The SMR for lung cancer is statistically significant using both reference populations (national O=51; E=19; SMR 268; 95% CI: 200–352; state O=51; E=21.2; SMR 241; 95% CI: 180–317).

SMRs also were calculated by year of hire, duration of employment, time since first employment and cumulative Cr(VI) exposure, mg/m ^{3}-years. The highest lung cancer SMRs were for those hired during the earliest time periods. For the period 1940–1949, the lung cancer SMR was 326 (O=30; E=9.2; 95% CI: 220–465); for 1950–1959, the lung cancer SMR was 275 (O=15; E=5.5; 95% CI: 154–454). For the period 1960–1971, the lung cancer SMR was just under 100 based upon six deaths with 6.5 expected.

Lung cancer SMRs based upon duration of employment (years) increased as duration of employment increased. For those with one to four years of employment, the lung cancer SMR was 137 based upon nine deaths (E=6.6; 95% CI: 62–260); for five to nine years of employment, the lung cancer SMR was 160 (O=8; E=5.0; 95% CI: 69–314). For those with 10–19 years of employment, the lung cancer SMR was 169 (O=7; E=4.1; 95% CI: 68–349) and for those with 20 or more years of employment, the lung cancer SMR was 497 (O=27; E=5.4; 95% CI: 328–723).

Analyses of cumulative Cr(VI) exposure found the lung cancer SMR (based upon the Ohio standard) in the highest exposure group (2.70–27.80 mg/m ^{3}-yrs) was 463 (O=20; E=4.3; 95% CI: 183–398). In the 1.05–2.69 mg/m ^{3}-yrs cumulative exposure group, the lung cancer SMR was 365 based upon 16 deaths (E=4.4; 95% CI: 208–592). For the cumulative exposure groups 0.49–1.04, 0.20–0.48 and 0.00–0.19, the lung cancer SMRs were 91 (O=4; E=4.4; 95% CI: 25–234; 184 (O=8; E=4.4; 95% CI: 79–362) and 67 (O=3; E=4.5; 95% CI: 14–196). A test for trend showed a strong relationship between lung cancer mortality and cumulative Cr(VI) exposure (p=0.00002). The authors claim that the SMRs are also consistent with a threshold effect since there was no statistically significant trend for excess lung cancer mortality with cumulative Cr(VI) exposures less than about 1 mg/m ^{3}-yrs. The issue of whether the cumulative Cr(VI) exposure-lung cancer response is best represented by a threshold effect is discussed further in preamble section VII on the preliminary quantitative risk assessment.

The Painesville cohort is small (482 employees). Excluded from the cohort were six employees who worked at other chromate plants after Painesville closed. However, exceptions were made for employees who subsequently worked at the company's North Carolina plant (number not provided) because exposure data were available from the North Carolina plant. Subsequent exposure to Cr(VI) by other terminated employees is unknown and not taken into account by the investigators. Therefore, the extent of the bias introduced is unknown.

The 10% lost to follow-up (47 employees) in a cohort of this size is striking. Four of the forty-seven had "substantial" follow-up that ended in 1997 just before the end date of the study. For the remaining 43, most were lost in the 1950s and 1960s (most is not defined). Since person-years are truncated at the time individuals are lost to follow up, the potential implication of lost person years could impact the width of the confidence intervals.

The authors used U.S. and Ohio mortality rates for the standards to compute the expectations for the SMRs, stating that the use of Ohio rates minimizes bias that could occur from regional differences in mortality. It is unclear why county rates were not used to address the differences in regional mortality.

c. *Other Cohort Studies.* The first study of cancer of the respiratory system in the U.S. chromate producing industry was reported by Machle and Gregorius (Ex. 7–2). The study involved a total of 11,000 person-years of observation between 1933 and 1947. There were 193 deaths; 42 were due to cancer of the respiratory system. The proportion of respiratory cancer deaths among chromate workers was compared with proportions of respiratory cancer deaths among Metropolitan Life Insurance industrial policyholders. A non-significant excess respiratory cancer among chromate production workers was found. No attempt was made to control for confounding factors (*e.g.*, age). While some exposure data are presented, the authors state that one cannot associate tumor rates with tasks (and hence specific exposures) because of "shifting of personnel" and the lack of work history records.

Baetjer reported the results of a case-control study based upon records of two Baltimore hospitals (Ex. 7–7). A history of working with chromates was determined from these hospital records and the proportion of lung cancer cases determined to have been exposed to chromates was compared with the proportion of controls exposed. Of the lung cancer cases, 3.4% had worked in a chromate manufacturing plant, while none of the controls had such a history recorded in the medical record. The results were statistically significant and Baetjer concluded that the data confirmed the conclusions reached by Machle and Gregorius that "the number of deaths due to cancer of the lung and bronchi is greater in the chromate-producing industry than would normally be expected" (Ex. 7–7, p. 516).

As a part of a larger study carried out by the U.S. Public Health Service, the morbidity and mortality of male workers in seven U.S. chromate manufacturing plants during the period 1940–1950 was reported (Exs. 7–1; 7–3). Nearly 29 times as many deaths from respiratory cancer (excluding larynx) were found among workers in the chromate industry when compared to mortality rates for the total U.S. for the period 1940–1948. The lung cancer risk was higher at the younger ages (a 40-fold risk at ages 15–45; a 30-fold risk at ages 45–54 and a 20-fold risk at ages 55–74). Analysis of respiratory cancer deaths (excluding larynx) by race showed an observed to expected ratio of 14.29 for white males and 80 for nonwhite males.

Taylor conducted a mortality study in a cohort of 1,212 chromate workers followed over a 24 year (1937–1960) period (Ex. 7–5). The workers were from three chromate plants that included approximately 70% of the total population of U.S. chromate workers in 1937. In addition, the plants had been in continuous operation for the study period (January 1, 1937 to December 31, 1960). The cohort was followed utilizing records of Old Age and Survivors Disability Insurance (OASDI). Results were reported both in terms of SMRs and conditional probabilities of survival to various ages comparing the mortality experience of chromate workers to the U.S. civilian male population. No measures of chromate exposure were reported although results are provided in terms of duration of employment. Taylor concluded that not only was there an excess in mortality from respiratory cancer, but from other causes as well, especially as duration of employment increased.

In a reanalysis of Taylor's data, Enterline excluded those workers born prior to 1989 and analyzed the data by follow-up period using U.S. rates (Ex. 7–4). The SMR for respiratory cancer for all time periods showed a nine-fold excess (O=69 deaths; E=7.3). Respiratory cancer deaths comprised 28% of all deaths. Two of the respiratory cancer deaths were malignant neoplasms of the maxillary sinuses, a number according to Enterline, "greatly in excess of that expected based on the experience of the U.S. male population." Also slightly elevated were cancers of the digestive organs (O=16; E=10.4) and non-malignant respiratory disease (O=13; E=8.9).

Pastides *et al.* conducted a cohort study of workers at a North Carolina chromium chemical production facility (Ex. 7–93). Opened in 1971, this facility is the largest chromium chemical production facility in the United States. Three hundred and ninety eight workers employed for a minimum of one year between September 4, 1971 and December 31, 1989 comprised the study cohort. A self-administered employee questionnaire was administered to collect data concerning medical history, smoking, plant work history, previous employment and exposure to other potential chemical hazards. Personal air monitoring results for Cr(VI) were available from company records for the period February 1974 through April 1989 for 352 of the 398 cohort members. A job matrix utilizing exposure area and calendar year was devised. The exposure means from the matrix were linked to each employee's work history to produce the individual exposure estimates by multiplying the mean Cr(VI) value from the matrix by the duration (time) in a particular exposure area (job). Annual values were summed to estimate total cumulative exposure.

Personal air monitoring indicated that TWA Cr(VI) air concentrations were generally very low. Roughly half the samples were less than 1 $\mu g/m^3$, about 75 percent were below 3 $\mu g/m^3$, and 96 percent were below 25 $\mu g/m^3$. The average age was 42 years and mean duration of employment was 9.5 years. Two thirds of the workers had accumulated less than 0.01mg/m^3-yr cumulative Cr(VI) exposure. SMRs were computed using national, state (not reported) and county mortality rates (eight adjoining North Carolina counties, including the county in which the plant is located). Two of the 17 recorded deaths in the cohort were from lung cancers. The SMRs for lung cancer were 127 (95% CI: 22–398) and 97 (95% CI: 17–306) based on U.S. and North Carolina county mortality rates, respectively. The North Carolina cohort is still relatively young and not enough time has elapsed to reach any conclusions regarding lung cancer risk and Cr(VI) exposure.

A study of four chromate producing facilities in New Jersey was reported by Rosenman (Ex. 35–104). A total of 3,408 individuals were identified from the four facilities over different time periods (plant A from 1951–1954; plant B from

1951–1971; plant C from 1937–1964 and plant D 1937–1954). No Cr(VI) exposure data was collected for this study. Proportionate mortality ratios (PMRs) and proportionate cancer mortality ratios (PCMRs), adjusted by race, age, and calendar year, were calculated for the three companies (plants A and B are owned by one company). Unlike SMRs, PMRs are not based on the expected mortality rates in a standardized population but, instead, merely represent the proportional distribution of deaths in the cohort relative to the general U.S. population. Analyses were done evaluating duration of work and latency from first employment.

Significantly elevated PMRs were seen for lung cancer among white males (170 deaths, PMR=1.95; 95% CI: 1.67–2.27) and black males (54 deaths, PMR=1.88; 95% CI: 1.41–2.45). PMRs were also significantly elevated (regardless of race) for those who worked 1–10, 11–20 and >20 years and consistently higher for white and black workers 11–20 years and >20 years since first hire. The results were less consistent for those with 10 or fewer years since first hire.

Bidstrup and Case reported the mortality experience of 723 workers at three chromate producing factories in Great Britain (Ex. 7–20). Lung cancer mortality was 3.6 times that expected (O=12; E=3.3) for England and Wales. Alderson *et al.* conducted a follow-up of workers from the three plants in the U.K. (Bolton, Rutherglen and Eaglescliffe) originally studied by Bidstrup (Ex. 7–22). Until the late 1950s, all three plants operated a "high-lime" process. This process potentially produced significant quantities of calcium chromate as a by-product as well as the intended sodium dichromate. Process changes occurred during the 1940s and 1950s. The major change, according to the author, was the introduction of the "no-lime" process, which eliminated unwanted production of calcium chromate. The no-lime process was introduced at Eaglescliffe 1957–1959 and by 1961 all production at the plant was by this process. Rutherglen operated a low-lime process from 1957/1959 until it closed in 1967. Bolton never changed to the low-lime process. The plant closed in 1966. Subjects were eligible for entry into the study if they had received an X-ray examination at work and had been employed for a minimum of one year between 1948 and 1977. Of the 3,898 workers enumerated at the three plants, 2,715 met the cohort entrance criteria, (alive: 1,999; deceased: 602; emigrated: 35; and lost to follow-up: 79). Those lost to follow-up were not included in the analyses. Eaglescliffe contributed the greatest number of subjects to the study (1,418). Rutherglen contributed the largest number of total deaths (369, or 61%). Lung cancer comprised the majority of cancer deaths and was statistically significantly elevated for the entire cohort (O=116; E=47.96; SMR=240; p <0.001). Two deaths from nasal cancer were observed, both from Rutherglen.

SMRs were computed for Eaglescliffe by duration of employment, which was defined, based upon plant process updates (those who only worked before the plant modification, those who worked both before and after the modifications, or those who worked only after the modifications were completed). Of the 179 deaths at the Eaglescliffe plant, 40 are in the pre-change group; 129 in the pre-/post-change and 10 in the post-change. A total of 36 lung cancer deaths occurred at the plant, in the pre-change group O=7; E=2.3; SMR=303; in the pre-/post-change group O=27; E=13; SMR=2.03 and in the post-change group O=2; E=1.07; SMR=187.

In an attempt to address several potential confounders, regression analysis examined the contributions of various risk factors to lung cancer. Duration of employment, duration of follow-up and working before or after plant modification appear to be greater risk factors for lung cancer, while age at entry or estimated degree of chromate exposure had less influence.

Davies updated the work of Alderson, *et al.* concerning lung cancer in the U.K. chromate producing industry (Ex. 7–99). The study cohort included payroll employees who worked a minimum of one year during the period January 1, 1950 and June 30, 1976 at any of the three facilities (Bolton, Eaglescliffe or Rutherglen). Contract employees were excluded unless they later joined the workforce, in which case their contract work was taken into account.

Based upon the date of hire, the workers were assigned to one of three groups. The first, or "early" group, consists of workers hired prior to January 1945 who are considered long term workers, but do not comprise a cohort since those who left or died prior to 1950 are excluded. The second group, "pre-change" workers, were hired between January 1, 1945 to December 31, 1958 at Rutherglen or to December 31, 1960 at Eaglescliffe. Bolton employees starting from 1945 are also termed pre-change. The cohort of pre-change workers is considered incomplete since those leaving 1946–1949 could not be included and because of gaps in the later records. For those who started after 1953 and for all men staying 5+ years, this subcohort of pre-change workers is considered complete. The third group, "post-change" workers, started after the process changes at Eaglescliffe and Rutherglen became fully effective and are considered a "complete" cohort. A "control" group of workers from a nearby fertilizer facility, who never worked in or near the chromate plant, was assembled.

A total of 2,607 employees met the cohort entrance criteria. As of December 31, 1988, 1,477 were alive, 997 dead, 54 emigrated and 79 could not be traced (total lost to follow-up: 133). SMRs were calculated using the mortality rates for England and Wales and the mortality rates for Scotland. Causes of death were ascertained for all but three decedents and deaths were coded to the revision of the *International Classification of Diseases* in effect at the time of death. Lung cancer in this study is defined as those deaths where the underlying cause of death is coded as 162 (carcinoma of the lung) or 239.1 (lung neoplasms of unspecified nature) in the 9th revision of the ICD. Two deaths fell into the latter category. The authors attempted to adjust the national mortality rates to allow for differences based upon area and social class.

There were 12 lung cancer deaths at Bolton, 117 at Rutherglen, 75 at Eaglescliffe and one among staff for a total of 205 lung cancer deaths. A statistically significant excess of lung cancer deaths (175 deaths) among early and pre-change workers is seen at Rutherglen and Eaglescliffe for both the adjusted and unadjusted SMRs. For Rutherglen, for the early period based upon 68 observed deaths, the adjusted SMR was 230 while the unadjusted SMR was 347 (for both SMRs p<0.001). For the 41 pre-change lung cancer deaths at Rutherglen, the adjusted SMR was 160 while the unadjusted SMR was 242 (for both SMRs p<0.001). At Eaglescliffe, there were 14 lung cancer deaths in the early period resulting in an adjusted SMR of 196 and an unadjusted SMR of 269 (for both SMRs p<0.05). For the pre-change period at Eaglescliffe, the adjusted SMR was 195 and the unadjusted was 267 (p<0.001 for both SMRs). At Bolton there is a non-significant excess among pre-change men. There are no apparent excesses in the post-change groups, the staff groups or in the non-exposed fertilizer group.

There is a highly significant overall excess of nasal cancers with two cases at Eaglescliffe and two cases at Rutherglen (O=4, Eadjusted=0.26; SMR=1538). All four men with nasal

cancer had more than 20 years of exposure to chromates.

Aw reported on two case-control studies conducted at the previously studies Eaglescliffe plant (Ex. 35–245). In 1960, the plant, converted from a "high-lime" to a 'no-lime' process, reducing the likelihood of calcium chromate formation. As of March 1996, 2,672 post-change workers had been employed, including 891 office personnel. Of the post-change plant personnel, 56% had been employed for more than one year. Eighteen lung cancer cases were identified among white male post-change workers (13 deceased; five alive). Duration of employment for the cases ranged from 1.5 to 25 years with a mean of 14.4. Sixteen of the lung cancer cases were smokers.

In the first case-control study reported, the 15 lung cancer cases identified up to September 1991 were matched to controls by age and hire date (five controls per case). Cases and controls were compared based upon their job categories within the plant. The results showed that cases were more likely to have worked in the kiln area than the controls. Five of the 15 cases had five or more years in the kiln area where Cr(VI) exposure occurred vs. six of the 75 controls. A second case-control study utilized the 18 lung cancer cases identified in post change workers up to March 1996. Five controls per case were matched by age (+/−5 years), gender and hire date. Both cases and controls had a minimum of one year of employment. A job exposure matrix was being constructed that would allow the investigators to "estimate exposure to hexavalent chromates for each worker in the study for all the jobs done since the start of employment at the site until 1980." Starting in 1970 industrial hygiene sampling was performed to determine exposure for all jobs at the plant. Cr(VI) exposure levels for the period between 1960 and 1969 were being estimated based on the recall of employees regarding past working conditions relative to current conditions from a questionnaire. The author stated that preliminary analysis suggests that the maximum recorded or estimated level of exposure to Cr(VI) for the cases was higher than that of the controls. However, specific values for the estimated Cr(VI) exposures were not reported.

Korallus *et al.* conducted a study of 1,140 active and retired workers with a minimum of one year of employment between January 1, 1948 and March 31, 1979 at two German chromate production plants (Ex. 7–26). Workers employed prior to January 1, 1948 (either active or retired) and still alive at that date were also included in the cohort. The primary source for determining cause of death was medical records. Death certificates were used only when medical records could not be found. Expected deaths were calculated using the male population of North Rhineland-Westphalia. Elevated SMRs for cancer of the respiratory system (50 lung cancers and one laryngeal cancer) were seen at both plants (O=21; E=10.9; SMR=192 and O=30; E=13.4; SMR=224).

Korallus *et al.* reported an update of the study. The cohort definition was expanded to include workers with one year of employment between January 1, 1948 and December 31, 1987 (Ex. 7–91). One thousand four hundred and seventeen workers met the cohort entrance criteria and were followed through December 31, 1988. While death certificates were used, where possible, to obtain cause of death, a majority of the cause of death data was obtained from hospital, surgical and general practitioner reports and autopsies because of Germany's data protection laws. Smoking data for the cohort were incomplete.

Process modifications at the two plants eliminated the high-lime process by January 1, 1958 at one location and January 1, 1964 at the second location. In addition, technical measures were introduced which led to reductions in the workplace air concentrations of chromate dusts. Cohort members were divided into pre- and post-change cohorts, with subcohorts in the pre-change group. SMRs were computed with the expected number of deaths derived from the regional mortality rates (where the plants are located). One plant had 695 workers (279 in the pre-change group and 416 in the post change group). The second plant had 722 workers (460 in the pre-change group and 262 in the post-change group). A total of 489 deaths were ascertained (225 and 264 deaths). Of the cohort members, 6.4% were lost to follow-up.

Lung cancer is defined as deaths coded 162 in the 9th revision of the *International Classification of Diseases.* There were 32 lung cancer deaths at one plant and 43 lung cancer deaths at the second plant. Lung cancer SMRs by date of entry (which differ slightly by plant) show elevated but declining SMRs for each plant, possibly due to lower Cr(VI) exposure as a result of improvements in production process. The lung cancer SMR for those hired before 1948 at Plant 1 is statistically significant (O=13; SMR=225; 95% CI: 122–382). The overall lung cancer SMR for Plant 1 is also statistically significantly elevated based upon 32 deaths (SMR=175; 95% CI: 120–246). At Plant 2, the only lung cancer SMR that is not statistically significant is for those hired after 1963 (based upon 1 death). Lung cancer SMRs for those hired before 1948 (O=23; SMR=344; 95% CI: 224–508) and for those hired between 1948 and 1963 (O=19; SMR=196; 95% CI: 1.24–2.98) are statistically significantly elevated. The overall lung cancer SMR at Plant 2 based upon 43 deaths is 239 (95% CI: 177–317). No nasal cavity neoplasms were found. A statistically significant SMR for stomach cancer was observed at Plant 2 (O=12; SMR=192; 95% CI: 104–324).

DeMarco *et al.* conducted a cohort study of chromate production workers in northern Italy to assess the existence of excess risk of respiratory cancer, specifically lung cancer (Ex. 7–54). The cohort was defined as males who worked for a minimum of one year from 1948 to 1985 and had at least 10 years of follow-up. Five hundred forty workers met the cohort definition. Vital status follow-up, carried out through June 30, 1985, found 427 cohort members alive, 110 dead and three lost to follow-up. Analysis utilizing SMRs based on Italian national rates was conducted. Of the 110 deaths, 42 were cancer deaths. The statistically significant SMR for lung cancer based upon 14 observed deaths with 6.46 expected was 217 (95% CI: 118–363

Exposure estimates were based upon the duration of cumulative exposure and upon a risk score (low, medium, high and not assessed) assigned to the department in which the worker was primarily employed. A committee assigned the scores, based upon knowledge of the production process or on industrial hygiene surveys taken in 1974, 1982 and 1984. The risk score is a surrogate for the workplace concentrations of Cr(VI) in the different plant departments. Since no substantial changes had been made since World War II, the assumption was made that exposures remained relatively stable. Lung cancer SMRs based upon type of exposure increased with level of exposure (Low: O=1; E=1.43; SMR=70; Medium: O=5; E=202; SMR=2.48; High: O=6; E=1.4; SMR=420; Not Assessed: O=2; E=1.6; SMR=126). Only the SMR for those classified as having worked in departments characterized as high exposure was statistically significant at the $p<0.05$ level.

A cohort study of workers at a chromium compounds manufacturing plant in Tokyo, Japan by Satoh *et al.* included males employed between 1918 and 1975 for a minimum of one year and for whom the necessary data were

available (Ex. 7–27). Date and cause of death data were obtained from the death certificate (85%) or from other "reliable" written testimony (15%). Of the 1,061 workers identified, 165 were excluded from the study because information was missing. A total of 896 workers met the cohort inclusion criteria and were followed through 1978. The causes of 120 deaths were ascertained. SMRs based on age-cause specific mortality for Japanese males were calculated for four different time periods (1918–1949; 1950–1959; 1960–1969 and 1970–1978) and for the entire follow-up period (1918–1978). An elevated SMR for lung cancer is seen for the entire follow-up period (O=26; E=2.746; SMR=950). A majority of the lung cancer deaths (20) occurred during the 1970–1978 interval.

Results from the many studies of chromate production workers from different countries indicate a relationship between exposure to chromium and malignant respiratory disease. The epidemiologic studies done between 1948 and 1952 by Machle and Gregorius (Ex. 7–2), Mancuso and Hueper (Ex. 7–12) and Brinton, *et al.* (Ex. 7–1) suggest a risk for respiratory cancer among chromate workers between 15 and 29 times expectation. Despite the potential problems with the basis for the calculations of the expectations or the particular statistical methods employed, the magnitude of the difference between observed and expected is powerful enough to overcome these potential biases.

It is worth noting that the magnitude of difference in the relative risks reported in a mortality study among workers in three chromate plants in the U.K. (Ex.7–20) were lower than the relative risks reported for chromate workers in the U.S. during the 1950s and 1960s. The observed difference could be the result of a variety of factors including different working conditions in the two countries, a shorter follow-up period in the British study, the larger lost-to-follow-up in the British study or the different statistical methods employed. While the earlier studies established that there was an excess risk for respiratory cancer from exposure to chromium, they were unable to specify either a specific chromium compound responsible or an exposure level associated with the risk. Later studies were able to use superior methodologies to estimate standardized lung cancer mortality ratios between chromate production cohorts and appropriate reference populations (Exs. 7–14; 7–22; 7–26; 7–99; 7–91). These studies generally found statistically increased lung cancer risk of around two-fold. The studies usually found trends with duration of employment, year of hire, or some production process change that tended to implicate chromium exposure as the causative agent.

The most recent studies were able to use industrial hygiene data to reconstruct historical Cr(VI) exposures and show statistically significant associations between cumulative airborne Cr(VI) and lung cancer mortality (Exs. 23; 31–22–11; Ex. 31–18–4). Gibb *et al.* found the significant association between Cr(VI) and lung cancer was evident in models that accounted for smoking. The exposure'response relationship from these chromate production cohorts provide strong evidence that occupational exposure to Cr(VI) dust can increase cancer in the respiratory tract of workers.

The Davies, Korallus, and Luippold studies examine mortality patterns at chromate producing facilities where one production process modification involved conversion from a high-lime to a low-lime or a lime-free process (Exs. 7–99; 7–91; 31–18–4). In addition to process modification, technical improvements also were implemented that lowered Cr(VI) exposure. One of the plants in the Davies study retained the high-lime process and is not discussed. The lung cancer SMRs for one British plant and both of the German plants declined from early, to pre-change to post change time periods. In the remaining British plants, the lung cancer SMR is basically identical for the early and pre-change period, but does decline in the post-change time period. The lung cancer SMR in the Luippold cohort also declined over time as the amount of lime was reduced in the roasting process. Other modifications at the Painesville plant that reduced airborne Cr(VI) exposure, such as installation of covered conveyors and conversion from batch to continuous process occurred at the same time (Ex. 35–61). It is not clear whether reduced levels of the high-lime byproduct, calcium chromate, or the roasting/leaching end product, sodium dichromate that resulted from the various process changes is the reason for the decrease in lung cancer SMRs in these cohorts. However, it should be noted increased lung cancer risk was experienced by workers at the Baltimore plant (*e.g.*, Hayes and Gibb cohorts) even though early air monitoring studies suggest that a lime-free process was probably used at this facility (Ex. 7–17).

2. Evidence From Chromate Pigment Production Workers

Chromium compounds are used in the manufacture of pigments to produce a wide range of vivid colors. Lead and zinc chromates have historically been the predominant hexavalent chromium pigments, although others such as strontium and barium chromate have also been produced. These chromates vary considerably in their water solubility with lead and barium chromates being the most water insoluble. All of the above chromates are less water-soluble than the highly water-soluble sodium chromate and dichromate that usually serve as the starting material for chromium pigment production. The reaction of sodium chromate or dichromate with the appropriate zinc or lead compound to form the corresponding lead or zinc chromate takes place in solution. The chromate pigment is then precipitated, separated, dried, milled, and packaged. Worker exposures to chromate pigments are greatest during the milling and packaging stages.

There have been a number of cohort studies of chromate pigment production workers from the United States, the United Kingdom, France, Germany, the Netherlands, Norway and Japan. Most of the studies found significantly elevated lung cancers in workers exposed to Cr(VI) pigments over many years when compared against standardized reference populations. In general, the studies of chromate pigment workers lack the historical exposure data found in some of the chromate production cohorts. The consistently higher lung cancers across several worker cohorts exposed to the less water-soluble Cr(VI) compounds complements the lung cancer findings from the studies of workers producing highly water soluble chromates and adds to the further evidence that occupational exposure to Cr(VI) compounds should be regarded as carcinogenic. A summary of selected human epidemiologic studies in chromate production workers is presented in Table VI–2.

TABLE VI–2.—SUMMARY OF SELECTED EPIDEMIOLOGIC STUDIES OF LUNG CANCER IN WORKERS EXPOSED TO HEXAVALENT CHROMIUM—CHROMATE PIGMENT PRODUCTION

Reference/exhibit No.	Study population	Reference population	Chromium (VI) exposure	Lung cancer risk
Langard & Vigander (1983, Ex. 7–36). Langard & Vigander (1975, Ex. 7–33).	133 Norwegian chromium pigment production workers employed between 1948 and 1972; 24 workers with 3+ years exposure to chromate dust; follow up through 1980.	Cancer incidence from Norwegian Cancer Registry 1955–1976.	Lead and zinc chromates with some sodium dichromate as starting material; Cr(VI) levels between 10 and 30 µg/m³ 1975–1980. No reporting <1975.	–O/E of 44 for subcohort of 24 workers based on 6 cancer cases. –5 of 6 cases were exposed primarily to zinc chromate.
Davies (1984, Ex. 7–42) ..... Davies (1979, Ex. 7–41).	1152 British chromate pigment workers from 3 plants with a minimum of 1 year employment between 1930–June, 1975; follow up through 1981.	Mortality of England and Wales	Factory A: chromates—primarily lead; some zinc; minor barium Factory B: mostly lead and zinc chromates; minor strontium. Factory C: lead chromate only No Cr(VI) levels reported.	—O/E of 2.2 ($p<0.05$) for high exposed in Factory A 1932–1954; 21 deaths. —O/E of 4.4 ($p<0.05$) for high exposed in Factory B 1948–1967; 11 deaths. —O/E of 1.1 (NS) for exposed Factory C 1946–1967; 7 deaths.
Hayes *et al.* (1989, Ex. 7–46) Sheffet *et al.* (1982, Ex. 7–48).	1,946 male pigment workers from New Jersey facility employed for a minimum of one month between 1940 and 1969; follow up through March, 1982.	U.S. Mortality	–Primarily lead chromate with some zinc chromate. –Cr(VI) levels in later years reported to be >500 µg/m$_3$ for exposed workers.	—O/E of 1.2 (NS) for entire cohort based on 41 deaths. —O/E of 1.5 ($p<0.5$) for workers employed >10 yr based on 23 deaths. —Upward trend ($p<0.01$) with duration of exposure.
Equitable Environmental Health (1983, Ex. 2–D–1). Equitable Environmental Health (1976, Ex. 2–D–3)	574 male chromate workers from three plants (West Virginia, New Jersey or Kentucky) with a minimum of 6 months of exposure to lead chromate prior to 1974.	U.S. white male mortality rates	West Virginia: lead chromates Kentucky: chromates—mostly lead, some zinc, minor strontium and barium. —New Jersey; mostly lead and some zinc chromate. —Median Cr(VI) in 1975 reported to equal or exceed 52 µg/m³	—O/E of 1.30 (NS) for West Virginia plant based on 3 deaths. —O/E of 2.16 (NS) for Kentucky plant based on 3 deaths. —O/E of 2.31 ($p<.05$) for New Jersey plant based on 9 deaths.
Deschamps *et al.* (1995, 35–234). Haguenoer *et al.* (1981, Ex. 7–44)	294 male pigment workers from French facility employed for a minimum of six months between 1958 and 1987.	Death rates from northern France.	—Mostly lead chromate with some zinc chromate. —Cr(VI) levels in 1981 between 2 and 180 µg/m³	—O/E of 3.6 ($p<0.01$) based on 18 deaths. —Upward trend ($p<0.01$) with duration of exposure.

Observed/Expected (O/E).
Relative Risk (RR).
Not Statistically Significant (NS).
Odds Ratio (OR).

Langard and Vigander updated a cohort study of lung cancer incidence in 133 workers employed by a chromium pigment production company in Norway (Ex. 7–36). The cohort was originally studied by Langard and Norseth (Ex. 7–33). Twenty-four men had more than three years of exposure to chromate dust. From 1948, when the company was founded, until 1951, only lead chromate pigment was produced. From 1951 to 1956, both lead chromate and zinc chromate pigments were produced and from 1956 to the end of the study period in 1972 only zinc chromate was produced. Workers were exposed to chromates both as the pigment and its raw material, sodium dichromate.

The numbers of expected lung cancers in the workers were calculated using the age-adjusted incidence rates for lung cancer in the Norwegian male population for the period 1955–1976. Follow-up using the Norwegian Cancer Registry through December 1980, found the twelve cancers of which seven were lung cancers. Six of the seven lung cancers were observed in the subcohort of 24 workers who had been employed for more than three years before 1973. There was an increased lung cancer incidence in the subcohort based on an observed to expected ratio of 44 (O=6; E=0.135). Except for one case, all lung cancer cases were exposed to zinc chromates and only sporadically to other chromates. Five of the six cases were known to be smokers or ex-smokers. Although the authors did not report any formal statistical comparisons, the extremely high age-adjusted standardized incidence ratio suggests that the results would likely be statistically significant.

Davies reported on a cohort study of English chromate pigment workers at three factories that produced chromate pigments since the 1920s or earlier (Ex. 7–41). Two of the factories produced both zinc and lead chromate. Both products were made in the same sheds and all workers had mixed exposure to both substances. The only product at the third factory was lead chromate.

Cohort members are defined as males with a minimum of one year of employment first hired between 1933 and 1967 at plant A; 1948 and 1967 at plant B and 1946–1961 at plant C. The analysis excludes men who entered employment later than 1967 because of the short follow-up period. Three hundred and ninety-six (396) men from Factory A, 136 men from Factory B and 114 men from Factory C were followed to mid-1977. Ninety-four workers with 3–11 months employment during 1932–1945 at Factory A were also included. Expectations were based upon calendar time period-, gender- and age-specific national cancer death rates for England and Wales. The author adjusted the death rates for each factory for local differences, but the exact methods of adjustment were not explicit.

Exposure to chromates was assigned as high for those in the dry departments where pigments were ground, blended and packed; medium for those in the wet departments where precipitates were washed, pressed and stove dried and in maintenance or cleaning which required time in various departments; or low for those jobs which the author states involved "slight exposure to chromates such as most laboratory jobs, boiler stoking, painting and bricklaying" (Ex. 7–41, p. 159). The high and

medium exposure categories were combined for analytical purposes.

For those entering employment from 1932 to 1954 at Factory A, there were 18 lung cancer deaths in the high/medium exposure group, with 8.2 deaths expected. The difference is significant at p<. 01. In the low exposure group, the number of observed and expected lung cancer deaths was equal (two deaths). There were no lung cancer deaths at Factory A for those hired between 1955–1960 and 1961–1967.

For those entering employment between 1948 and 1967 at Factory B, there were seven observed lung cancer deaths in the high/medium exposure group with 1.4 expected which is statistically significant at p<. 001. At Factory C (which manufactured only lead chromate), there was one death in the high/medium exposure group and one death in the low exposure group for those beginning employment between 1946 and 1967.

The author points out that:

> There has been no excess lung cancer mortality amongst workers with chromate exposure rated as "low", nor among those exposed only to lead chromate. High and medium exposure-rated workers who in the past had mixed exposure to both lead and zinc chromate have experienced a marked excess of lung cancer deaths, even if employed for as little as one year" (Ex. 7–41, p. 157).

It is the author's opinion that the results "suggest that the manufacture of zinc chromate may involve a lung cancer hazard" (Ex. 7–41, p. 157).

Davies updated the lung cancer mortality at the three British chromate pigment production factories (Ex. 7–42). The follow-up was through December 31, 1981. The cohort was expanded to include all male workers completing one year of service by June 30, 1975 but excluded office workers.

Among workers at Factory A with high and medium exposure, mortality was statistically significantly elevated over the total follow-up period among entrants hired from 1932 to 1945 (O/E=2.22). A similar, but not statistically significant, excess was seen among entrants hired from 1946 to 1954 (O/E=2.23). The results for Factory B showed statistically significantly elevated lung cancer mortality among workers classified with medium exposures entering service during the period from 1948 to 1960 (O/E=3.73) and from 1961 to 1967 (O/E=5.62). There were no lung cancer deaths in the high exposure group in either time period. At Factory C, analysis by entry date (early entrant and the period 1946–1960) produced no meaningful results since the number of deaths was small. When the two periods are combined, the O/E was near unity. The author concluded that in light of the apparent absence of risk at Factory C, "it seems reasonable to suggest that the hazard affecting workers with mixed exposures at factories A and B * * * is attributable to zinc chromates" (Ex. 7–42, p. 166).

Davies also studied a subgroup of 57 chromate pigment workers, mostly employed between 1930 and 1945, who suffered clinical lead poisoning (Ex. 7–43). Followed through 1981, there was a statistically significantly elevated SMR for lung cancer based upon four cases (O=4; E=2.8; SMR=145).

Haguenoer studied 251 French zinc and lead chromate pigment workers employed for six months or more between January 1, 1958 and December 31, 1977 (Ex. 7–44). As of December 31, 1977, 50 subjects were identified as deceased. Cause of death was obtained for 30 of the 50 deaths (60%). Lung cancer mortality was significantly elevated based on 11 fatalities (SMR=461; 95% CI: 270–790). The mean time from first employment until detection of cancer was 17 years. The mean duration of employment among cases was 15 years.

The Haguenoer cohort was followed up in a study by Deschamps *et al.* (Ex. 234). Both lead and zinc chromate pigments were produced at the plant until zinc chromate production ceased in 1986. The cohort consisted of 294 male workers employed for at least six months between 1958 and 1987. At the end of the follow-up, 182 cohort members were alive, 16 were lost to follow-up and 96 were dead. Because of French confidentiality rules, the cause of death could not be obtained from the death certificate; instead physicians and hospital records were utilized. Using cause of death data from sources other than death certificates raises the potential for misclassification bias. Cause of death could not be obtained for five decedents. Data on smoking habits was not available for a number of workers and was not used in the analysis.

Since individual work histories were not available, the authors made the assumption that the exposure level was the same for all workers during their employment at the plant. Duration of employment was used as a surrogate for exposure. Industrial hygiene measurements taken in 1981 provide some idea of the exposure levels at the plant. In the filtration department, Cr(VI) levels were between 2 and 3 μg/m^3; in the grinding department between 6 and 165 μg/m^3; in the drying and sacking department between 6 and 178 μg/m^3; and in the sacks marking department more than 2000 μg/m^3.

The expected number of deaths for the SMR analysis was computed from age-adjusted death rates in the northern region of France where the plant was located. There was a significant increase in lung cancer deaths based on 18 fatalities with five expected (SMR=360; 95% CI: 213–568). Using duration of employment as a surrogate for exposure, statistically significant SMRs were seen for the 10–15 years of exposure (O=6, SMR=720, 95% CI: 264–1568), 15–20 years (O=4, SMR=481, 95% CI: 131–1231), and 20+ years (O=6, SMR=377, 95% CI: 1.38–8.21) time intervals. There was a significantly elevated SMR for brain cancer based upon two deaths (SMR=844, 95% CI: 102–3049). There was a non-statistically significant increase for digestive tract cancer (O=9, SMR=130) consisting of three esophageal cancers, two stomach cancers and four colon cancers.

Equitable Environmental Health, Inc., on behalf of the Dry Color Manufacturers Association, undertook a historical prospective mortality study of workers involved in the production of lead chromate (Exs. 2–D–3; 2–D–1). The cohort was defined as male employees who had been exposed to lead chromate for a minimum of six months prior to December 1974 at one of three facilities in West Virginia, Kentucky or New Jersey. The New Jersey facility had a unit where zinc chromate was produced dating back to 1947 (Ex. 2–D–3). Most workers rotated through this unit and were exposed to both lead and zinc chromates. Two men were identified at the New Jersey facility with exposure solely to lead chromate; no one with exposure only to zinc chromate was identified.

Subsequent review of the data found that the Kentucky plant also produced zinc chromates from the late 1930s to early 1964. During the period 1961–1962, zinc chromates accounted for approximately 12% of chromate production at the plant. In addition, strontium chromate and barium chromate also were produced at the plant.

The cohort consisted of 574 male employees from all three plants (Ex. 2–D–1). Eighty-five deaths were identified with follow up through December 1979. Six death certificates were not obtained. SMRs were reported based on U.S. white male death rates. There were 53 deaths from the New Jersey plant including a statistically significant SMR for cancer of the trachea, bronchus and lung based upon nine deaths (E=3.9; SMR=231; 95% CI: 106–438). One lung cancer decedent worked solely in the

production of lead chromates. Three of the lung cancer deaths were black males. In addition, there were six deaths from digestive system cancers, five of which were stomach cancers reported at the New Jersey plant. The SMR for stomach cancer was statistically significantly elevated (O=5; E=0.63; SMR=792; 99% CI: 171–2243). There were 21 deaths from the West Virginia plant, three of which were cancer of the trachea, bronchus and lung (E=2.3; SMR=130; 95% CI: 27–381). There were 11 deaths at the Kentucky plant, two of which were cancer of the trachea, bronchus and lung (E=0.9; SMR=216; 95% CI: 26–780).

Sheffet *et al.* examined the lung cancer mortality among 1,946 male employees in a chromate pigment factory in Newark, New Jersey who were exposed to both lead chromate and zinc chromate pigments (Ex. 7–48). The men worked for a minimum of one month between January 1, 1940 and December 31, 1969. As of March 31, 1979, a total of 321 cohort members were identified as deceased (211 white males and 110 non-white males). Cause of death could not be ascertained for 37 white males and 12 non-white males. The proportion of the cohort lost to follow up was high (15% of white males and 20% of non-white males).

Positions at the plant were classified into three categories according to intensity of exposure: high (continuous exposure to chemical dust), moderate (occasional exposure to chemical dust or to dry or wet pigments) and low (infrequent exposure by janitors or office workers). Positions were also classified by type of chemical exposure: chromates, other inorganic substances, and organics. The authors' state that in almost all positions individuals "who were exposed to any chemicals were also exposed to hexavalent chromium in the form of airborne lead and zinc chromates (Ex. 7–48, p. 46)." The proportion of lead chromate to zinc chromate was approximately nine to one. Calculations, based upon air samples during later years, give an estimate for the study period of more than 2000 µg airborne chromium/m^3 for the high exposure category, between 500 and 2000 µg airborne chromium/m^3 and less than 100 µg airborne chromium/m^3 for the low exposure category. Other suspected carcinogens present in the workplace air at much lower levels were nickel sulfate and nickel carbonate.

Because of the large proportion of workers lost to follow-up (15% of white males and 20% of non-white males) and the large numbers of unknown cause of death (21% of white males and 12% of non-white males), the authors calculated three separate mortality expectations based upon race-, gender-, age- and time-specific U.S. mortality ratios. The first expectation was calculated upon the assumption that those lost to follow-up were alive at the end of the study follow-up period. The second expectation was calculated on the assumption that those whose vital status was unknown were lost to follow-up as of their employment termination date. The third expectation was calculated excluding those of unknown vital status from the cohort. Deaths with unknown cause were distributed in the appropriate proportions among known causes of death which served as an adjustment to the observed deaths. The adjusted deaths were used in all of the analyses.

A statistically significant ratio for lung cancer deaths among white males (O/E=1.6) was observed when using the assumption that either the lost to follow-up were assumed lost as of their termination date or were excluded from the cohort (assumptions two and three above). The ratio for lung cancer deaths for non-white males results in an identical O/E of 1.6 for all three of the above scenarios, none of which was statistically significant.

In addition, the authors also conducted Proportionate Mortality Ratio (PMR) and Proportionate Cancer Mortality Ratio (PCMR) analyses. For white males, the lung cancer PMR was 200 and the lung cancer PCMR was 160 based upon 25.5 adjusted observed deaths (21 actual deaths). Both were statistically significantly elevated at the $p<.05$ level. For non-white males, the lung cancer PMR was 200 and the lung cancer PCMR was 150 based upon 11.2 adjusted observed deaths (10 actual deaths). The lung cancer PMR for non-white males was statistically significantly elevated at the $p<.05$ level. Statistically significantly elevated PMRs and PCMRs for stomach cancer in white males were reported (PMR=280; PCMR=230) based upon 6.1 adjusted observed deaths (five actual).

The Sheffet cohort was updated in a study by Hayes *et al.* (Ex. 7–46). The follow up was through December 31, 1982. Workers employed as process operators or in other jobs which involved direct exposure to chromium dusts were classified as having exposure to chromates. Airborne chromium concentrations taken in "later years" were estimated to be >500 µg g/m^3 for "exposed" jobs and >2000 µg /m^3 for "highly exposed" jobs.

The cohort included 1,181 white and 698 non-white males. Of the 453 deaths identified by the end of the follow-up period, 41 were lung cancers. For the entire study group, no statistically significant excess was observed for lung cancer (SMR=116) or for cancer at any other site. Analysis by duration of employment found a statistically significant trend (p=. 04) for lung cancer SMRs (67 for those employed < 1 year; 122 for those employed 1–9 years and 151 for those employed 10+ years).

Analysis of lung cancer deaths by duration of employment in chromate dust associated jobs found no elevation in risk for subjects who never worked in these jobs (SMR=92) or for subjects employed less than one year in these jobs (SMR=93). For those with cumulative employment of 1–9 and 10+ years in jobs with chromate dust exposure, the SMRs were 176 (nine deaths) and 194 (eight deaths) respectively.

Frentzel-Beyme studied the mortality experience of 1,396 men employed for more than six months in one of five factories producing lead and zinc chromate pigments located in Germany and the Netherlands (Ex. 7–45). The observed deaths from the five factories were compared with the expected deaths calculated on the basis of mortality figures for the region in which the plant was located. Additional analysis was conducted on relevant cohorts which included workers with a minimum of 10 years exposure, complete records for the entire staff, and exclusion of foreign nationals. Jobs were assigned into one of three exposure categories: high (drying and milling of the filtered pigment paste), medium (wet processes including precipitation of the pigment, filtering and maintenance, craftsmen and cleaning) and low or trivial exposure (storage, dispatch, laboratory personnel and supervisors).

There were 117 deaths in the entire cohort of which 19 were lung cancer deaths (E=9.3). The lung cancer SMRs in the relevant cohort analyses were elevated at every plant; however, in only one instance was the increased lung cancer SMR statistically significant, based upon three deaths (SMR=386, $p<0.05$). Analysis by type of exposure is not meaningful due to the small number of lung cancer death per plant per exposure classification.

Kano *et al.* conducted a study of five Japanese manufacturers who produced lead chromates, zinc chromate, and/or strontium chromate to assess if there was an excess risk of lung cancer (Ex. 7–118). The cohort consisted of 666 workers employed for a minimum of one year between 1950 and 1975. At the end of 1989, 604 subjects were alive, five lost to follow-up and 57 dead. Three lung cancer deaths were observed

in the cohort with 2.95 expected (SMR=102; 95% CI: 0.21–2.98). Eight stomach cancer deaths were reported with a non-statistically significant SMR of 120.

In response to OSHA's August 2002 Request for Information, the Color Pigment Manufacturers Association suggested that OSHA consider reviewing the Davies (Ex. 7–43), Cooper [Equitable Environmental Health, Inc.] (Ex. 2–D–1) and Kano (Ex. 14–1–B) epidemiologic studies with respect to the health effects of lead chromate color pigments. The Equitable Environmental Health and the Kano *et al.* studies each report three deaths from lung cancer among chromate pigment production workers. The number of lung cancer deaths is too small to be meaningful. Even if there were a sufficient number of deaths for analysis, no quantitative exposure data are provided. In the case of the Davies study, there were seven lung cancer deaths at the one manufacturing facility that made only lead chromate pigments. When analyzed by period (early, 1946–1967) and high/medium and low exposure category, the numbers are too small in any category to be meaningful. Studies of lead and zinc chromate pigment worker cohorts that experienced a greater number of lung cancer deaths (*e.g.*, >10 deaths) consistently found significant elevations in lung cancer risk, particularly those workers with the longest latency and durations of exposure (Exs. 234; 7–46; 7–42).

3. Evidence From Workers in Chromium Plating

Chrome plating is the process of depositing chromium metal onto the surface of an item using a solution of chromic acid. The items to be plated are suspended in a diluted chromic acid bath. A fine chromic acid mist is produced when gaseous bubbles, released by the dissociation of water, rise to the surface of the plating bath and burst. There are two types of chromium electroplating. Decorative or "bright" involves depositing a thin (0.5–1 μm) layer of chromium over nickel or nickel-type coatings to provide protective, durable, non-tarnishable surface finishes. Decorative chrome plating is used for automobile and bicycle parts. Hard chromium plating produces a thicker (exceeding 5 μm) coating which makes it resistant and solid where friction is usually greater, such as in crusher propellers and in camshafts for ship engines. Limited air monitoring indicates that Cr(VI) levels are five to ten times higher during hard plating than decorative plating (Ex. 35–116).

There are fewer studies that have examined the lung cancer mortality of chrome platers than of soluble chromate production and chromate pigment production workers. The largest and best described cohort studies investigated chrome plating cohorts in the United Kingdom (Exs. 7–49; 7–57; 271; 35–62). They generally found elevated lung cancer mortality among the chrome platers, especially those engaged in chrome bath work, when compared to various reference populations. The studies of British chrome platers are summarized in Table VI–3.

TABLE VI–3.—SUMMARY OF SELECTED EPIDEMIOLOGIC STUDIES OF LUNG CANCER IN WORKERS EXPOSED TO HEXAVALENT CHROMIUM—CHROMIUM PLATING

Reference/exhibit No.	Study population	Reference population	Chromium (VI) exposure	Lung cancer risk
Sorahan & Harrington (2000, Ex. 35–62). Royle (1975, Ex. 7–49)	920 male platers employed in 54 plants in Yorkshire, UK for a minimum of three months between 1969 and 1972; follow up through 1997.	—Mortality rates for the general population of England and Wales. —Age-, sex-matched comparison group unexposed to CR(VI).	—Chromic acid mist with some nickel and cadmium co-exposure. —Cr(VI) levels in 1970 reported to range from <30 μg/m^3 to >100 μg/m^3.	—O/E of 1.85 (p=0.001) based on 60 deaths and general pop. —O/E of 1.39 (p=0.06) based on unexposed comparison group. —No upward trend w/duration of exposure.
Sorahan *et al.* (1998, Ex. 35–271). Sorahan *et al.* (1987, Ex. 7–57).	1,762 platers employed for a minimum of six months between 1946 and 1975 from a Midlands, UK plant; follow up through 1995.	—Mortality rates for the general population of England and Wales.	—Chromic acid mist with nickel co-exposure. —No reported Cr(VI) exposure levels.	—O/E of 1.6 (p<0.01) for male chrome bath workers based on 40 deaths. —O/E of 0.66 (NS) for other chrome workers based on 9 deaths. —Upward trend (p<0.05) with duration of chrome bath work.

Observed/Expected (O/E).
Relative Risk (RR).
Not Statistically Significant (NS).
Odds Ratio (OR).

Cohort studies of chrome platers in Italy, the United States, and Japan are also discussed in this subsection. Co-exposure to nickel, another suspected carcinogen, during plating operations can complicate evaluation of an association between Cr(VI) and an increased risk of lung cancer in chrome platers. Despite this, the International Agency for Research on Cancer concluded that the epidemiological studies provide sufficient evidence for carcinogenicity of Cr(VI) as encountered in the chromium plating industry; the same conclusion reached for chromate production and chromate pigment production (Exs. 18–1; 35–43). The findings implicate the highly water-soluble chromic acid as an occupational carcinogen. This adds to the weight of evidence that water-soluble (*e.g.*, sodium chromates, chromic acid) and water-insoluble forms (*e.g.*, lead and zinc chromates) of Cr(VI) are able to cause cancer of the lower respiratory tract.

Royle reported on a cohort mortality study of 1,238 chromium platers employed for a minimum of three consecutive months between February 20, 1969 and May 31, 1972 in 54 plating plants in West Riding, Yorkshire, England (Ex. 7–49). A control population was enumerated from other departments of the larger companies where chromium plating was only a portion of the companies' activities and from the former and current employees of two industrial companies in York where information on past workers was available. Controls were matched for gender, age (within two years) and date last known alive. In addition, 229 current workers were matched for smoking habits.

As of May 1974, there were 142 deaths among the platers (130 males and 12 females) and 104 deaths among the controls (96 males and 8 females). Among the male platers, there were 24 deaths from cancer of the lung and pleura compared to 13 deaths in the control group. The difference was not statistically significant. There were eight deaths from gastrointestinal cancer among male platers versus four deaths in the control group. The finding was not statistically significant.

The Royle cohort was updated by Sorahan and Harrington (Ex. 35–62). Chrome plating was the primary activity at all 54 plants, however 49 of the plants used nickel and 18 used cadmium. Also used, but in smaller quantities according to the authors, were zinc, tin, copper, silver, gold, brass or rhodium. Lead was not used at any of the plants. Four plants, including one of the largest, only used chromium. Thirty-six chrome platers reported asbestos exposure versus 93 comparison workers.

Industrial hygiene surveys were carried out at 42 plants during 1969–1970. Area air samples were done at breathing zone height. With the exception of two plants, the chromic acid air levels were less than 30 $\mu g/m^3$. The two exceptions were large plants, and in both the chromic acid levels exceeded 100 $\mu g/m^3$.

The redefined cohort consisted of 1087 platers (920 men and 167 women) from 54 plants employed for a minimum of three months between February 1969 and May 31, 1972 who were alive on May 31, 1972. Mortality data were also available for a comparison group of 1,163 workers (989 men and 174 women) with no chromium exposure. Both groups were followed for vital status through 1997.

The lung cancer SMR for male platers was statistically significant (O=60; E=32.5; SMR=185; 95% CI: 141–238). The lung cancer SMR for the comparison group, while elevated, was not statistically significant (O=47; E=36.9; SMR=127; 95% CI: 94–169). The only statistically significant SMR in the comparison group was for cancer of the pleura (O=7; E=0.57; SMR=1235; 95% CI: 497–2545).

Internal regression analyses were conducted comparing the mortality rates of platers directly with those of the comparison workers. For these analyses, lung cancers mentioned anywhere on the death certificate were considered cases. The redefinition resulted in four additional lung cancer cases in the internal analyses. There was a statistically significant relative risk of 1.44 ($p<0.05$) for lung cancer mortality among chrome platers that was slightly reduced to 1.39 after adjustment for smoking habits and employment status. There was no clear trend between lung cancer mortality and duration of Cr(VI) exposure. However, any positive trend may have been obscured by the lack of information on worker employment post-1972 and the large variation in chromic acid levels among the different plants.

Sorahan reported the experience of a cohort of 2,689 nickel/chromium platers from the Midlands, U.K. employed for a minimum of six months between 1946 and 1975 and followed through December 1983 (Ex. 7–57). There was a statistically significant lung cancer SMR for males (O=63; E=40; SMR=158; $p<0.001$). The lung cancer SMR for women, while elevated (O=9; E=8.1; SMR=111), was not statistically significant. Other statistically significant cancer SMRs for males included: stomach (O=21; E=11.3; SMR=186; $p<0.05$); liver (O=4; E=0.6; SMR=667; $p<0.01$); and nasal cavities (O=2; E=0.2; SMR=1000; $p<0.05$). While there were several elevated SMRs for women, none were statistically significant. There were nine lung cancers and one nasal cancer among the women.

Analysis by type of first employment (i.e., chrome bath workers vs. other chrome work) resulted in a statistically significant SMR for lung cancer of 199 (O=46; E=23.1; $p<0.001$) for chrome bath workers and a SMR of 101 for other chrome work. The SMR for cancer of the stomach for male chrome bath workers was also statistically significantly elevated (O=13; E=6.3; SMR=206; $p<0.05$); for stomach cancer in males doing other chrome work, the SMR was 160 with 8 observed and 5 expected. Both of the nasal cancers in males and the one nasal cancer in women were chrome bath workers. The nasal cancer SMR for males was statistically significantly elevated (O=2; E=0.1; SMR=2000; $p<0.05$).

Regression analysis was used to examine evidence of association of several types of cancers and Cr(VI) exposure duration among the cohort. There was a significant positive association between lung cancer mortality and exposure duration as a chrome bath worker controlling for gender as well as year and age at the start of employment. There was no evidence of an association between other cancer types and duration of Cr(VI) exposure. There was no positive association between duration of exposure to nickel bath work and cancer of the lung. The two largest reported SMRs were for chrome bath workers 10–14 years (O=13; E=3.8; SMR=342; $p<0.001$) and 15–19 years (O=12; E=4.9; SMR=245; $p<0.01$) after starting employment. The positive associations between lung cancer mortality and duration of chrome bath work suggests Cr(VI) exposure may be responsible for the excess cancer risk.

Sorahan *et al.* reported the results of a follow-up to the nickel/chromium platers study discussed above (Ex. 271). The cohort was redefined and excluded employees whose personnel records could not be located (650); those who started chrome work prior to 1946 (31) and those having no chrome exposure (236). The vital status experience of 1,762 workers (812 men and 950 women) was followed through 1995. The expected number of deaths was based upon the mortality of the general population of England and Wales.

There were 421 deaths among the men and 269 deaths among the women, including 52 lung cancers among the men and 17 among the women. SMRs were calculated for different categories of chrome work: period from first chrome work; year of starting chrome work, and cumulative duration of chrome work categories. Poisson regression modeling was employed to investigate lung cancer in relation to type of chrome work and cumulative duration of work.

A significantly elevated lung cancer SMR was seen for male workers with some period of chrome bath work (O=40; E=25.4; SMR=157; 95% CI: 113–214, $p<0.01$) that was not the case for male workers engaged in other chrome work away from the chromic acid bath (O=9; E=13.7; SMR=66; 95% CI: 30–125). Similar lung cancer mortality results were found for female chrome bath workers (O=15; E=8.6; SMR=175; 95% CI: 98–285; $p<0.06$). After adjusting for sex, age, calendar year, year starting chrome work, period from first chrome work, and employment status, regression modeling showed a statistically significant positive trend ($p<0.05$) between duration of chrome bath work and lung cancer mortality risk. The relative lung cancer risk for chrome bath workers with more than five years of Cr(VI) exposure (i.e., relative to the risk of those without any chrome bath work) was 4.25 (95% CI: 1.83–9.37).

Since the Sorahan cohort consists of nickel/chromium workers, the question arises of the potential confounding of nickel. In the earlier study, 144 of the 564 employees with some period of chrome bath work had either separate or simultaneous periods of nickel bath employment. According to the authors, there was no clear association between cancer deaths from stomach, liver, respiratory system, nose and larynx, and

lung and bronchus and the duration of nickel bath employment. In the follow-up report, the authors re-iterate this result stating, "findings for lung cancer in a cohort of nickel platers (without any exposure to chrome plating) from the same factory are unexceptional" (Ex. 271, p. 241).

Silverstein *et al.* reported the results of a cohort study of hourly employees and retirees with at least 10 years of credited pension service in a Midwestern plant manufacturing hardware and trim components for use primarily in the automobile industry (Ex. 7–55). Two hundred thirty eight deaths occurred between January 1, 1974 and December 31, 1978. Proportional Mortality Ratio (PMR) analysis adjusted for race, gender, age and year of death was conducted. For white males, the PMR for cancer of the lung and pleura was 1.91 ($p<0.001$) based upon 28 deaths. For white females, the PMR for cancer of the lung and pleura was 3.70 ($p<0.001$) based upon 10 deaths.

White males who worked at the plant for less than 15 years had a lung cancer PMR of 1.65. Those with 15 or more years at the plant had a lung cancer PMR of 2.09 ($p<0.001$). For white males with less than 22.5 years between hire and death (latency) the lung cancer PMR was 1.78 ($p<0.05$) and for those with 22.5 or more years, the PMR was 2.11 ($p<0.01$).

A case-control analysis was conducted on the Silverstein cohort to examine the association of lung cancer risk with work experience. Controls were drawn from cardiovascular disease deaths (ICD 390–458, 8th revision). The 38 lung cancer deaths were matched to controls for race and gender. Odds ratios (ORs) were calculated by department depending upon the amount of time spent in the department (ever/never; more vs. less than one year; and more vs. less than five years). Three departments showed increasing odds ratios with duration of work; however, the only statistically significant result was for those who worked more than five years in department 5 (OR=9.17, p=0.04, Fisher's exact test). Department 5 was one of the major die-casting and plating areas of the plant prior to 1971.

Franchini *et al.* conducted a mortality study of employees and retirees from nine chrome plating plants in Parma, Italy (Ex. 7–56). Three plants produced hard chrome plating. The remaining six plants produced decorative chromium plates. A limited number of airborne chromium measurements were available. Out of a total of 10 measurements at the hard chrome plating plants, the air concentrations of chromium averaged 7 $\mu g/m^3$ (range of 1–50 $\mu g/m^3$) as chromic acid near the baths and 3 $\mu g/m^3$ (range of 0–12 $\mu g/m^3$) in the middle of the room.

The cohort consisted of 178 males (116 from the hard chromium plating plants and 62 from the bright chromium plating plants) who had worked for at least one year between January 1, 1951 and December 31, 1981. In order to allow for a 10 year latency period, only those employed before January 1972 were included in further analysis. There were three observed lung cancer deaths among workers in the hard chrome plating plants, which was significantly greater than expected (O=3; E=0.6; $p<0.05$). There were no lung cancer deaths among decorative chrome platers.

Okubo and Tsuchiya conducted a study of plating firms with five or more employees in Tokyo (Exs. 7–51; 7–52). Five hundred and eighty nine firms were sent questionnaires to ascertain information regarding chromium plating experience. The response rate was 70.5%. Five thousand one hundred seventy platers (3,395 males and 1,775 females) met the cohort entrance criteria and were followed from April 1, 1970 to September 30, 1976. There were 186 deaths among the cohort; 230 people were lost to follow-up after retirement. The cohort was divided into two groups: chromium platers who worked six months or more and a control group with no exposure to chromium (clerical, unskilled workers). There were no deaths from lung cancer among the chromium platers.

The Okubo cohort was updated by Takahashi and Okubo (Ex. 265). The cohort was redefined to consist of 1,193 male platers employed for a minimum of six months between April 1970 and September 1976 in one of 415 Tokyo chrome plating plants and who were alive and over 35 years of age on September 30, 1976. The only statistically significant SMR was for lung cancer for all platers combined (O=16; E=8.9; SMR=179; 95% CI: 102–290). The lung cancer SMR for the chromium plater subcohort was 187 based upon eight deaths and 172 for the nonchromium plater subcohort, also based upon eight deaths. The cohort was followed through 1987. Itoh *et al.* updated the Okubo metal plating cohort through December 1992 (Ex. 35–163). They reported a lung cancer SMR of 118 (95% CI: 99–304).

4. Evidence From Stainless Steel Welders

Welding is a term used to describe the process for joining any materials by fusion. The fumes and gases associated with the welding process can cause a wide range of respiratory exposures which may lead to an increased risk of lung cancer. The major classes of metals most often welded include mild steel, stainless and high alloy steels and aluminum. The fumes from stainless steel, unlike fumes from mild steel, contain nickel and Cr(VI). There are several cohort and case-control studies as well as two meta analyses of welders potentially exposed to Cr(VI). In general, the studies found an excess number of lung cancer deaths among stainless steel welders. However, few of studies found clear trends with Cr(VI) exposure duration or cumulative Cr(VI). In most studies, the reported excess lung cancer mortality among stainless steel welders was no greater than mild steel welders, even though Cr(VI) exposure is much greater during stainless steel welding. This weak association between lung cancer and indices of exposure limits the evidence provided by these studies. Another limitation was the co-exposures to other potential lung carcinogens, such as nickel, asbestos, and cigarette smoke. Nevertheless, these studies add some further support to the much stronger link between Cr(VI) and lung cancer found in soluble chromate production workers, chromate pigment production workers, and chrome platers. The key studies are summarized in Table VI–4.

TABLE VI–4.– SUMMARY OF SELECTED EPIDEMIOLOGIC STUDIES OF LUNG CANCER IN WORKERS EXPOSED TO HEXAVALENT CHROMIUM—STAINLESS STEEL WELDING

Reference/Exhibit No.	Study population	Reference population	Chromium (VI) exposure	Lung cancer risk
Moulin (1997, Ex. 35–285)	Meta analysis of epidemiological studies of lung cancer risk among welders in five categories including stainless steel welding and mild steel welding.	Stainless steel welding cohort studies: Simonato *et al.*, 1991; Polednak *et al.*, 1981 case control studies: Hull *et al.*, 1989; Gerin *et al.*, 1984; Kjuus *et al.* 1986.	Stainless steel welders exposed to higher Cr(VI) than mild steel welders.	—RR of 1.50 ($p<0.05$) for stainless steel welders based on combined 114 deaths from five studies —RR of 1.50 ($p<0.05$) for mild steel welders based on combined 137 deaths from four studies.
Sjogren *et al.* (1994, Ex. 7–113).	Meta analysis of epidemiological studies of exposure to stainless steel welding fumes and lung cancer.	Stainless steel welding cohort studies: Moulin et al., 1993; Sjogren *et al.*, 1987 case control studies: Lauritsen *et al.*, 1996; Gerin *et al.*, 1984; Kjuus *et al.* 1986.	Cr(VI) exposure was not part of the analysis.	RR of 1.94 ($p<0.05$) for stainless steel welders based on combined 70 deaths from five studies.
Simonato *et al.* (1991, Ex.7–114). Gerin *et al.* (1993, Ex. 35–220)	Cohort of 11,092 male welders from 135 companies in nine European countries. Cohort entrance criteria varied by country.	Age and sex specific mortality rates computed using the WHO mortality data bank.	Avg cumulative Cr(VI) exposures estimated between 0.05 to 1.5 mg/ m^3-yr based on job process matrix.	—O/E of 1.23 (NS) for primarily stainless steel welders based on 20 deaths. —Upward trend ($p<0.05$) with time since first exposure. —No trend with cumulative exposure
Moulin *et al.* (1993, Ex. 7–92)	Cohort of 2,721 French male welders from 13 factories with a minimum of one year of employment from 1975 to 1988.	6,683 unexposed manual workers from 13 factories with a minimum of one year of employment from 1975 to 1988.	—Primarily manual metal arc welding. —Cr(VI) exposures not recorded	—O/E of 1.03 (NS) for primarily stainless steel welders based on 2 deaths. —No trend with exposure duration.
Hansen *et al.* (1996, Ex. 35–247).	Cohort of 10,059 male welders and other steel workers from 79 Danish companies employed for a minimum of one year between 1964 and 1984.	National cancer incidence rates from the Danish Cancer Registry.	Cr(VI) exposure not recorded ..	—O/E of 2.38 (NS) for stainless steel only welders based on 5 deaths. No trend with exposure duration.
Lauritsen *et al.* (1996, Ex. 35–291).	Nested case-control study of 94 lung cancer deaths from Hansen study.	439 eligible controls who were not cases and did not have respiratory disease or unknown malignancy as cause of death.	Cr(VI) exposure not recorded ..	—OR of 1.3 (NS) for stainless steel only welders. —No trend with exposure duration.
Sjogren *et al.* (1987, Ex. 795)	Cohort of 234 male stainless steel welders and 208 male railway track welders. Minimum employment was 5 years between 1950 and 1965. Follow-up through 1984.	Mortality rates for Swedish males.	Median Cr level for stainless steel welding was 57 $\mu g/m^3$ and for gas shielded welding [railway welders] was 5 $\mu g/m^3$ in Sweden during 1975.	—O/E of 2.5 (NS) for stainlesssteel welders based on 5 deaths. —O/E of 0.3 (NS) for railway welders based on 1 death.
Kjuus *et al.* (1986, Ex. 7–72) ...	A hospital-based case-control study of 176 male incident lung cancer cases admitted to two hospitals in Norway during 1979–1983.	186 controls admitted to the same hospitals in Norway during 1979–1983 and matched to cases for age +/- 5 years.	Cr(VI) exposure not recorded ..	—OR of 3.0 ($p<0.05$, adjusted for smoking) for stainless steel welding based on 16 deaths. —Welding not significant in logistic model with smoking, asbestos.
Hull, *et al.* (1989, Ex. 35–243)	Case-control study of 85 lung cancer cases in white male welders identified through the LA County tumor registry (1972–1987).	Controls were 74 welders with non-pulmonary malignancies.	No direct Cr(VI) exposure measurements recorded.	—OR of 0.9 (NS) for stainless steel welding based on 34 cases. —OR of 1.3 (NS) for manual metal arc welding on stainless steel based on 61 cases.

Observed/Expected (O/E)
Relative Risk (RR)
Not Statistically Significant (NS)
Odds Ratio (OR)

Sjogren *et al.* reported on the mortality experience in two cohorts of welders (Ex. 7–95). The cohort characterized as "high exposure" consisted of 234 male stainless steel welders with a minimum of five years of employment between 1950 and 1965. An additional criterion for inclusion in the study was assurance from the employer that asbestos had not been used or had been used only occasionally and never in a dust-generating way. The cohort characterized as "low exposure" consisted of 208 male railway track welders working at the Swedish State Railways for at least five years between 1950 and 1965. In 1975, air pollution in stainless steel welding was surveyed in Sweden. The median time weighted average (TWA) value for Cr(VI) was 110 $\mu g\ CrO_3/m^3$ (57 $\mu g/m^3$ measured as CrVI). The highest concentration was 750 $\mu g\ CrO_3/m^3$ (390 $\mu g/m^3$ measured as CrVI) found in welding involving coated electrodes. For gas-shielded welding, the median Cr(VI) concentration was 10 $\mu g\ CrO_3/m^3$ (5.2 $\mu g/m^3$ measured as CrVI) with the highest concentration measured at 440 $\mu g\ CrO_3/m^3$ (229 $\mu g/m^3$ measured as CrVI). Follow-up for both cohorts was through December 1984. The expected number of deaths was based upon Swedish male death rates. Of the 32 deaths in the "high exposure" group, five were cancers of the trachea, bronchus and lung (E=2.0; SMR=249;

95% CI: 0.80–5.81). In the low exposure group, 47 deaths occurred, one from cancer of the trachea, bronchus and lung.

Polednak compiled a cohort of 1,340 white male welders who worked at the Oak Ridge nuclear facilities from 1943 to 1977 (Ex. 277). One thousand fifty-nine cohort members were followed through 1974. The cohort was divided into two groups. The first group included 536 welders at a facility where nickel-alloy pipes were welded; the second group included 523 welders of mild steel, stainless steel and aluminum materials. Smoking data were available for 33.6% of the total cohort. Expectations were calculated based upon U.S. mortality rates for white males. There were 17 lung cancer deaths in the total cohort (E=11.37; SMR=150; 95% CI: 87–240). Seven of the lung cancer deaths occurred in the group which routinely welded nickel-alloy materials (E=5.65; SMR=124; 95% CI: 50–255) versus 10 lung cancer deaths in the "other" welders (E=6.12; SMR=163; 95% CI: 78–300).

Becker *et al.* compiled a cohort of 1,213 stainless steel welders and 1,688 turners from 25 German metal processing factories who had a minimum of six months employment during the period 1950–1970 (Exs. 227;250;251). The data collected included the primary type of welding (*e.g.*, arc welding, gas-shielded welding, etc.) used by each person, working conditions, average daily welding time and smoking status. The most recent follow-up of the cohort was through 1995. Expected numbers were developed using German mortality data. There were 268 deaths among the welders and 446 deaths among the turners. An elevated, but non-statistically significant, lung cancer SMR (O=28; E=23; SMR=121.5; 95% CI: 80.7–175.6) was observed among the welders. There were 38 lung cancer deaths among the turners with 38.6 expected, resulting in a SMR slightly below unity. Seven deaths from cancer of the pleura (all mesotheliomas) occurred among the welders with only 0.6 expected (SMR=1,179.9; 95% CI: 473.1–2,430.5), compared to only one death from cancer of the pleura among the turners, suggesting that the welders had exposure to asbestos. Epidemiological studies have shown that asbestos exposure is a primary cause of pleural mesotheliomas.

The International Agency for Research on Cancer (IARC) and the World Health Organization (WHO) cosponsored a study on welders. IARC and WHO compiled a cohort of 11,092 male welders from 135 companies in nine European countries to investigate the relationship between the different types of exposure occurring in stainless steel, mild steel and shipyard welding and various cancer sites, especially lung cancer (Ex. 7–114). Cohort entrance criteria varied by country. The expected number of deaths was compiled using national mortality rates from the WHO mortality data bank.

Results indicated the lung cancer deaths were statistically significant in the total cohort (116 cases; E=86.81; SMR=134; 95% CI: 110–160). Cohort members were assigned to one of four subcohorts based upon type of welding activity. While the lung cancer SMRs were elevated for all of the subcohorts, the only statistically significant SMR was for the only mild steel welders (O=40; E=22.42; SMR=178; 95% CI: 127–243). Results for the other subgroups were: shipyard welders (O=36; E=28.62; SMR=126; 95% CI: 88–174); ever stainless steel welders (O=39; E=30.52; SMR=128; 95% CI: 91–175); and predominantly stainless steel welders (O=20; E=16.25; SMR=123; 95% CI: 75–190). When analyzed by subcohort and time since first exposure, the SMRs increased over time for every group except shipyard welders. For the predominantly stainless steel welder subcohort, the trend to increase with time was statistically significant ($p < .05$).

An analysis was conducted of lung cancer mortality in two stainless steel welder subgroups (predominantly and ever) with a minimum of five years of employment. Cumulative Cr(VI) was computed from start of exposure until 20 years prior to death. A lung cancer SMR of 170, based upon 14 cases, was observed in the stainless steel ever subgroup for those welders with >0.5 μg-years/m^3 Cr(VI) exposure; the lung cancer SMR for those in the <0.5 μg-years/m^3 Cr(VI) exposure group was 123 (based upon seven cases). Neither SMR was statistically significant. For the predominantly stainless steel welders, which is a subset of the stainless steel ever subgroup, the corresponding SMRs are 167 (>0.5 μg-years/m^3 Cr(VI) exposure) based upon nine cases and 191 (<0.5 μg-years/m^3 Cr(VI) exposure) based upon three cases. Neither SMR is statistically significant.

In conjunction with the IARC/WHO welders study, Gerin *et al.* reported the development of a welding process exposure matrix relating 13 combinations of welding processes and base metals used to average exposure levels for total welding fumes, total chromium, Cr(VI) and nickel (Ex. 7–120). Quantitative estimates were derived from the literature supplemented by limited monitoring data taken in the 1970s from only eight of the 135 companies in the IARC/WHO mortality study. An exposure history was constructed which included hire and termination dates, the base metal welded (stainless steel or mild steel), the welding process used and changes in exposure over time. When a detailed welding history was not available for an individual, the average company welding practice profile was used. In addition, descriptions of activities, work force, welding processes and parameters, base metals welded, types of electrodes or rods, types of confinement and presence of local exhaust ventilation were obtained from the companies.

Cumulative dose estimates in mg/m^3 years were generated for each welder's profile (number of years and proportion of time in each welding situation) by applying a welding process exposure matrix associating average concentrations of welding fumes (mg/m^3) to each welding situation. The corresponding exposure level was multiplied by length of employment and summed over the various employment periods involving different welding situations. No dose response relationship was seen for exposure to Cr(VI) for either those who were "ever stainless steel welders" or those who were "predominantly stainless steel welders". The authors note that if their exposure estimates are correct, the study had the power to detect a significant result in the high exposure group for Cr(VI).

The IARC/WHO multicenter study is the sole attempt to undertake even a semi-quantified exposure analysis of stainless steel welders' potential exposure to nickel and Cr(VI) for <5 and ≥0.5 mg-years/m^3 Cr(VI) exposures. The IARC/WHO investigators noted that there was more than a twofold increase in SMRs between the long (≥20 years since first exposure) and short (<20 years since first exposure) observation groups for the predominantly stainless steel welders "suggesting a relation of lung cancer mortality with the occupational environment for this group" (Ex. 7–114, p. 152). The authors conclude that the increase in lung cancer mortality does not appear to be related to either duration of exposure or cumulative exposure to total fume, chromium, Cr(VI) or nickel.

Moulin compiled a cohort of 2,721 French male welders and an internal comparison group of 6,683 manual workers employed in 13 factories (including three shipyards) with a minimum of one year of employment from 1975 to 1988 (Ex. 7–92). Three

controls were selected at random for each welder. Smoking data were abstracted from medical records for 86.6% of welders and 86.5% of the controls. Smoking data were incorporated in the lung cancer mortality analysis using methods suggested by Axelson. Two hundred and three deaths were observed in the welders and 527 in the comparison group. A non-statistically significant increase was observed in the lung cancer SMR (O=19; E=15.33; SMR=124; 95% CI: 0.75–1.94) for the welders. In the control group, the lung cancer SMR was in deficit (O=44; E=46.72; SMR=94; 95% CI: 0.68–1.26). The resulting relative risk was a non-significant 1.3. There were three deaths from pleural cancer in the comparison group and none in the welders suggesting asbestos exposure in the comparison group. The welders were divided into four subgroups (shipyard welders, mild steel only welders, ever stainless steel welders and stainless steel predominantly Cr(VI) welders). The highest lung cancer SMR was for the mild steel welders O=9; SMR of 159). The lowest lung cancer SMRs were for ever stainless steel welders (O=3; SMR=92) and for stainless steel predominantly Cr(VI) welders (O=2; SMR=103). None of the SMRs are statistically significant.

Hansen conducted a study of cancer incidence among 10,059 male welders, stainless steel grinders and other metal workers from 79 Danish companies (Ex. 9–129). Cohort entrance criteria included: Alive on April 1, 1968; born before January 1, 1965; and employed for at least 12 months between April 1, 1964 and December 31, 1984. Vital status follow-up found 9,114 subjects alive, 812 dead and 133 had emigrated. A questionnaire was sent to subjects and proxies for decedents/emigrants in an attempt to obtain information about lifetime occupational exposure, smoking and drinking habits. The overall response rate was 83%. The authors stated that no major differences in smoking habits were found between exposure groups with or without a significant excess of lung cancer.

The expected number of cancers was based on age-adjusted national cancer incidence rates from the Danish Cancer Registry. There were statistically significantly elevated Standardized Incidence Ratios (SIRs) for lung cancer in the welding (any kind) group (O=51; E=36.84; SIR=138; 95% CI: 103–181) and in the mild steel only welders (O=28; E=17.42; SIR=161; 95% CI: 107–233). The lung cancer SIR for mild steel ever welders was 132 (O=46; E=34.75; 95% CI: 97–176); for stainless steel ever welders 119 (O=23; E=19.39; 95% CI: 75–179) and for stainless steel only welders 238 (O=5; E=2.10; 95% CI: 77–555).

Laurtitsen reported the results of a nested case-control conducted in conjunction with the Hansen cancer incidence study discussed above (Exs. 291; 9–129). Cases were defined as the 94 lung cancer deaths. Controls were defined as anyone who was not a case, but excluded deaths from respiratory diseases other than lung cancer (either as an underlying or a contributing cause of death), deaths from "unknown malignancies" and decedents who were younger than the youngest case. There were 439 decedents eligible for use as controls.

The crude odds ratio (OR) for welding ever (yes/no) was 1.7 (95% CI: 1.0–2.8). The crude OR for mild steel welding only was 1.3 (95% CI: 0.8–2.3) and for stainless steel welding only the crude OR was 1.3 (95% CI: 0.3–4.3). When analyzed by number of years exposed, "ever" stainless steel welding showed no relationship with increasing number of years exposed. The highest odds ratio (2.9) was in the lowest category (1–5 years) based upon seven deaths; the lowest odds ratio was in the highest category (21+ years) based upon three deaths.

Kjuus *et al.* conducted a hospital-based case-control study of 176 male incident lung cancer cases and 186 controls (matched for age, +/−5 years) admitted to two county hospitals in southeast Norway during 1979–1983 (Ex. 7–72). Subjects were classified according to exposure status of main occupation and number of years in each exposure category and assigned into one of three exposure groups according to potential exposure to respiratory carcinogens and other contaminants. A statistically significantly elevated risk ratio for lung cancer (adjusted for smoking) for the exposure factor "welding, stainless, acid proof" of 3.3 ($p<0.05$) was observed based upon 16 lung cancer deaths. The unadjusted odds ratio is not statistically significant (OR=2.8). However, the appropriateness of the analysis is questionable since the exposure factors are not discrete (a case or a control may appear in multiple exposure factors and therefore is being compared to himself). In addition, the authors note that several exposure factors were highly correlated and point out specifically that one-half of the cases "exposed to either stainless steel welding fumes or fertilizers also reported moderate to heavy asbestos exposure." When put into a stepwise logistic regression model, exposure to stainless steel fumes, which was initially statistically significant, loses its significance when smoking and asbestos are first entered into the model.

Hull *et al.* conducted a case-control study of lung cancer in white male welders aged 20–65 identified through the Los Angeles County tumor registry (Southern California Cancer Surveillance Program) for the period 1972 to 1987 (Ex. 243). Controls were welders 40 years of age or older with non-pulmonary malignancies. Interviews were conducted to obtain information about sociodemographic data, smoking history, employment history and occupational exposures to specific welding processes, metals welded, asbestos and confined space welding. Interviews were completed for 90 (70%) of the 128 lung cancer cases and 116 (66%) of the controls. Analysis was conducted using 85 deceased cases and 74 deceased controls after determining that the subject's vital status influenced responses to questions concerning occupational exposures. The crude odds ratio (ever vs. never exposed) for stainless steel welding, based upon 34 cases, was 0.9 (95% CI: 0.3–1.4). For manual metal arc welding on stainless steel, the crude odds ratio was 1.3 (95% CI: 0.6–2.3) based upon 61 cases.

While the relative risk estimates in both cohort and case-control of stainless steel welders are elevated, none are statistically significant. However, when combined in two meta-analyses, a small but statistically significant increase in lung cancer risk was reported. Two meta-analyses of welders have been published. Moulin carried out a meta-analysis of epidemiologic studies of lung cancer risk among welders, taking into account the role of asbestos and smoking (Ex. 285). Studies published between 1954 and 1994 were reviewed. The inclusion criteria were clearly defined: only the most recent updates of cohort studies were used and only the mortality data from mortality/morbidity studies were included. Studies that did not provide the information required by the meta-analysis were excluded.

Five welding categories were defined (shipyard welding, non-shipyard welding, mild steel welding, stainless steel welding and all or unspecified welding). The studies were assigned to a welding category (or categories) based upon the descriptions provided in the paper's study design section. The combined relative risks (odds ratios, standardized mortality ratios, proportionate mortality ratios and standardized incidence ratios) were calculated separately for the population-based studies, case-control studies and

cohort studies and for all the studies combined.

Three case-control studies (Exs. 243; 7–120; 7–72) and two cohort studies (Exs. 7–114; 277) were included in the stainless steel welding portion of the meta-analysis. The combined relative risk was 2.00 (O=87; 95% CI: 1.22–3.28) for the case-control studies and 1.23 (O=27; 95% CI: 0.82–1.85) for the cohort studies. When all five studies were combined, the relative risk was 1.50 (O=114; 95% CI: 1.10–2.05).

By contrast, the combined risk ratio for the case-control studies of mild steel welders was 1.56 (O=58; 95% CI: 0.82–2.99) (Exs. 7–120; 243). For the cohort studies, the risk ratio was 1.49 (O=79; 95% CI: 1.15–1.93) (Exs. 270; 7–114). For the four studies combined, the risk ratio was 1.50 (O=137; 95% CI: 1.18–191). The results for the stainless steel welders and the mild steel welders are basically the same.

The meta-analysis by Sjogren of exposure to stainless steel welding fumes and lung cancer included studies published between 1984 and 1993, which took smoking and potential asbestos exposure into account (Ex. 7–113). Five studies met the author's inclusion criteria and were included in the meta-analysis: two cohort studies, Moulin *et al.* (Ex. 283) and Sjogren *et al.* (Ex. 7–95); and three case-control studies, Gerin, *et al.* (Ex. 7–120, Hansen *et al.* (Ex. 9–129) and Kjuus *et al.* (Ex. 7–72). The calculated pooled relative risk for welders exposed to stainless steel welding fumes was 1.94 (95% CI: 1.28–2.93).

5. Evidence From Ferrochromium Workers

Ferrochromium is produced by the electrothermal reduction of chromite ore with coke in the presence of iron in electric furnaces. Some of the chromite ore is oxidized into Cr(VI) during the process. However, most of the ore is reduced to chrome metal. The manufacture of ferroalloys results in a complex mixture of particles, fumes and chemicals including nickel, Cr(III) and Cr(VI). Polycyclic aromatic hydrocarbons (PAH) are released during the manufacturing process. The co-exposure to other potential lung carcinogens combined with the lack of a statistically significant elevation in lung cancer mortality among ferrochromium workers were limitations in the key studies. Nevertheless, the observed increase in the relative risks of lung cancer add some further support to the much stronger link between Cr(VI) and lung cancer found in soluble chromate production workers, chromate pigment production workers, and chrome platers. The key studies are summarized in Table VI–5.

TABLE VI–5.—SUMMARY OF SELECTED EPIDEMIOLOGIC STUDIES OF LUNG CANCER IN WORKERS EXPOSED TO HEXAVALENT CHROMIUM—FERROCHROMIUM PRODUCTION

Reference/Exhibit No.	Study population	Reference population	Chromium (VI) exposure	Lung cancer risk
Axelsson *et al.* (1980, Ex. 7–62).	1932 Swedish males employed at least one year in a ferrochromium between 1930 to 1975.	Swedish county mortality and incidence rates.	"Recent" job-specific Cr(VI) levels estimated at 10 to 250 µg/m³.	—O/E of 0.7 (NS) for ferrochromium workers based on 5 cases. —No trend with job-specific Cr(VI).
Langard *et al.* (1990, Ex. 7–37)	1235 males employed at least one year who started working prior to 1965 in a Norway ferrochromium plant. Follow-up was through 1985.	—Norwegian Cancer Registry —Subcohort of ferrosilicon workers at same plant not exposed to Cr(VI).	Avg total Cr exposure was 50 µg/m³ in 1975 with 11 to 33% soluble Cr(VI).	—O/E of 1.5 (NS) for ferrochromium workers based on 10 cases. —O/E of 0.3 for ferrosilicon workers based on 2 cases.

Observed/Expected (O/E).
Relative Risk (RR).
Not Statistically Significant (NS).
Odds Ratio (OR).

Langard *et al.* conducted a cohort study of male workers producing ferrosilicon and ferrochromium for more than one year between 1928 and 1977 at a plant located on the west coast of Norway (Exs. 7–34; 7–37). The cohort and study findings are summarized in Table VI.5. Excluded from the study were workers who died before January 1, 1953 or had an unknown date of birth. The cohort was defined in the 1980 study as 976 male employees who worked for a minimum of one year prior to January 1, 1960. In the 1990 study, the cohort definition was expanded to include those hired up to 1965.

Production of ferrosilicon at the plant began in 1928 and ferrochromium production began in 1932. Job characterizations were compiled by combining information from company personnel lists and occupational histories contained in medical records and supplemented with information obtained via interview with long-term employees. Ten occupational categories were defined. Workers were assigned to an occupational category based upon the longest time in a given category.

Industrial hygiene studies of the plant from 1975 indicated that both Cr(III) and Cr(VI) were present in the working environment. The ferrochromium furnance operators were exposed to measurements of 0.04–0.29 mg/m³ of total chromium. At the charge floor the mean concentration of total chromium was 0.05 mg/m³, 11–33% of which was water soluble. The water soluble chromium was considered to be in the hexavalent state.

Both observed and expected cases of cancer were obtained via the Norwegian Cancer Registry. The observation period for cancer incidence was January 1, 1953 to December 31, 1985. Seventeen incident lung cancers were reported in the 1990 study (E=19.4; SIR=88). A deficit of lung cancer incidence was observed in the ferrosilicon group (O=2; E=5.8; SIR=35). In the ferrochromium group there were a significant excess of lung cancer; 10 observed lung cancers with 6.5 expected (SIR=154).

Axelsson *et al.* conducted a study of 1,932 ferrochromium workers to examine whether exposure in the ferrochromium industry could be associated with an increased risk of developing tumors, especially lung cancer (Ex. 7–62). The study cohort and findings are summarized in Table VI.5. The study cohort was defined as males employed at a ferrochromium plant in Sweden for at least one year during the period January 1, 1930 to December 31, 1975.

The different working sites within the industry were classified into four groups with respect to exposure to Cr(VI) and Cr(III). Exposure was primarily to metallic and trivalent chromium with estimated levels ranging from 0–2.5 mg/m³. Cr(VI) was also present in certain operations with estimated levels ranging from 0–0.25 mg/m³. The highest exposure to Cr(VI) was in the arc-furnace operations. Cr(VI) exposure also

occurred in a chromate reduction process during chromium alum production from 1950–1956. Asbestos-containing materials had been used in the plant. Cohort members were classified according to length and place of work in the plant.

Death certificates were obtained and coded to the revision of the *International Classification of Diseases* in effect at the time of death. Data on cancer incidence were obtained from the Swedish National Cancer Registry. Causes of death in the cohort for the period 1951–1975 were compared with causes of death for the age-adjusted male population in the county in which the plant was located.

There were seven cases of cancers of the trachea, bronchus and lung and the pleura with 5.9 expected (SIR=119) for the period 1958–1975. Four of the seven cases in the lung cancer group were maintenance workers and two of the four cases were pleural mesotheliomas. In the arc furnace group, which was thought to have the highest potential exposure to both Cr(III) and Cr(VI), there were two cancers of the trachea, bronchus and lung and the pleura. One of the cases was a mesothelioma. Of the 380 deaths that occurred during the period 1951–1975, five were from cancer of the trachea, bronchus and lung and the pleura (E=7.2; SMR=70). For the "highly" exposed furnace workers, there was one death from cancer of the trachea, bronchus and lung and the pleura.

Moulin *et al.* conducted a cohort mortality study in a French ferrochromium/stainless steel plant to determine if exposure to chromium compounds, nickel compounds and polycyclic aromatic hydrocarbons (PAHs) results in an increased risk of lung cancer (Ex. 282). The cohort was defined as men employed for at least one year between January 1, 1952 and December 31, 1982; 2,269 men met the cohort entrance criteria. No quantitative exposure data were available and no information on the relative amounts of Cr(VI) and Cr(III) was provided. In addition, some workers were also exposed to other carcinogens, such as silica and asbestos. The authors estimated that 75.7% of the cohort had been exposed to combinations of PAH, nickel and chromium compounds. Of the 137 deaths identified, the authors determined 12 were due to cancer of the trachea, bronchus and lung (E=8.56; SMR=140; 95% CI: 0.72–2.45). Eleven of the 12 lung cancers were in workers employed for at least one year in the ferrochromium or stainless steel production workshops (E=5.4; SMR=204; 95% CI: 1.02–3.64).

Pokrovskaya and Shabynina conducted a cohort mortality study of male and female workers employed "some time" between 1955 and 1969 at a chromium ferroalloy production plant in the U.S.S.R (Ex. 7–61). Workers were exposed to both Cr(III) and Cr(VI) as well as to benzo [a] pyrene. Neither the number of workers nor the number of cancer deaths by site were provided. Death certificates were obtained and the deaths were compared with municipal mortality rates by gender and 10 year age groups. The investigators state that they were able to exclude those in the comparison group who had chromium exposures in other industries. The lung cancer SMR for male chromium ferroalloy workers was 440 in the 30–39 year old age group and 660 in the 50–59 year old age group (p=0.001). There were no lung cancer deaths in the 40–49 and the 60–69 year old age groups. The data suggest that these ferrochromium workers may have been had an excess risk of lung cancer.

The association between Cr(VI) exposure in ferrochromium workers and the incidence of respiratory tract cancer these studies is difficult to assess because of co-exposures to other potential carcinogens (*e.g.*, asbestos, PAHs, nickel, etc.), absence of a clear exposure-response relationship and lack of information on smoking. There is suggestive evidence of excess lung cancer mortality among Cr(VI)-exposed ferrochromium workers in the Norwegian (Langard) cohort when compared to a similar unexposed cohort of ferrosilicon workers. However, there is little consistency for this finding in the Swedish (Axelsson) or French (Moulin) cohorts.

6. Evidence From Workers in Other Industry Sectors

There are several other epidemiological studies that do not fit into the five industry sectors previously reviewed. These include worker cohorts in the aerospace industry, paint manufacture, and leather tanning operations, among others. The two cohorts of aircraft manufacturing workers are summarized in Table VI–6. All of the cohorts had some Cr(VI) exposure but, certain cohorts may have included a sizable number of workers with little or no exposure to Cr(VI). This creates an additional complexity in assessing whether the study findings support a Cr(VI) etiology for cancer of the respiratory system.

TABLE VI–6.—SUMMARY OF SELECTED EPIDEMIOLOGIC STUDIES OF LUNG CANCER IN WORKERS EXPOSED TO HEXAVALENT CHROMIUM—AIRCRAFT MANUFACTURE

Reference/Exhibit No.	Study population	Reference population	Chromium (VI) exposure	Lung Cancer risk
Alexander *et al.* (1996, Ex. 31–16–3).	2429 aerospace workers with a minimum six months employment in Washington State from 1974 to 1994. Median age at end of study was 42 years with median 9 years follow-up.	Incidence rates from regional cancer surveillance system registry.	Painters/sanders exposed to zinc strontium and lead chromates. Platers/tank tenders exposed primarily to chromic acid Median cumulative chromate exposure between 0.01 and 0.18 mg/m^3-yr based on 1974 to 1994 data.	—O/E of 0.8 (NS) for aerospace cohort based on 15 deaths. —No clear trend with chromate exposure.
Boice *et al.* (1999, Ex. 31–16–4).	77,965 workers employed for minimum of one year in California aircraft manufacturing plant on or after 1960. Follow-up through 1996.	Mortality rates for white population of California and for non-white U.S. population.	8 percent of cohort had potential for routine Cr(VI) exposure as painters and platers. No Cr(VI) exposure levels reported.	—O/E of 1.02 (NS) for workers with routine Cr(VI) exposures based on 87 deaths. —Upward trend (NS) with duration of exposure. —O/E of 0.71 ($p<0.05$) for non-factory workers.

Observed/Expected (O/E)
Relative Risk (RR)
Not Statistically Significant (NS)
Odds Ratio (OR)

Alexander *et al.* conducted a cohort study of 2,429 aerospace workers with a minimum of six months of cumulative employment in jobs involving chromate exposure during the period 1974 through 1994 (Ex. 31–16–3). Exposure estimates were based on industrial hygiene measurements and work history records. Jobs were classified into categories of "high" (spray painters, decorative painters), "moderate" (sanders/maskers, maintenance painters) and "low" (chrome platers, surface processors, tank tenders, polishers, paint mixers) exposure. Each exposure category was assigned a summary TWA exposure based upon the weighted TWAs and information from industrial hygienists. The use of respiratory protection was accounted for in setting up the job exposure matrix. The index of cumulative total chromium exposure (reported as $\mu g/m^3$ chromate TWA-years) was computed by multiplying the years in each job by the summary TWAs for each exposure category.

In addition to cumulative chromate exposure, chromate exposure jobs were classified according to the species of chromate. According to the authors, in painting operations the exposure is to chromate pigments with moderate and low solubility such as zinc chromate, strontium chromate and lead chromate; in sanding and polishing operations the same chromate pigments exist as dust; while platers and tank tenders are exposed to chromium trioxide, which is highly soluble.

Approximately 26% of the cohort was lost to follow-up. The cohort was followed for a relatively short 8.9 years per cohort member. Cases were identified through the Cancer Surveillance System (CSS) at the Fred Hutchinson Cancer Research Center in Seattle, Washington. CSS records primary cancer diagnoses in 13 counties in western Washington. Expected numbers were calculated using race-, gender-, age- and calendar-specific rates from the Puget Sound reference population for 1974 through 1994. Fifteen lung cancer cases were identified with an overall standardized incidence ratio (SIR) of 80 (95% CI: 0.4–1.3). The SIRs for lung cancer by cumulative years of employment in the "high exposure" painting job category were based upon only three deaths in each of the cumulative years categories (<5 and ≥5); years of employment was inversely related to the risk of lung cancer. For those in the "low exposure" category, the SIRs were 130 for those who worked less than five years in that category (95% CI: 0.2–4.8) and 190 for those who worked five years or more (95% CI: 0.2–6.9). However, there were only two deaths in each category. The SIR for those who worked ≥5 years was 270 (95% CI: 0.5–7.8), but based only on three deaths.

Boice *et al.* conducted a cohort mortality study of 77,965 workers employed for a minimum of one year on or after January 1960 in aircraft manufacturing (Ex. 31–16–4). Routine exposures to Cr(VI) compounds occurred primarily while operating plating and coating process equipment or when using chromate based primers or paints. According to the authors, 3,634 workers, or 8% of the cohort, had the potential for routine exposure to chromate and 3,809 workers, or 8.4%, had the potential for intermittent exposure to chromate. Estimates of chromate exposure were not provided in the study.

Follow up of the cohort was through 1996. Expectations were calculated based on the general population of California for white workers, while general population rates for the U.S. were used for non-white workers. For the 3,634 cohort members who had potential for routine exposure to chromates, the lung cancer SMR (race and gender combined) was 102 based upon 87 deaths (95% CI: 0.82–1.26). There was a slight non-significant positive trend (p value>2.0) for lung cancer with duration of potential exposure. The SMR was 108 (95% CI: 0.75–1.57) for workers exposed to chromate for ≥5 years. Among the painters, there were 41 deaths from lung cancer yielding a SMR of 111 (95% CI: 0.80–1.51). For those who worked as a process operator or plater the SMR for lung cancer was 103 based upon 38 deaths (95% CI: 0.73–1.41).

OSHA believes the Alexander (Ex. 31–16–3) and the Boice *et al.* (Ex. 31–16–4) studies have several limitations. The Alexander cohort is small and lacks smoking data. In addition, the study's authors cite the relatively young age of the population. Considering these three factors, the authors note, "limits the overall power of the study and the stability of the risk estimates, especially in exposure-related subanalyses" (Ex. 31–16–3, p. 1256). Another limitation of the study is the 26.3% of cohort members lost to follow-up. Boice *et al.* is a well conducted study of workers in the aircraft manufacturing industry, but lacks information on Cr(VI) exposure (Ex. 31–16–4).

Dalager *et al.* conducted a proportionate mortality study of 977 white male spray painters potentially exposed to zinc chromate in the aircraft maintenance industry who worked at least three months and terminated employment within ten years prior to July 31, 1959 (Ex. 7–64). Follow-up was through 1977. The expected numbers of deaths were obtained by applying the cause-specific proportionate mortality of U.S. white males to the total numbers of deaths in the study group by five year age groups and five year time intervals. Two hundred and two deaths were observed. There were 21 deaths from cancer of the respiratory system (PMR=184), which was statistically significant. The Proportionate Cancer Mortality Ratio for cancer of the respiratory system was not statistically significant (PCMR=146). Duration of employment as a painter with the military as indicated on the service record was used as an estimate of exposure to zinc chromate pigments, which were used as a metal primer. The PMRs increased as duration of employment increased (<5 years, O=9, E=6.4, PMR=141; 5–9 years, O=6, E=3, PMR=200; and 10+ years, O=6, E=2, PMR=300) and was statistically significant for those who worked 10 or more years.

Bertazzi *et al.* studied the mortality experience of 427 workers employed for a minimum of six months between 1946 and 1977 in a plant manufacturing paint and coatings (Ex. 7–65). According to the author, chromate pigments represented the "major exposure" in the plant. The mortality follow-up period was 1954–1978. There were eight deaths from lung cancer resulting in a SMR of 227 on the local standard (95% CI: 156–633) and a SMR of 334 on the national standard (95% CI: 106–434). The authors were unable to differentiate between exposures to different paints and coatings. In addition, asbestos was used in the plant and may be a potential confounding exposure.

Morgan conducted a cohort study of 16,243 men employed after January 1, 1946 for at least one year in the manufacture of paint or varnish (Ex. 8–4). Analysis was also conducted for seven subcohorts, one of which was for work with pigments. Expectations were calculated based upon the mortality experience of U.S. white males. The SMR for cancer of the trachea, bronchus and lung was below unity based upon 150 deaths. For the pigment subcohort, the SMR for cancer of the trachea, bronchus and lung was 117 based upon 43 deaths. In a follow-up study of the subcohorts, case-control analyses were conducted for several causes of death including lung cancer (Ex. 286). The details of matching were not provided. The authors state that no significant excesses of lung cancer risk by job were found. No odds ratios were presented.

Pippard *et al.* conducted a cohort mortality study of 833 British male tannery workers employed in 1939 and followed through December 31, 1982 (Ex. 278). Five hundred and seventy three men worked in tanneries making vegetable tanned leathers and 260 men worked in tanneries that made chrome tanned leathers. The expected number of deaths was calculated using the mortality rates of England and Wales as a whole. The lung cancer SMR for the vegetable tanned leather workers was in deficit (O=31; E=32.6; 95% CI: 65–135), while the lung cancer SMR for the chrome tanned leather workers was slightly elevated but not statistically significant (O=13; E=12; SMR=108; 95% CI: 58–185).

In a different study of two U.S. tanneries, Stern *et al.* investigated mortality in a cohort of all production workers employed from January 1, 1940 to June 11, 1979 at tannery A (N=2,807) and from January 1, 1940 to May 1, 1980 at tannery B (N=6,558) (Ex. 7–68). Vital status was followed through December 31, 1982. There were 1,582 deaths among workers from the two tanneries. Analyses were conducted employing both U.S. mortality rates and the mortality rates for the state in which the plant is located. There were 18 lung/pleura cancer deaths at tannery A and 42 lung/pleura cancer deaths at tannery B. The lung cancer/pleura SMRs were in deficit on both the national standard and the state standard for both tanneries. The authors noted that since the 1940s most chrome tanneries have switched to the one-bath tanning method in which Cr(VI) is reduced to Cr(III).

Blot *et al.* reported the results of a cohort study of 51,899 male workers of the Pacific Gas & Electric Company alive in January 1971 and employed for at least six months before the end of 1986 (Ex. 239). A subset of the workers were involved in gas generator plant operations where Cr(VI) compounds were used in open and closed systems from the 1950s to early 1980s. One percent of the workers (513 men) had worked in gas generator jobs, with 372 identified from post-1971 listing at the company's three gas generator plants and 141 from gas generator job codes. Six percent of the cohort members (3,283) had trained at one of the gas generator plants (Kettleman).

SMRs based on national and California rates were computed. Results in the paper are based on the California rates, since the overall results reportedly did not differ substantially from those using the national rates. SMRs were calculated for the entire cohort and for subsets defined by potential for gas generator plant exposure. No significant cancer excesses were observed and all but one cancer SMR was in deficit. There were eight lung cancer deaths in the gas generator workers (SMR=81: 95% CI: 0.35–1.60) and three lung cancer deaths among the Kettleman trainees (SMR=57; 95% CI: 0.12–1.67). There were no deaths from nasal cancer among either the gas generator workers or the Kettleman trainees. The risk of lung cancer did not increase with length of employment or time since hire.

Rafnsson and Johannesdottir conducted a study of 450 licensed masons (cement finishers) in Iceland born between 1905 and 1945, followed from 1951 through 1982 (Ex. 7–73). Stonecutters were excluded. Expectations were based on the male population of Iceland. The SMR for lung cancer was 314 and is statistically significant based upon nine deaths (E=2.87; 95% CI: 1.43–5.95). When a 20 year latency was factored into the analysis, the lung cancer SMR remained statistically significant (O=8; E=2.19; SMR=365; 95% CI: 1.58–7.20).

Svensson *et al.* conducted a cohort mortality study of 1,164 male grinding stainless steel workers employed for three months or more during the period 1927–1981 (Ex.266). Workers at the facility were reportedly exposed to chromium and nickel in the stainless steel grinding process. Records provided by the company were used to assign each worker to one of three occupational categories: Those considered to have high exposure to chromium, nickel as well as total dust, those with intermediate exposure, and those with low exposure. Mortality rates for males in Blekinge County, Sweden were used as the reference population. Vital status follow-up was through December 31, 1983. A total of 194 deaths were observed (SMR= 91). No increased risk of lung cancer was observed (SMR=92). The SMR for colon/rectum cancer was 2.47, but was not statistically significant.

Cornell and Landis studied the mortality experience of 851 men who worked in 26 U.S. nickel/chromium alloy foundries between 1968 and 1979 (Ex. 7–66). Standardized Proportionate Mortality Ratio (SPMR) analyses were done using both an internal comparison group (foundry workers not exposed to nickel/chromium) and the mortality experience of U.S. males. The SPMR for lung cancer was 105 (O=60; E=56.9). No nasal cancer deaths were observed.

Brinton *et al.* conducted a case-control study of 160 patients diagnosed with primary malignancies of the nasal cavity and sinuses at one of four hospitals in North Carolina and Virginia between January 1, 1970 and December 31, 1980 (Ex. 8–8). For each case determined to be alive at the time of interview, two hospital controls were selected matched on vital status, hospital, year of admission (+/− 2 years), age (+/− 5 years), race and state economic area or county or usual residence. Excluded from control selection were malignant neoplasms of the buccal cavity and pharynx, esophagus, nasal cavity, middle ear and accessory sinuses, larynx, and secondary neoplasms. Also excluded were benign neoplasms of the respiratory system, mental disorders, acute sinusitis, chronic pharyngitis and nasopharyngitis, chronic sinusitis, deflected nasal septum or nasal polyps. For those cases who were deceased at the time of interview, two different controls were selected. One control series consisted of hospital controls as described previously. The second series consisted of decedents identified through state vital statistics offices matched for age (+ / − 5 years), sex, race, county of usual residence and year of death. A total of 193 cases were identified and 160 case interviews completed. For those exposed to chromates, the relative risk was not significantly elevated (OR=5.1) based upon five cases. According to the authors, chromate exposure was due to the use of chromate products in the building industry and in painting, rather than the manufacture of chromates.

Hernberg *et al.* reported the results of a case-control study of 167 living cases of nasal or paranasal sinus cancer diagnosed in Denmark, Finland and Sweden between July 1, 1977 and December 31, 1980 (Exs. 8–7; 7–71). Controls were living patients diagnosed with malignant tumors of the colon and rectum matched for country, gender and age at diagnosis (+ / − 3 years) with the cases. Both cases and controls were interviewed by telephone to obtain occupational histories. Patients with work-related exposures during the ten years prior to their illness were excluded. Sixteen cases reported exposure to chromium, primarily in the "stainless steel welding" and "nickel" categories, versus six controls (OR=2.71; 95% CI: 1.1–6.6).

7. Evidence From Experimental Animal Studies

Most of the key animal cancer bioassays for chromium compounds were conducted before 1988. These studies have been critically reviewed by the IARC in the Monograph *Chromium, Nickel, and Welding* (Ex. 35–43) and by ATSDR in their toxicological profile for chromium (Ex. 35–41). OSHA reviewed

the critical studies from both the IARC Monograph and the ATSDR toxicological profile on chromium and conducted its own literature search to update and supplement the review.

In the experimental studies, Cr(VI) compounds were administered by various routes including inhalation, intratracheal instillation, intrabronchial implantation, and intrapleural injection, as well as intramuscular and subcutaneous injection. For assessing human health effects from occupational exposure, the most relevant route is inhalation. However, as a whole, there were very few inhalation studies. In addition to inhalation studies, OSHA is also relying on intrabronchial implantation and intratracheal instillation studies for hazard identification because these studies examine effects directly administered to the respiratory tract, the primary target organ of concern, and they give insight into the relative potency of different Cr(VI) compounds. In comparison to studies examining inhalation, intrabronchial implantation, and intratracheal instillation, studies using subcutaneous injection and intramuscular administration of Cr(VI) compounds were of lesser significance but were still considered for hazard identification.

In its evaluation, OSHA took into consideration the exposure regimen and experimental conditions under which the experiments were performed, including the exposure level and duration; route of administration; number, species, strain, gender, and age of the experimental animals; the inclusion of appropriate control groups; and consistency in test results. Some studies were not included if they did not contribute to the weight of evidence, lacked adequate documentation, were of poor quality, or were less relevant to occupational exposure conditions (*e.g.*, some intramuscular injection studies).

The summarized animal studies are organized by Cr(VI) compound in order of water solubility (*i.e.*, compounds that are considered highly soluble in water, followed by those considered slightly soluble in water, and then those considered insoluble in water) since it has been suggested that solubility may be an important factor in determining the carcinogenic potency of Cr(VI) compounds (Ex 35–47). Solubility characteristics described in this section are based on those cited in the IARC Monograph (as cited in Ex. 35–43, pages 56–59).

a. *Highly Water Soluble Cr(VI) Compounds.* Multiple animal carcinogenicity studies have been conducted on highly water soluble sodium dichromate and chromic acid. The key studies are summarized in Table VI–7.

TABLE VI–7.—SUMMARY OF SELECTED CARCINOGENICITY STUDIES IN EXPERIMENTAL ANIMALS ADMINISTERED HEXAVALENT CHROMIUM—HIGHLY WATER SOLUBLE CHROMATES

Compound	Route	Sex/species/strain (# in exposed groups)	Dose administered [1] and observation periods	Tumor incidence	Reference/exhibit #
Chromic acid (Chromium trioxide).	Inhalation	Female ICR mice (50 per exposed group.	3.6 mg Cr(VI)/m^3 for 30 min per day, 2 d/wk up to 12 mo. Histopatholoical evaluation at periods up to 18 mo.	—Lung tumors: 7/48 vs 2/20 for control. —5 benign adenomas and 2 adenocarcinomas.	Adachi *et al.* (1986, Ex. 35–26–1).
	Inhalation	Female C57BL mice (23 examined at 12 mo; 20 examined at 18 mo).	1.8 mg Cr(VI)/m^3 120 min 2 x week for 12 months; Histopatholoical evaluation at 12 and 18 mo.	Nasal papilloma: 6/20 (<0.05) at 18 mo; Lung adenoma: 1/20 (NS) at 18 mo.	Adachi (1987, Ex. 35–219).
	Intrabronchial	Male/female Porton-Wistar rats (50 per exposed group).	1.0 mg Cr(VI) as single dose mixed w cholesterol in steel pellet and evaluated at 2 years.	Bronchial carcinoma (M/F combined): 2/100 (N.S.).	Levy *et al.* (1986, Ex. 11–2).
Sodium dichromate	Inhalation	Male Wistar rats (20 per exposed group).	0.025, 0.050 and 0.10 mg Cr(VI)m^3 22–23 hr/day, 7 d/wk for 18 months; evaluated at up to 30 months.	Lung tumors: 0.025 mg/m^3—0/18; 0.05 mg/m^3—0/018; 0.1 mg/m^3—3/19(NS).	Glaser *et al.* (1936, Ex. 10–11).
	Intrabronchial	Male/female Porton-Wistar rats (50 per exposed group).	0.8 mg Cr(VI) as a single dose mixed w cholesterol in steel pellet and evaluated at 2 years.	Bronchial carcinoma (M/F combined): 1/100 (NS).	Levy *et al.* (1986, 11–2).
	Intratracheal	Male/female Sprague Dawley rats (40 per exposed group).	5 x weekly: 0.0034, 0.017, 0.086 mg Cr(VI)/kg bw for 30 mo; 1 x weekly: 0.017, 0.086, 0.43 mg Cr(VI)/kg bw for 30 mo.	Lung tumors (M/F combined)— 5 x weekly: 0/80 in all groups; 1 x weekly: 0.017 mg/kg–0/80; 0.086 mg/kg–1/80; 0.043 mg/kg–14/80 ($p<0.01$).	Steinhoff *et al.* (1986, Ex. 11–7).

[1] Doses calculated and recorded as mg of Cr(VI), rather than specific chromate compound, where possible.
Not Statistically Significant—NS
Male/Female M/F.

Sodium dichromate. Glaser *et al.* exposed male Wistar rats to aerosolized sodium dichromate by inhalation for 22–23 hours per day, seven days per week for 18 months (Exs. 10–10; 10–11). The rats were held for an additional 12 months at which point the study was terminated. Lung tumor incidences among groups exposed to 25, 50, and 100 µg Cr(VI)/m^3 were 0/18, 0/18, and 3/19, respectively, vs. 0/37 for the control animals. Histopathology revealed one adenocarcinoma and two adenomas in the highest group. The slightly elevated tumor incidence at the highest dose was not statistically significant. As noted by IARC, a small number of animals (20 per group) were used in this study. In addition, the administered doses used in this study were fairly low, such that the maximum tolerated dose (i.e., the maximum dose level that does not lead to moderate reduction in body weight gain) may not have been achieved. Together, these factors limit the interpretation of the study.

In an analysis prepared by Exponent and submitted by the Chrome Coalition in response to OSHA's RFI, Exponent stated that "inhalation studies of Glaser *et al.* support a position that exposures to soluble Cr(VI) at concentrations at least as high as the current PEL (i.e., 52 $\mu g/m^3$) do not cause lung cancer" (Ex. 31–18–1, page 2). However, it should be noted that the Glaser *et al.* studies found that 15% (3/19) of the rats exposed to an air concentration just above the current PEL developed lung tumors, and that the elevated tumor incidence was not statistically significant in the highest dose group because the study used a small number of animals. OSHA believes the Glaser study lacks the statistical power to state with sufficient confidence that Cr(VI) exposure does not cause lung cancer at the current PEL, especially when given the elevated incidence of lung tumors at the next highest dose level.

Steinhoff *et al.* studied the carcinogenicity of sodium dichromate in Sprague-Dawley rats (Ex. 11–7). Forty male and 40 female Sprague-Dawley rats were divided into two sets of treatment groups. In the first set, doses of 0.01, 0.05 or 0.25 mg/kg body weight in 0.9% saline were instilled intratracheally five times per week. In the second set of treatment groups, 0.05, 0.25 or 1.25 mg/kg body weight in 0.9% saline doses were instilled intratracheally once per week. Duration of exposure in both treatment groups was 30 months. The total cumulative dose for the lowest treatment group of animals treated once per week was the same as the lowest treatment group treated five times per week. Similarly, the medium and high dose groups treated once per week had total doses equivalent to the medium and high dose animals treated five times per week, respectively. No increased incidence of lung tumors was observed in the animals dosed five times weekly. However, in the animals dosed once per week, tumor incidences were 0/80 in control animals, 0/80 in 0.05 mg/kg exposure group, 1/80 in 0.25 mg/kg exposure group and 14/80 in 1.25 mg/kg exposure group ($p < 0.01$). The tumors were malignant in 12 of the 14 animals in the 1.25 mg/kg exposure group. The authors believe that the results of this study suggest that the dose-rate for sodium dichromate is a significant factor in its carcinogenic potency and that limiting occasional high dose exposures may be critical to reducing the risk of carcinogenicity in humans occupationally exposed to sodium dichromate.

In separate but similar studies, Levy *et al.* and Levy and Venitt implanted stainless steel mesh pellets filled with a single dose of 2 mg sodium dichromate (0.80 mg Cr(VI)) mixed 50:50 with cholesterol in the bronchi of male and female Porton-Wistar rats (Exs. 11–2; 11–12). Control groups (males and females) received blank pellets or pellets loaded with cholesterol. The rats were observed for two years. Levy *et al.* and Levy and Venitt reported a bronchial tumor incidence of 1/100 and 0/89, respectively, for exposed rats. However, the latter study reported a statistically significant increase in squamous metaplasia, a lesion believed capable of progressing to carcinoma, among exposed rats when compared to unexposed rats. The earlier Levy *et al.* study did not report the incidence of squamous metaplasia. There were no bronchial tumors or squamous metaplasia in any of the control animals and no significant increases in lung tumors were observed in the two studies.

In the Hueper study, 26 rats (sex, age, and strain not specified) were given intrapleural implantation for 27 months (Ex. 10–4). Dosage was not specified. No significant increases in tumor incidence were observed in rats exposed to sodium dichromate or in the control group (0/26 vs. 0/34 in control).

Chromic acid (Chromium trioxide). In a study by Adachi et al, ICR/JcI mice were exposed by inhalation to 3.63 mg/m^3 for 30 minutes per day, two days per week for up to 12 months (Ex. 35–26–1). The mice were observed for an additional six months. The authors used a miniaturized chromium electroplating system to generate chromic acid for the study. The authors found there were elevations in lung adenomas at 10–14 months (3/14 vs. 0/10) and lung adenocarcinomas at 15–18 months (2/19 vs. 0/10), but the results were not statistically significant. Statistically significant increases in nasal papillomas were observed in another study by Adachi *et al.*, in which 43 C57B1 mice were exposed by inhalation to 1.81 mg/m^3 chromic acid for 120 min per day, two days per week for up to 12 months (Ex. 35–26). At 18 months, the tumor incidence was 6/20 in exposed animals vs. 0/20 in the control animals ($p < 0.05$).

In separate but similar studies, Levy *et al.* and Levy and Venitt, using similar exposure protocol, conducted bronchial implantation experiments in which 100 male and female Porton-Wistar rats were dosed with single intrabronchial implantations of 2 mg chromic acid (1.04 mg Cr(VI)) mixed 50:50 with cholesterol in stainless steel mesh pellets (Exs. 11–2; 11–12). The authors found no statistically significant increases in lung tumors, although Levy *et al.* found a bronchial carcinoma incidence of 2/100 in exposed rates compared with 0/100 in control rats. Levy and Venitt found a bronchial carcinoma incidence of 1/100 accompanied by a statistically significant increase in squamous metaplasia, a lesion believed capable of progressing to carcinoma. There was no statistically significant increase in the incidence of squamous metaplasia in control rats or rats treated with Cr(III) compounds in the same study. This finding suggests that squamous metaplasia is specific to Cr(VI) and is not evoked by a non-specific stimuli, the implantation procedure itself, or a treatment with Cr(III) containing materials. The incidence of squamous metaplasia was not investigated in the 1986 Levy *et al.* study.

Similar to Levy *et al.* and Levy and Venitt studies, Laskin *et al.* gave a single intrabronchial implantation of 3–5 mg chromic acid mixed 50:50 with cholesterol in stainless steel mesh pellets to 100 male and female Porton-Wistar rats (Ex. 10–1). The rats were observed for 2 years. No tumors were identified in the treated or control animals (0/100 vs. 0/24).

Potassium chromate. No studies were found that administered this compound by way of the respiratory tract. Borneff *et al.* exposed mice to potassium chromate in drinking water for three generations at a dose of 9 mg Cr(VI)/kg/day (as cited in ATSDR, Ex. 35–41, Pages 108 and 345). In treated mice, two of 66 females developed forestomach carcinoma and 10/66 females and 1/35 males developed forestomach papillomas. The controls also developed forestomach papillomas (2/79 females, 3/47 males), but no carcinomas were observed. The incidence of forestomach tumors was not statistically significant.

b. *Slightly Water Soluble Cr(VI) Compounds.* Animal carcinogenicity studies have been conducted on slightly water soluble calcium chromate and strontium chromate. The key studies are summarized in Table VI–8.

TABLE VI–8: SUMMARY OF SELECTED CARCINOGENICITY STUDIES IN EXPERIMENTAL ANIMALS ADMINISTERED HEXAVALENT CHROMIUM—SLIGHTLY WATER SOLUBLE CHROMATES

Compound	Route	Sex/species/strain (# in exposed groups)	Dose administered [1] and observation periods	Tumor incidence	Reference/exhibit
Calcium chromate	Inhalation	Male/female C57BL/6 mice (136 per group).	4.3 mg Cr(VI)/m³, 5 hr/d, 5d/wk over animal lifetime.	Lung adenoma (M/F combined): 14/272 vs 5/272 for controls.	Nettesheim *et al.* (1971, Ex. 10–8).
	Intrabronchial	Male/female Porton-Wistar rats (100 per group).	0.67 mg Cr(VI) as a single dose mixed w cholesterol in steel pellet and evaluated at 2 years.	Bronchial carcinoma (M/F combined): 25/100 ($p<0.01$).	Levy *et al.* (1986, Ex. 11–2).
	Intratracheal	Male/female Sprague Dawley rats (40 per group).	5 x weekly: 0.083 mg Cr(VI)/kg bw for 30 mo; 1 x weekly: 0.41.mg Cr(VI)/kg bw for 30 mo.	Lung tumors (M/F combined)—5 x weekly: 0.083 mg/kg-6/80 ($p<0.01$); 1 x weekly: 0.41 mg/kg-13/80 ($p<0.01$).	Steinhoff *et al.* (1986, Ex. 11–7).
	Intratracheal	Male Sprague Dawley rats (50 per exposed group).	0.67 mg Cr(VI)/kg bw x 13 installations over 20 wks and evaluated at 2 to 2.5 yr.	Lung tumors: 1/44 (NS)	Snyder *et al.* (1997, Ex. 31–18–12).
Strontium chromates (two different compounds).	Intrabronchial	Male/female Porton-Wistar rats (50 per exposed group).	0.48 mg Cr(VI) as a single dose mixed w cholesterol in steel pellet and evaluated at 2 years.	Bronchial carcinoma (M/F combined): 43/99 & 62/99 ($p<0.01$).	Levy *et al.* (1986, Ex. 11–2).

[1] Doses calculated and recorded as mg of Cr(VI), rather than specific chromate compound, where possible.
Not Statistically significant—NS.
Male/Female—M/F.

Calcium chromate. Nettesheim *et al.* conducted the only available inhalation carcinogenicity study with calcium chromate showing borderline statistical significance for increased lung adenomas in C57B1/6 mice exposed to 13 mg/m³ for 5 hours per day, 5 days per week over the life of the mice. The tumor incidences were 6/136 in exposed male mice vs. 3/136 in control male mice and 8/136 in exposed female mice vs. 2/136 in control female mice (Ex. 10–8).

Steinhoff *et al.* observed a statistically significant increase in lung tumors in Sprague-Dawley rats exposed by intratracheal instillation to 0.25 mg/kg body weight calcium chromate in 0.9% saline five times weekly for 30 months (Ex. 11–7). Tumors were found in 6/80 exposed animals vs. 0/80 in unexposed controls ($p<0.01$). Increased incidence of lung tumors was also observed in those rats exposed to 1.25 mg/kg calcium chromate once per week (14/80 vs. 0/80 in controls) for 30 months. At the highest dose, the authors observed 11 adenomas, one adenocarcinoma, and two squamous carcinomas. The total administered doses for both groups of dosed animals (1×1.25 mg/kg and 5×0.25 mg/kg) were equal, but the tumor incidence in the rats exposed once per week was approximately double the incidence in rats exposed to the same weekly dose divided into five smaller doses. The authors suggested that the dose-rate for calcium chromate compounds may be important in determining carcinogenic potency and that limiting higher single exposures may offer greater protection against carcinogenicity than reducing the average exposure alone.

Snyder *et al.* administered Cr(VI)-contaminated soil of defined aerodynamic diameter (2.9 to 3.64 micron) intratracheally to male Sprague-Dawley rats (Ex. 31–18–12). For the first six weeks of treatment, the rats were instilled with weekly suspensions of 1.25 mg of material per kg body weight, followed by 2.5 mg/kg every other week, until treatments were terminated after 44 weeks. The investigation included four exposure groups: Control animals (50 rats), rats administered Cr(VI)-contaminated soil (50 rats), rats administered Cr(VI)-contaminated soil supplemented with calcium chromate (100 rats), and rats administered calcium chromate alone (100 rats). The total Cr(VI) dose for each group was: Control group (0.000002 mg Cr(VI)/kg), soil alone group (0.324 mg Cr(VI)/kg), soil plus calcium chromate group (7.975 mg Cr(VI)/kg), and calcium chromate alone group (8.700 mg Cr(VI)/kg). No primary tumors were observed in the control group or the chromium contaminated soil group. Four primary tumors of the lung were found in the soil plus calcium chromate group and one primary lung tumor was observed in the group treated with calcium chromate alone; however, these incidences did not reach statistical significance.

In the analysis submitted to OSHA by the Chrome Coalition, Exponent stated that the "intratrachael instillation data of Steinhoff *et al.* 1986 and Snyder *et al.* 1997 indicates there is a likely threshold for lung cancer" (Ex. 31–18–1, page 2). OSHA believes the results of the Steinhoff *et al.* 1986 study show that the rate at which Cr(VI) is administered may be an important determinant for carcinogenic potency and thus useful for hazard identification purposes. However, in accordance with the Agency's long standing cancer policy, OSHA believes it is inappropriate to establish a threshold or "no effect" level of exposure to a carcinogen (*see* 29 CFR 1990.143). Moreover, the Snyder 1997 study, in particular, used contaminated soil samples and an irregular dosing protocol, creating additional complexities in relating the results to workplace inhalation exposures.

Statistically significant increases in the incidence of bronchial carcinoma in rats exposed to calcium chromate through intrabronchial instillation were reported by Levy *et al.* (Ex. 11–2) and Levy and Venitt (Ex. 11–12). These studies, using a similar protocol, implanted a single dose of 2 mg calcium chromate (0.67 mg Cr(VI)) mixed 50:50 with cholesterol in stainless steel pellets into the bronchi of Porton-Wistar rats. Levy *et al.* and Levy and Venitt found bronchial carcinoma incidences of 25/100 and 8/84, respectively, following a 24-month observation. The increased incidences were statistically significant when compared to the control group. Levy and Venitt also reported statistically significant increases in squamous metaplasia in the calcium chromate-treated rats (Ex. 11–12).

Laskin *et al.* observed 8/100 tumors in rats exposed to a single dose of 3–5 mg calcium chromate mixed with cholesterol in stainless steel mesh

pellets implanted in the bronchi (Ex. 10–1). Animals were observed for a total of 136 weeks. The sex, strain, and species of the rats were not specified in the study. Tumor incidence in control animals was 0/24. Although tumor incidence did not reach statistical significance in this study, OSHA agrees with IARC that the incidences are due to calcium chromate itself rather than background variation.

Strontium chromate. Strontium chromate was tested by intrabronchial implantation and intrapleural injection. In a study by Levy *et al.*, two strontium chromate compounds mixed 50:50 with cholesterol in stainless steel mesh pellets were administered by intrabronchial instillation of a 2 mg (0.48 mg Cr(VI)) dose into 100 male and female Porton-Wistar rats (Ex. 11–2). Animals were observed for up to 136 weeks. The strontium chromate compounds induced bronchial carcinomas in 43/99 (Sr, 42.2%; CrO_4, 54.1%) and 62/99 rats (Sr, 43.0%; Cr, 24.3%), respectively, compared to 0/100 in the control group. These results were statistically significant. The strontium chromates produced the strongest carcinogenic response out of the 20 Cr(VI) compounds tested by the intrabronchial implantation protocol.

In the study by Hueper, strontium chromate was administered by intrapleural injection (doses unspecified) lasting 27 months (Ex. 10–4). Local tumors were observed in 17/28 treated rats vs. 0/34 for the untreated rats. Although the authors did not examine the statistical significance of tumors, the results clearly indicate a statistical significance.

c. *Water Insoluble Cr(VI) Compounds.* There have been a number of animal carcinogenicity studies involving implantation or injection of principally water insoluble zinc, lead, and barium chromates. The key studies are summarized in Table VI–9.

TABLE VI–9.—SUMMARY OF SELECTED CARCINOGENICITY STUDIES IN EXPERIMENTAL ANIMALS ADMINISTERED HEXAVALENT CHROMIUM—WATER INSOLUBLE CHROMATES

Compound	Route	Sex/species/strain (# in exposed groups)	Dose administered [1] and observation periods	Tumor incidence	Reference/exhibit #
Zinc chromates (three different compounds).	Intrabronchial	Male/female Porton-Wistar rats (50 per exposed group).	0.42 to 0.52 mg Cr(VI) as a single dose mixed w cholesterol in steel pellet and evaluated at 2 years.	Bronchial carcinoma (M/F combined): 3/61 ($p<0.05$), 5/100 ($p<0.05$), 3/100 ($p=0.07$).	Levy *et al.* (1986, Ex. 11–2); Levy and Venitt (1986, Ex. 11–12).
Zinc tetroxychromate	Intrabronchial	Male/female Porton-Wistar rats (50 per exposed group).	0.18 mg Cr(VI) as a single dose mixed w cholesterol in steel pellet and evaluated at 2 years.	Bronchial carcinoma (M/F combined): 1/100 (NS).	Levy *et al.* (1986, Ex. 11–2).
Lead chromates (seven different compounds).	Intrabronchial	Male/female Porton-Wistar rats (50 per exposed group).	0.25 to 0.32 mg Cr(VI) as single dose mixed w cholesterol in steel pellet and evaluated at 2 years.	Bronchial carcinoma (M/F combined): 0–1/100 (N.S.).	Levy *et al.* (1986, Ex. 11–2).
Lead chromates (three different compounds).	Subcutaneous	Male/female Sprague Dawley rats (20 per exposed group).	1.5 to 4.8 mg Cr(VI) as a single dose in water and evaluated after 2 years.	Sarcomas at injection site (M/F combined): 26–36/40 vs 0/40 for controls.	Maltoni *et al.* (1974, Ex. 8–25); Maltoni (1976, Ex. 5–2).
Lead chromate	Intramuscular	Male/female Fischer 344 rats (25 per exposed group).	1.29 mg Cr(VI) in trioctyanoin 1 x mo for 9 mo and evaluated at up to 2 yr.	Sarcomas at injection site (M/F combined): 31/47 vs 0/44 for controls.	Furst *et al.* (1976, Ex. 10–2).
		Female NIH-Swiss mice (25 per exposed group).	0.72 mg Cr(VI) in trioctyanoin 1 x mo for 4 mo and evaluated at up to 2 yr.	Sarcomas at injection site: 0/22 (NS).	
Barium chromate	Intrabronchial	Male/female Porton-Wistar rats (50 per exposed group).	0.37 mg Cr(VI) as a single dose mixed w cholesterol in steel pellet and evaluated at 2 years.	Bronchial carcinoma (M/F combined): 0/100 (NS).	Levy *et al.* (1986, Ex. 11–2).

[1] Doses calculated and recorded as mg of Cr(VI), rather than specific chromate compound, where possible.
Not Statistically significant—NS.
Male/Female—M/F.

Zinc chromate compounds. Animal studies have been conducted to examine several zinc chromates that range from water insoluble to slightly water soluble compounds depending on the form and composition. In separate, but similarly conducted studies, Levy *et al.* and Levy and Venitt studied two water-insoluble compounds (zinc chromate—lW and zinc tetroxychromate) and two slightly water-soluble compounds (zinc chromate—Norge composition and zinc potassium chromate) (Exs. 11–2; 11–12). Two milligrams of the compounds were administered by intrabronchial implantation to 100 male and female Porton-Wistar rats. The slightly water soluble zinc potassium chromate (0.52 mg Cr(VI)) produced a bronchial tumor incidence of 3/61 which was statistically significant ($p<0.05$) when compared to a control group (Ex. 11–12). There was also a statistically significant increase in bronchial tumors in rats receiving water-insoluble zinc chromate—lW (5/100; $p=0.04$). The bronchial tumor incidence with slightly water soluble zinc chromate—Norge (3/100; $p= 0.068$) and water-insoluble zinc tetroxychromate (1/100) were not statistically significant when compared to a control group. Zinc potassium chromate (slightly water soluble) was administered at doses of 0.42 mg Cr(VI), zinc chromate—Norge (slightly water soluble) was administered at doses of 0.45 mg Cr(VI), and zinc tetroxychromate (insoluble in water) was administered at doses of 0.18 mg Cr(VI). These studies show that insoluble to slightly water soluble zinc chromate compounds may produce statistically significant elevated incidences of tumors in rats.

Basic potassium zinc chromate (slightly water soluble) was administered to mice, guinea pigs and rabbits via intratracheal instillation (Ex. 35–46). Sixty-two Strain A mice were given six injections of 0.03 ml of a 0.2% saline suspension of the zinc chromate at six week intervals and observed until death. A statistically significant increase in tumor incidence was observed in exposed animals when compared to controls (31/62 vs. 7/18). Statistically significant effects were not observed

among guinea pigs or rabbits. Twenty-one guinea pigs (sex and strain not given) received six injections of 0.3 ml of a 1% suspension of zinc chromate at three monthly intervals and observed until death. Results showed pulmonary adenomas in only 1/21 exposed animals vs. 0/18 in controls. Seven rabbits (sex and strain not given) showed no increase in lung tumors when given 3–5 injections of 1 ml of a saline suspension of 10 mg zinc chromate at 3-month intervals. However, as noted by IARC, the small numbers of animals used in the guinea pig and rabbit experiments (as few as 13 guinea pigs and 7 rabbits per group) limit the power of the study to detect increases in cancer incidence.

Hueper found that intrapleural injection of slightly water soluble zinc yellow (doses were unspecified) resulted in statistically significant increases in local tumors in rats (sex, strain, and age of rat unspecified; dose was unspecified). The incidence of tumors in exposed rats was 22/33 vs. 0/34 in controls (Ex. 10–4).

Maltoni *et al.* observed increases in the incidence of local tumors after subcutaneous injection of slightly water soluble zinc yellow in 20 male and 20 female Sprague-Dawley rats (statistical significance was not evaluated) (Ex. 8–37). Tumor incidences were 6/40 in 20% CrO_3 dosed animals at 110 weeks and 17/40 in 40% CrO_3 dosed animals at 137 weeks compared to 0/40 in control animals.

Lead chromate and lead chromate pigments. Levy *et al.* examined the carcinogenicity of lead chromate and several lead chromate-derived pigments in 100 male and female Porton-Wistar rats after a single intrabronchial implantation followed by a two year observation period (Ex. 11–12). The rats were dosed with two mg of a lead chromate compound and lead chromate pigments, which was mixed 50:50 with cholesterol in stainless steel mesh pellets and implanted in the bronchi of experimental animals. The lead chromate and lead chromate pigment compositions consisted of the following: lead chromate (35.8% CrO_4; 0.32 mg Cr(VI)), primrose chrome yellow (12.6% Cr; 0.25 mg Cr(VI)), molybdate chrome orange (12.9% Cr; 0.26 mg Cr(VI)), light chrome yellow (12.5% Cr; 0.25 mg Cr(VI)), supra LD chrome yellow (26.9% CrO_3; 0.28 mg Cr(VI)), medium chrome yellow (16.3% Cr; 0.33 mg Cr(VI)) and silica encapsulated medium chrome yellow (10.5% Cr; 0.21 mg Cr(VI)). No statistically significant tumors were observed in the lead chromate group compared to controls (1/98 vs. 0/100), primrose chrome yellow group (1/100 vs. 0/100), and supra LD chrome yellow group (1/100 vs. 0/100). The authors also noted no tumors in the molybdate chrome orange group, light chrome yellow group, and silica encapsulated medium chrome yellow group.

Maltoni (Ex. 8–25), Maltoni (Ex. 5–2), and Maltoni *et al.* (Ex. 8–37) examined the carcinogenicity of lead chromate, basic lead chromate (chromium orange) and molybdenum orange in 20 male and 20 female Sprague-Dawley rats by a single subcutaneous administration of the lead chromate compound in water. Animals were observed for 117 to 150 weeks. After injection of 30 mg lead chromate, local injection site sarcomas were observed in 26/40 exposed animals vs. 0/60 and 1/80 in controls. Although the authors did not examine the statistical significance of sarcomas, the results clearly indicate a statistical significance. Animals injected with 30 mg basic lead chromate (chromium orange) were found to have an increased incidence of local injection site sarcomas (27/40 vs. 0/60 and 1/80 in controls). Animals receiving 30 mg molybdenum orange in 1 ml saline were also found to have an increased incidence of local injection site sarcomas (36/40 vs. 0/60 controls).

Carcinogenesis was observed after intramuscular injection in a study by Furst *et al.* (Ex. 10–2). Fifty male and female Fischer 344 rats were given intramuscular injections of 8 mg lead chromate in trioctanoin every month for nine months and observed up to 24 months. An increase in local tumors at the injection site (fibrosarcomas and rhabdomyosarcomas) was observed (31/47 in treated animals vs. 0/22 in controls). These rats also had an increased incidence of renal carcinomas (3/23 vs. 0/22 in controls), but IARC noted that the renal tumors may be related to the lead content of the compound. In the same study, 3 mg lead chromate was administered to 25 female NISH Swiss weanling mice via intramuscular injection every 4 months for up to 24 months. In the exposed group, the authors observed three lung alveologenic carcinomas after 24 months of observation and two lymphomas after 16 months of observation. Two control groups were used: an untreated control group (22 rats) and a vehicle injected control group (22 rats). The authors noted one alveologenic carcinoma and one lymphoma observed in each control group.

In response to OSHA's RFI, the Color Pigments Manufacturers Association (CPMA) stated that the lack of carcinogenic response in two studies (Levy *et al.* 1986 and Furst *et al.* 1976) upon exposure to lead chromate and lead chromate pigments in animals indicate these Cr(VI) compounds are not carcinogenic to workers (Ex. 31–15). As described above, the results of the Levy *et al.* 1986 study showed little tumor development (0–1 tumor observed per 100 rats studied in each experiment) after receiving a single dose of 2 mg of lead chromate or a lead chromate compound by an intrabronchial implantation procedure in which the compounds were imbedded in a metal mesh mixed with cholesterol (Ex. 11–2). The total administered dose of the Levy *et al.* study was relatively low at 0.67 mg Cr(VI)/kg when administered only one time (body weight of the rat was around 0.5 kg). A small, single total dose (*e.g.*, 1.6 mg Cr(VI)/kg) of sodium dichromate implanted in the lung also did not result in tumors. However, repeated weekly intratracheal instillations of a lower dose level (0.43 mg Cr(VI)/kg) of sodium dichromate over 30 months for a cumulative total dose of about 56 mg Cr(VI)/kg produced a 17.5 percent lung cancer incidence. Thus, a greater *total* dose of lead chromate instilled in the respiratory tract may also produce a significant tumor incidence. The lack of tumors in the Levy *et al.* study may also have resulted from the inability of water insoluble lead chromate to leach out of the highly non-polar cholesterol environment and gain entry into target lung cells. OSHA, therefore, does not believe that the findings of this study establish that lead chromate and lead chromate pigments are not carcinogenic. OSHA does not believe the results of the Furst *et al.* study show a lack of carcinogenic effect. The study found a 66 percent tumor incidence at the site of injection after multiple intramuscular administrations of lead chromate in rats (Ex. 10–2). Although the route of exposure is not comparable to that found in occupational settings, the carcinogenic potential of lead chromate is supported by the results of several studies showing that pigment workers exposed to lead chromate have significantly elevated lung cancer mortality (see section V.B.2). Several short-term tests have also linked lead chromate with genotoxicity and neoplastic transformation (see section VI.B.8).

Barium chromate. In the studies reviewed by IARC, barium chromate was tested in rats via intrabronchial, intrapleural and intramuscular administration. No excess lung or local tumors were observed (Ex. 11–2; Ex. 10–4; Ex. 10–6).

d. *Summary.* Several Cr(VI) compounds produced tumors in

laboratory animals under a variety of experimental conditions using different routes of administration. The animals were generally given the test material(s) by routes other than inhalation (*e.g.*, intratracheal administration, intramuscular injection, intrabronchial implantation, and subcutaneous injection). Although the route of administration may have differed from that found in an occupational setting, these studies have value in the identification of potential health hazards associated with Cr(VI) and in assessing the relative potencies of various Cr(VI) compounds.

OSHA believes that the results from Adachi *et al.* (Ex. 35–26–1), Adachi *et al.* (Ex. 35–26), Glaser *et al.* (Ex. 10–4), Glaser *et al.* (Ex. 10–10), Levy *et al.* (Ex. 11–2), Steinhoff *et al.* (Ex. 11–7), and Snyder *et al.* (Ex. 31–18–12) studies provide valuable insight on the carcinogenic potency of Cr(VI) compounds in laboratory animals. Total dose administered, dose rate, amount of dosage, dose per administration, number of times administered, exposure duration and the type of Cr(VI) compound are major influences on the observed tumor incidence in animals. It was found that slightly water soluble calcium, strontium, and some zinc chromates showed the highest incidence of lung tumors, as indicated in the results of the Steinhoff, Snyder, and Levy studies, even when compared to similar doses of the more water soluble sodium chromates and chromic acid compounds. The highly insoluble lead chromates did not produce lung tumors by the intrabronchial implantation procedure but did produce tumors by subcutaneous injection and intramuscular injection.

8. Mechanistic Considerations

Mechanistic information can provide insight into the biologically active form(s) of chromium, its interaction with critical molecular targets, and the resulting cellular responses that trigger neoplastic transformation. There has been considerable scientific study in recent years of Cr(VI)-initiated cellular and molecular events believed to impact development of respiratory carcinogenesis. Much of the research has been generated using *in vitro* techniques, cell culture systems, and animal administrations. The early mechanistic data were reviewed by IARC in 1990 (Ex. 35–43). More recent reviews have been done by Singh *et al.* in 1998 (Ex. 35–149), ATSDR in 2000 (Ex. 35–41), and K.S. Crump Group in 2000 (Ex. 35–47).

Recent experimental research has identified several biological steps critical to the mode of action by which Cr(VI) transforms normal lung cells into a neoplastic phenotype. These are: (a) Cellular uptake of Cr(VI) and its extracellular reduction, (b) intracellular Cr(VI) reduction to produce biologically active products, (c) damage to DNA, and (d) activation of signaling pathways in response to cellular stress. Each step will be described in detail below.

a. *Cellular Uptake and Extracellular Reduction.* The ability of different Cr(VI) particulate forms to be taken up by the bronchoalveolar cells of the lung is an essential early step in the carcinogenic process. Particle size and solubility are key physical factors that influence uptake into these cells. Large particulates (>10 μm) are generally deposited in the upper nasopharygeal region of the respiratory tract and do not reach the bronchoalveolar region of the lungs. Smaller Cr(VI) particulates will increasingly reach these lower regions and come into contact with target cells.

Once deposited in the lower respiratory tract, solubility of Cr(VI) particulates becomes a major influence on disposition. Aqueous Cr(VI), such as sodium chromate and chromic acid, rapidly dissolves in the fluids lining the lung epithelia and can be taken up by lung cells via facilitated diffusion mediated by sulfate/phosphate anion transport channels (Ex. 35–148). This is because Cr(VI) exists in a tetrahedral configuration as a chromate oxyanion similar to the physiological anions, sulfate and phosphate (Ex. 35–231). Using cultured human epithelial cells, Liu *et al.* showed that soluble Cr(VI) uptake was time- and dose-dependant over a range of 1 to 300 μM in the medium with 30 percent of the Cr(VI) transported into the cells within two hours and 67 percent at 16 hours at the lowest concentration (Ex. 31–22–18).

Aqueous insoluble Cr(VI) particulates do not readily dissolve into epithelial lining fluids of the bronchoalveolar region. This has led to claims that insoluble chromates, such as lead chromate pigments, are not bioavailable and, therefore, are unable to cause carcinogenesis (Ex. 31–15). However, several scientific studies indicate that insoluble Cr(VI) particulates can come in close contact with the bronchoalveolar epithelial cell surface, allowing enhanced uptake into cells. Wise *et al.* showed that respirable lead chromate particles adhere to the surface of rodent cells in culture causing cell-enhanced dissolution of the chromate ion as well as phagocytosis of lead chromate particles (Exs. 35–68; 35–67). The intracellular accumulation was both time- and dose-dependant. Cellular uptake resulted in damage to DNA, apoptosis (i.e., form of programmed cell death), and neoplastic transformation (Ex. 35–119). Singh *et al.* showed that treatment of normal human lung epithelial cells with insoluble lead chromate particulates (0.4 to 2.0 μg/cm^2) or soluble sodium chromate (10 μM) for 24 hours caused Cr(VI) uptake, Cr-DNA adduct formation, and apoptosis (Ex. 35–66). The proximate genotoxic agent in these cell systems was determined to be the chromate rather than the lead ions (Ex. 35–327). Elias *et al.* reported that cell-enhanced particle dissolution and uptake was also responsible for the cytotoxicity and neoplastic transformation in Syrian hamster embryo cells caused by Cr(VI) pigments, including several complex industrial chrome yellow and molybdate orange pigments (Ex. 125).

Reduction to the poorly permeable Cr(III) in the epithelial lining fluid limits cellular uptake of Cr(VI). Ascorbic acid and glutathione (GSH) are believed to be the key molecules responsible for the extracellular reduction. Cantin *et al.* reported high levels of GSH in human alveolar epithelial lining fluid and Susuki *et al.* reported significant levels of ascorbic acid in rat lung lavage fluids (Exs. 35–147; 35–143). Susuki and Fukuda studied the kinetics of soluble Cr(VI) reduction with ascorbic acid and GSH *in vitro* and following intratracheal instillation (Ex. 35–90). They reported that the reduction was pseudo-first order (i.e., rate of Cr(VI) reduction appeared to be proportional to metal concentration rather than concentration of reductant) with respect to Cr(VI), with a half-life of just under one minute to several hours. They found the greatest reduction rates with higher levels of reductants. Ascorbic acid was more active than GSH. Cr(VI) reduction was slower *in vivo* than predicted from *in vitro* and principally involved ascorbic acid, not GSH. This research indicates that extracellular Cr(VI) reduction to Cr(III) is variable depending on the concentration and nature of the reductant in the epithelial fluid lining regions of the respiratory tract. De Flora *et al.* determined the amount of soluble Cr(VI) reduced *in vitro* by human bronchiolar alveolar fluid and pulmonary alveolar macrophage fractions over a short period and used these specific activities to estimate an "overall reducing capacity" of 0.9–1.8 mg Cr(VI) and 136 mg Cr(VI) per day per individual, respectively (Ex. 35–140).

De Flora, Jones, and others have interpreted the extracellular reduction data to mean that very high levels of Cr(VI) are required to "overwhelm" the reductive defense mechanism before target cell uptake can occur and, as

such, impart a "threshold" character to the exposure-response (Exs. 35–139; 31–22–7). However, the threshold capacity concept does not consider that facilitated lung cell uptake and extracellular reduction are dynamic and parallel processes that happen concurrently. If their rates are comparable then some cellular uptake of Cr(VI) would be expected, even at levels that do not "overwhelm" the reductive capacity. Based on the *in vitro* kinetic data, it would appear that such situations are plausible, especially when concentrations of ascorbic acid are low. Unfortunately, there has been little systematic study of the dose-dependence of Cr(VI) uptake in the presence of physiological levels of ascorbate and GSH using experimental systems that possess active anion transport capability.

Wise *et al.* did study uptake of a single concentration of insoluble lead chromate particles (0.8 μg/cm^2) and soluble sodium chromate (1.3 μM) in Chinese hamster ovary cells co-treated with a physiological concentration (1mM) of ascorbate (Ex. 35–68). They found that the ascorbate substantially reduced, but did not eliminate, chromate ion uptake over a 24 hour period. Interestingly, ascorbate did not affect phagocytic uptake of lead chromate particles, although it eliminated the Cr(VI)-induced clastogenesis (*e.g.*, DNA strand breakage and chromatid exchange) as measured under their experimental conditions.

Singh *et al.* suggested that cell surface interactions with insoluble lead chromate particulates created a concentrated microenvironment of chromate ions resulting in higher intracellular levels of chromium than would occur from soluble Cr(VI) (Ex. 35–149). The evidence for cell membrane mediated uptake of Cr(VI) is consistent with the intratracheal and intrabronchial instillation studies in rodents that show greater carcingenicity with sparingly soluble (*e.g.*, calcium chromate) than insoluble chromate (*e.g.*, lead chromate) particulates and soluble chromates (*e.g.*, sodium chromate) (Ex. 11–2).

Finally, Cr(VI) deposited in the tracheobronchial and alveolar regions of the respiratory tract is cleared by the mucocilliary escalator (soluble and particulate Cr(VI)) and macrophage phagocytosis (particulate Cr(VI) only). In most instances, these clearance processes take hours to days to completely clear Cr(VI) from the lung, but it can take considerably longer for particulates deposited at certain sites. For example, Ishikawa *et al.* showed that some workers had substantial amounts of chromium particulates at the bifurcations of the large bronchii for more than two decades after cessation of exposure (Ex. 35–81). Mancuso reported chromium in the lungs of six chromate production workers who died from lung cancer (as cited in Ex. 35–47). The interval between last exposure to Cr(VI) until autopsy ranged from 15 months to 16 years. Using hollow casts of the human tracheobronchial tree and comparing particle deposition with reported occurrence of bronchogenic tumors, Schlesinger and Lippman were able to show good correlations between sites of greatest deposition and increased incidence of bronchial tumors (Ex. 35–102).

b. *Intracellular Reduction of Cr(VI).* Once inside the cell, the hexavalent chromate ion is rapidly reduced to intermediate oxidation states, Cr(V) and Cr(IV), and the more chemically stable Cr(III). Unlike Cr(VI), these other chromium forms are able to react with DNA and protein to generate a variety of adducts and complexes. In addition, reactive oxygen species (ROS) are produced during the intracellular reduction of Cr(VI) that are also capable of damaging DNA. These reactive intermediates, and not Cr(VI) itself, are considered to be the ultimate genotoxic agents that initiate the carcinogenic process.

After crossing the cell membrane, Cr(VI) compounds can be non-enzymatically converted to Cr(III) by several intracellular reducing factors (Ex. 35–184). The most plentiful electron donors in the cell are GSH, and other thiols, such as cysteine, and ascorbate. Connett and Wetterhahn showed that a Cr(VI)-thioester initially forms in the presence of GSH (Ex. 35–206). A two-phase reduction then occurs with rapid conversion to Cr(V) and glutathionyl radical followed by relatively slower reduction to Cr(III) that requires additional molecules of GSH. Depletion of cellular GSH and other thiols is believed to retard complete reduction of Cr(VI) to Cr(III), allowing buildup of intermediates Cr(V) and Cr(IV). The molecular kinetics of the Cr(VI) to Cr(III) reduction with ascorbate is less well understood but can also involve intermediate formation of Cr(V) and free radicals (Ex. 35–184).

Another important class of intracellular Cr(VI) reductions are catalyzed by flavoenzymes, such as GSH reductase, lipoyl dehydrogenase, and ferredoxin-NADP oxidoreductase. The most prominent among these is GSH reductase that uses NADPH as a cofactor in the presence of molecular oxygen (O_2) to form Cr(V)-NADPH complexes. During the reaction, O_2 undergoes one electron reduction to the superoxide radical (O_2^-) which produces hydrogen peroxide (H_2O_2) through the action of the enzyme superoxide dismutase. The Cr(V)-NADPH can then react with H_2O_2 to regenerate Cr(VI) giving off hydroxyl radicals, a highly reactive oxygen species, by a Fenton-like reaction. It is, therefore, possible for a single molecule of Cr(VI) to produce many molecules of potentially DNA damaging ROS through a repeated reduction/oxidation cycling process. Shi and Dalal used electron spin resonance (ESR) to establish formation of Cr(V)-NADPH and hydroxyl radical in an *in vitro* system (Ex. 35–169; 35–171). Sugiyama *et al.* reported Cr(V) formation in cultured Chinese hamster cells treated with soluble Cr(VI) (Ex.35–133). Using a low frequency ESR, Liu *et al.* provided evidence of Cr(V) formation *in vivo* in mice injected with soluble Cr(VI) (Ex. 35–141–28). Several studies have documented that Cr(VI) can generate Cr(V) and ROS in cultured human lung epithelial cells and that this reduction/oxidation pathway leads to DNA damage, activation of the p53 tumor suppressor gene and stress-induced transcription factor NF–κB, cell growth arrest, and apptosis (Exs. 35–125; 35–142; 31–22–18; 35–135). Leonard *et al.* used ESR spin trapping, catalase, metal chelators, free radical scavengers, and O_2-free atmospheres to show that hydroxyl radical generation involves a Fenton-like reaction with soluble potassium dichromate (Ex. 31–22–17) and insoluble lead chromate (Ex. 35–137) *in vitro*. Liu *et al.* showed that the Cr(IV)/Cr(V) compounds are also able to generate ROS with H_2O_2 in a Fenton reduction/oxidation cycle *in vitro* (Ex. 35–183).

Although most intracellular reduction of Cr(VI) is believed to occur in the cytoplasm, Cr(VI) reduction can also occur in mitochondria and the endoplasmic reticulum. Cr(VI) reduction can occur in the mitochondria through the action of the electron transport complex (Ex. 35–230). The microsomal cytochrome P–450 system in the endoplasmic reticulum also enzymatically reduces Cr(VI) to Cr(V), producing ROS through reduction/oxidation cycling as described above (Ex. 35–171).

c. *Genotoxicity and Damage to DNA.* A large number of studies have examined multiple types of genotoxicity in a wide range of experimental test systems. Many of the specific investigations have been previously reviewed by IARC (Ex. 35–43), Klein (Ex. 35–134), ATSDR (Ex. 35–41), and the K.S. Crump Group (Ex. 35–47) and will only be briefly summarized here.

The body of evidence establishes that both soluble and insoluble forms of Cr(VI) cause structural DNA damage that can lead to genotoxic events such as mutagenisis, inhibition of DNA replication and transcription, and altered gene expression, all of which probably play a role in neoplastic transformation. The reactive intermediates and products that occur from intracellular reduction of Cr(VI) cause a wide variety of DNA lesions. At this time, it is not clear which types of DNA damage are the most critical to the carcinogenic process.

Cr(VI) compounds are mutagenic in most bacterial and mammalian test systems (Ex. 35–118). In the bacterial *Salmonella typhimurium* strains, soluble Cr(VI) caused base pair substitutions at A–T sites as well as frame shift mutations (Ex. 35–161). Nestmann *et al.* also reported forward and frame shift mutations in *Salmonella typhimurium* with insoluble Cr(VI) (Ex. 35–162). Several Cr(VI) compounds have produced mutagenic responses at various genetic loci in mammalian cells (Ex. 12–7). Clastogenic damage, such as sister chromatid exchange and chromosomal aberrations, have also been reported for insoluble Cr(VI) and soluble Cr(VI) (Exs. 35–132; 35–115). Mammalian cells undergo neoplastic transformation following treatment with soluble Cr(VI) or insoluble Cr(VI), including a number of zinc and lead chromate pigments (Exs. 12–5; 35–186).

Genotoxicity has been reported from Cr(VI) administration to animals *in vivo*. Soluble Cr(VI) induced micronucleated erythrocytes in mice following intraperitoneal (IP) administration (Ex. 35–150). It also increased the mutation frequency in liver and bone marrow following IP administration to *lacZ* transgenic mice (Exs. 35–168; 35–163). Izzotti *et al.* reported DNA damage in the lungs of rats exposed to soluble Cr(VI) by intratracheal instillation (Ex. 35–170). Intratracheal instillation of soluble Cr(VI) produced a time- and dose-dependant elevation in mutant frequency in the lung of Big Blue transgenic mice (Ex. 35–174). Oral administration of soluble Cr(VI) in animals did not produce genotoxicity in several studies probably due to route-specific differences in absorption. OSHA is not aware of genotoxicity studies from *in vivo* administration of insoluble Cr(VI).

Studies of chromosomal and DNA damage in workers exposed to Cr(VI) vary in their findings. Some studies reported higher levels of chromosomal aberrations, sister chromatid exchanges, or DNA strand breaks in peripheral lymphocytes of stainless steel welders (Exs. 35–265; 35–160) and electroplaters (Ex. 35–164). Other studies were not able to find excess damage in DNA from the blood lymphocytes of workers exposed to Cr(VI) (Exs. 35–185; 35–167). These reports are difficult to interpret since co-exposure to other genotoxic agents (*e.g.*, other metals, cigarette smoke) likely existed and the extent of Cr(VI) exposures were not known.

Because of the consistent positive response across multiple assays in a wide range of experimental systems from prokaryotic organisms (*e.g.*, bacteria) to human cells *in vitro* and animals *in vivo*, OSHA regards Cr(VI) as an agent able to induce carcinogenesis through a genotoxic mode of action. Both soluble and insoluble forms of Cr(VI) are reported to cause mutagenisis, clastogenesis, and neoplastic transformation. On the other hand, Cr(III) compounds do not easily cause mutations or chromosomal damage in intact cellular systems, presumably due to the inability of Cr(III) to penetrate cell membranes (Exs. 12–7; 35–186).

There has been a great deal of research to identify the types of damage to DNA caused by Cr(VI), the reactive intermediates that are responsible for the damage, and the specific genetic lesions critical to carcinogenesis. It was shown that Cr(VI) was inactive in DNA binding assays with isolated nuclei or purified DNA (Ex. 35–47). However, Cr(III) was able to produce DNA protein cross-links, sister chromatid exchanges, and chromosomal aberrations in an acellular system. Zhitkovich *et al.* showed that incubation of Chinese hamster ovary cells with soluble Cr(VI) produced ternary complexes of Cr(III) cross-linked to cysteine, other amino acids, or glutathione and the DNA phosphate backbone (Ex. 312). Utilizing the pSP189 shuttle vector plasmid, they showed these DNA-Cr(III)-amino acid cross-links were mutagenic when introduced in human fibroblasts (Ex. 35–131).

Another research group showed that plasmid DNA treated with Cr(III) produced intrastrand crosslinks and the production of these lesions correlated with DNA polymerase arrest (Ex. 35–126). The same intrastrand crosslinks and DNA polymerase arrest could also be induced by Cr(VI) in the presence of ascorbate as a reducing agent to form Cr(III) (Ex. 35–263). These results were confirmed in a cell system by treating human lung fibroblasts with soluble Cr(VI), isolating genomic DNA, and demonstrating dose-dependant guanine-specific arrest in a DNA polymerase assay (Ex. 35–188). Cr(V) may also form intrastrand crosslinks since Cr(V) interacts with DNA *in vitro* (Ex. 35–178). The Cr(V)-DNA crosslinks are probably readily reduced to Cr(III) in cell systems. Intrastrand crosslinks have also been implicated in inhibition of RNA polymerase and DNA topoisomerase, leading to cell cycle arrest, apoptosis and possibly other disturbances in cell growth that contribute to the carcinogenic pathway (Ex. 35–149).

DNA strand breaks and oxidative damage result from the one electron reduction/oxidation cycling of Cr(VI), Cr(V), and Cr(IV). Shi *et al.* showed that soluble Cr(VI) in the presence of ascorbate and H_2O_2 caused DNA double strand breaks and 8-hydroxy deoxyguanine (8-OHdG, a marker for oxidative DNA damage) *in vitro* (Ex. 35–129). Leonard *et al.* showed that the DNA strand breaks were reduced by several experimental conditions including an O_2-free atmosphere, catabolism of H_2O_2 by catalase, ROS depletion by free radical scavangers, and chelation of Cr(V). They concluded that the strand breaks and 8-OHdG resulted from DNA damage caused by hydroxyl radicals from Cr(VI) reduction/oxidation cycling (Ex. 31–22–17). Generation of ROS-dependant DNA damage could also be shown with insoluble Cr(VI) (Ex. 35–137). DNA strand breaks and related damage caused by soluble Cr(VI) have been reported in Chinese hamster cells (Ex. 35–128), human fibroblasts (Ex. 311), and human prostate cells (Ex. 35–255). Pretreatment of Chinese hamster cells with a metal chelator suppressed Cr(V) formation from Cr(VI) and decreased DNA strand breaks (Ex. 35–197). Chinese hamster cells that developed resistance to H_2O_2 damage also had reduced DNA strand breaks from Cr(VI) treatment compared to the normal phenotype (Ex. 35–176).

Several researchers have been able to modulate Cr(VI)-induced DNA damage using cellular reductants such as ascorbate, GSH and the free radical scavenger tocopherol (vitamin E). This has provided insight into the relationships between DNA damage, reduced chromium forms and ROS. Sugiyama *et al.* showed that Chinese hamster cells pretreated with ascorbate decreased soluble Cr(VI)-induced DNA strand damage (*e.g.*, alkali-labile sites), but enhanced DNA-amino acid crosslinks (Ex. 35–133). Standeven and Wetterhahn reported that elimination of ascorbate from rat lung cytosol prior to *in vitro* incubation with soluble Cr(VI) completely inhibited Cr-DNA binding (Ex. 35–180). However, not all types of Cr-DNA binding are enhanced by ascorbate. Bridgewater *et al.* found that high ratios of ascorbate to Cr(VI)

actually decreased intrastrand crosslinks *in vitro* while low ratios induced their formation (Ex. 35–263). This finding is consistent with research by Stearns and Watterhahn who showed that excessive ascorbate relative to Cr(VI) leads to two-electron reduction of Cr(III) and formation of Cr(III)-DNA monoadducts and DNA-Cr(III)-amino acid crosslinks (Ex. 35–166). Low amounts of ascorbate primarily cause one-electron reduction to intermediates Cr(V) and Cr(IV) that form crosslinks with DNA and ROS responsible for DNA strand breaks, alkali-labile sites, and clastogenic damage. This explains the apparent paradox that *extracellular* Cr(VI) reduction by ascorbate to Cr(III) reduces Cr(VI)-induced DNA binding but *intracellular* Cr(VI) reduction by ascorbate to Cr(III) enhances Cr-DNA binding. The aforementioned studies used soluble forms of Cr(VI), but Blankenship *et al.* showed that ascorbate pretreatment inhibited chromosomal aberrations in Chinese hamster ovary cells caused by both insoluble lead chromate particles as well as soluble Cr(VI) (Ex. 35–115). Pretreatment with the free radical scavenger tocopherol also inhibits chromosomal aberrations and alkali-labile sites in Cr(VI)-treated cells (Exs. 35–115; 35–128).

Studies of the different types of DNA damage caused by Cr(VI) and the modulation of that damage inside the cell demonstrate that Cr(VI) itself is not biologically active. Cr(VI) must undergo intracellular reduction to Cr(V), Cr(IV), and Cr(III) before the damage to DNA can occur. The evidence suggests that Cr(III) can cause DNA-Cr-amino acid, DNA-Cr-DNA crosslinks and Cr-DNA monoadducts. Cr(V) and possibly Cr(IV) contribute to intrastrand crosslinks and perhaps other Cr-DNA binding. ROS generated during intracellular reduction of Cr(VI) lead to lesions such as chromosomal aberrations, DNA strand breaks, and oxidative DNA damage. The specific DNA lesions responsible for neoplastic transformation have yet to be firmly established so all forms of DNA damage should, at this time, be regarded as potential contributors to carcinogenicity.

d. *Cr(VI)-induced Disturbances in the Regulation of Cell Replication.* Recent research has begun to elucidate how Cr(VI)-induced oxidative stress and DNA lesions trigger cell signaling pathways that regulate the cell growth cycle. The complex regulation of the cell growth cycle by Cr(VI) involves activation of the p53 protein and other transcription factors that respond to oxidative stress and DNA damage. The cellular response ranges from a temporary pause in the cell cycle to terminal growth arrest (i.e., viable cells that have lost the ability to replicate) and a programmed form of cell death, known as apoptosis. Apoptosis involves alterations in mitochondrial permeability, release of cytochrome c and the action of several kinases and caspases. Less is known about the molecular basis of terminal growth arrest. Terminal growth arrest and apoptosis serve to eliminate further growth of cells with unrepaired Cr(VI)-induced genetic damage. However, it is believed that cells which escape these protective mechanisms and regain replicative competence eventually become resistant to normal growth regulation and can transform to a neoplastic phenotype (Exs. 35–121; 35–122; 35–120).

Blankenship *et al.* first described apoptosis as the primary mode of cell death following a two hour treatment of Chinese hamster ovary cells with high concentrations (>150 μM) of soluble Cr(VI) (Ex. 35–144). Apoptosis also occurs in human lung cells following short-term treatment with soluble Cr(VI) (Ex. 35–125) as well as longer term treatment (*e.g.*, 24 hours) with lower concentrations of soluble Cr(VI) (*e.g.*, 10 μM) and insoluble Cr(VI) in the form of lead chromate (Ex. 35–166). Ye *et al.* found that the Cr(VI) treatment that caused apoptosis also activated expression of p53 protein (Ex. 35–125). This apoptotic response was substantially reduced in a p53-deficient cell line treated with Cr(VI), suggesting that the p53 activation was required for apoptosis. Other studies using p53 null cells from mice and humans confirmed that Cr(VI)-induced apoptosis is p53-dependent (Ex. 35–225).

The p53 protein is a transcription factor known to be activated by DNA damage, lead to cell cycle arrest, and regulate genes responsible for either DNA repair or apoptosis. Therefore, it is likely that the p53 activation is a response to the Cr(VI)-induced DNA damage. Apoptosis (i.e., programmed cell death) is triggered once the Cr(VI)-induced DNA damage becomes too extensive to successfully repair. In this manner, apoptosis serves to prevent replication of genetically damaged cells. Several researchers have gone on to further elucidate the molecular pathways involved in Cr(VI)-induced apoptosis. ROS produced by intracellular Cr(VI) reduction/oxidation cycling have been implicated in the activation of p53 and apoptosis (Exs. 35–255; 35–122). Using specific inhibitors, Pritchard *et al.* showed that mitochondrial release of cytochrome c is critical to apoptotic death from Cr(VI) (Ex. 35–159). Cytochrome c release from mitochondria could potentially result from either direct membrane damage caused by Cr(VI)-induced ROS or indirectly by enhanced expression of the p53-dependent apoptotic proteins, Bax and Nova, known to increase mitochondrial membrane permeability.

Cr(VI) causes cell cycle arrest and reduces clonogenic potential (i.e., normal cell growth) at very low concentrations (*e.g.*, 1 μM) where significant apoptosis is not evident. Xu *et al.* showed that human lung fibroblasts treated with low doses of Cr(VI) caused guanine-guanine intrastrand crosslinks, guanine-specific polymerase arrest, and inhibited cell growth at the G_1/S phase of the cell cycle (Ex. 35–188). Zhang et al. described a dose-dependent increase in growth arrest at the G_2/M phase of the cell cycle in a human lung epithelial cell line following 24 hour Cr(VI) treatment over a concentration range of 1 to 10 μM (Ex. 35–135). The cell cycle arrest could be partially eliminated by reducing production of Cr(VI)-induced ROS. Apoptosis was not detected in these cells until a concentration of 25 μM Cr(VI) had been reached. These data suggest that low cellular levels of Cr(VI) are able to cause DNA damage and disrupt the normal cell growth cycle.

Pritchard *et al.* studied the clonogenicity over two weeks of human fibroblasts treated 24 hours with soluble Cr(VI) concentrations from 1 to 10 μM (Ex. 35–120). They reported a progressive decline in cell growth with increasing Cr(VI) concentration. Terminal growth arrest (i.e., viable cells that have lost the ability to replicate) was primarily responsible for the decrease in clonogenic survival below 4 μM Cr(VI). At higher Cr(VI) concentrations, apoptosis was increasingly responsible for the loss in clonogenicity. Pritichard *et al.* and other research groups have suggested that a subset of cells that continue to replicate following Cr(VI) exposure could contain unrepaired genetic damage or could have become intrinsically resistant to processes (*e.g.*, apoptosis, terminal growth arrest) that normally control their growth (Exs. 35–121; 35–122; 35–120). These surviving cells would then be more prone to neoplastic progression and have greater carcinogenic potential.

e. *Summary.* Respirable chromate particulates are taken up by target cells in the bronchoalveolar region of the lung, become intracellularly reduced to several reactive genotoxic species able to damage DNA, disrupt normal regulation of cell division and cause neoplastic transformation. Scientific studies indicate that both aqueous

insoluble and soluble Cr(VI) can be transported into the cell. In fact, cell surface interactions with sparingly soluble and some insoluble chromates likely create a concentrated microenvironment of chromate ion resulting in higher intracellular levels of Cr(VI) than would occur from soluble chromates. This is consistent with the studies of respiratory tract carcinogenesis in animals that indicate the most tumorigenic chromates had low to moderate water solubility. Once inside the cell, Cr(VI) is converted to several lower oxidation forms able to bind to and crosslink DNA. ROS are produced during intracellular reduction/oxidation of Cr(VI) that further damage DNA. This genotoxicity is functionally translated into impaired DNA replication, mutagenesis, and altered gene expression that ultimately lead to neoplastic transformation.

9. Preliminary Conclusions

OSHA preliminarily concludes that the study data summarized in the previous sections support the determination that Cr(VI) compounds should be regarded as carcinogenic to workers. The strongest evidence comes from the many cohort studies reporting excess lung cancer mortality in workers exposed to Cr(VI) during production of chromates and chromate pigments. Additional evidence comes from the less consistent elevations in lung cancer mortality found in workers exposed to Cr(VI) in other occupations, increased tumor incidence in experimental animals treated with Cr(VI), and cellular and molecular data on mode of action.

Studies of chromate production workers in several countries have consistently found significantly greater mortality from lung cancer than expected. In the earliest studies of chromate workers in whom Cr(VI) exposures were believed to be highest, the risk for respiratory cancer was between 15 and 29 times expectation (Exs. 7–2; 7–13; 7–1). Lung cancer risks of this magnitude cannot be explained by potential confounders and other biases.

Later studies that were able to reconstruct exposure histories in workers from production plants located in Baltimore, MD and Painesville, OH found significant trends between lung cancer mortality and both cumulative exposure to Cr(VI) and duration of employment (Exs. 31–22–11; 33–10). Workers were predominantly exposed to the highly water soluble sodium chromate and sodium dichromate at these plants, although probable exposure to other chromates also occurred. Gibb *et al.* showed that a significant association between lung cancer and Cr(VI) was evident, even in models that accounted for smoking (Ex. 31–22–11). Other studies documented declines in lung cancer mortality rates with reduced Cr(VI) exposures due to improvements in the production process (Exs. 7–99; 7–91; 31–18–4). These trends serve to strengthen the evidence for causal association between Cr(VI) and lung cancer.

Studies of workers in the chromate pigment production industry also consistently show significantly elevated lung cancer mortality. These include cohorts from Norway, Great Britain, U.S., and France. The workers were principally exposed to zinc and lead chromate pigments, but the levels of Cr(VI) exposure were not well characterized. Some studies presented data that suggested excess lung cancer was more strongly associated with zinc chromate, although workers were exposed to several chromium pigments (Exs. 7–41; 7–42).

Significantly elevated lung cancer mortality was found in two British chromium electroplating cohorts (Exs. 35–62; 271). The workers were exposed to Cr(VI) in the form of chromic acid mist as well as nickel, another potential lung carcinogen. The association between lung cancer and Cr(VI) in stainless steel welders and ferrochromium production workers are confounded by substantial exposures to other potential carcinogens and Cr(III). However, the generally elevated lung cancer mortality in these workers supports the stronger evidence from the soluble chromate and chromate pigment production cohorts.

A number of the epidemiological studies cited above were evaluated by the IARC in 1990 (Ex. 35–43). IARC found "sufficient evidence in humans for the carcinogenicity of chromium [VI] compounds as encountered in chromate production, chromate pigment production and chromate plating industries" (Ex. 35–43, p. 213). IARC gave Cr(VI) compounds their highest Group 1 classification for agents considered carcinogenic to humans. The EPA and ACGIH have designated Cr(VI) compounds as known and confirmed human carcinogens, respectively (Exs. 35–52; 35–207). NIOSH considers Cr(VI) compounds to be potential occupational carcinogens (Ex. 31–22–22, p. 8).

Experimental animals have generally been administered Cr(VI) compounds by routes other than inhalation. A number of studies in which Cr(VI) compounds were directly instilled in the respiratory tract of rodents produced a significant incidence of lung tumors (Exs. 11–2; 11–12; 11–7). The findings indicate different tumorigenic potencies among Cr(VI) compounds. The less water soluble calcium chromate, strontium chromates, and zinc chromates cause higher numbers of lung tumors at similar doses than the more water soluble sodium dichromate and chromic acid. Experimental research suggests that cellular uptake of the water-insoluble lead chromate is enhanced by the ability to achieve a high local concentration at the lung cell surface that does not occur during uptake of soluble chromates (Ex. 35–149). Because of the greater cancer potency in animal studies, ACGIH has recommended a lower occupational TLV for insoluble Cr(VI) compounds (10 $\mu g/m^3$) than for water-soluble Cr(VI) compounds (50 $\mu g/m^3$).

The few available inhalation studies are limited by abbreviated exposure durations, low exposure levels, or small number of animals per dose group. These studies report slightly elevated lung tumor incidence that are not statistically significant (Exs. 10–11; 35–26–1) or marginally significant (Exs. 10–8; 35–26). Cr(VI) administered to animals by intramuscular, subcutaneous, and other routes of administration have consistently produced a high incidence of tumors, usually near the site of administration.

Evidence from *in vitro* research shows that Cr(VI) enters the cell and is rapidly converted to several lower oxidation forms able to bind to and crosslink DNA. ROS (reactive oxygen species) are produced during intracellular reduction/oxidation of Cr(VI) that can further damage DNA. Soluble and insoluble Cr(VI) compounds are reported to cause mutagenesis, clastogenesis, and neoplastic transformation across multiple assays in a wide range of experimental systems from prokaryotic organisms to human cells *in vitro* and animals *in vivo*. Therefore, OSHA regards all Cr(VI) compounds as agents able to induce carcinogenesis through a genotoxic mode of action.

The rate, as well as the magnitude of the Cr(VI) dose, that reaches the lung has been shown to influence carcinogenic outcome in experimental animals (Ex. 11–7). Less frequent, but higher dose levels of Cr(VI) instilled in the tracheas of rats caused greater tumor incidence than the same total amount of Cr(VI) instilled more frequently but at lower dose levels. This may result from a proliferation of neoplastic cells triggered by lung inflammation at the high Cr(VI) dose levels or from overwhelming any of a number of molecular pathways that serve to protect against Cr(VI)-induced respiratory

carcinogenesis, including extracellular reduction to poorly absorbed Cr(III), intracellular binding of reactive forms to non-critical macromolecules, or repair of DNA damage. The existence of dose rate effects could potentially introduce non-linearities in the Cr(VI) exposure-cancer response. As discussed in the quantitative risk assessment section (section VII), OSHA is not aware of reliable data on which to confidently predict the range of Cr(VI) air levels at which presumed non-linearities might occur or empirical data that convincingly establishes the existence of a threshold exposure for carcinogenicity.

C. Non-Cancer Respiratory Effects

The following sections describe the evidence from the literature on nasal irritation, nasal ulcerations, nasal perforations, asthma, and bronchitis following inhalation exposure to water soluble Cr(VI) compounds. The evidence clearly demonstrates that workers can develop impairment to the respiratory system (nasal irritation, nasal ulceration, nasal perforation, and asthma) after work place exposure by inhalation exposure to Cr(VI) compounds below the current PEL.

It is very clear from the evidence that workers may develop nasal irritation, nasal septum ulcerations, and nasal septum perforations at occupational exposures level at or below the current PEL of 52 $\mu g/m^3$. However, it is not clear what occupational exposure levels lead to the development of occupational asthma or bronchitis.

1. Nasal Irritation, Nasal Septum Ulcerations and Nasal Septum Perforations

Occupational exposure to Cr(VI) can lead to nasal septum ulcerations and nasal septum perforations. The nasal septum separates the nostrils and is composed of a thin strip of cartilage with an overlying mucous membrane known as the mucosa. The initial lesion after Cr(VI) exposure is characterized by localized inflammation or a reddening of the affected mucosa, which can later lead to atrophy. This may progress to an ulceration of the mucosa layer (Ex. 35–1; Ex. 7–3). If exposure is discontinued, the ulcer progression will stop and a scar may form. However, if exposure continues, the ulcer may break through the septum, resulting in a nasal septum perforation sometimes referred to chrome hole. Individuals with nasal perforations may experience a range of signs and symptoms, such as a whistling sound, bleeding, nasal discharge, and infection. Some individuals may experience no noticeable effects. It is currently not known precisely what level would trigger such nasal problems, but, as stated earlier, it is evident that workers are developing nasal problems at levels at or below the current PEL.

Several cohort and cross-sectional studies have described nasal lesions from airborne exposure to Cr(VI) at various electroplating and chrome production facilities. Most of these studies have been reviewed by the Center for Disease Control's Agency for Toxic Substances and Disease Registry (ATSDR) toxicological profile for chromium (Ex. 35–41). OSHA reviewed the studies summarized in the profile and conducted its own literature search to update and supplement the review. In its evaluation, OSHA took into consideration the exposure regimen and experimental conditions under which the studies were performed, including exposure levels, duration of exposure, number, and the inclusion of appropriate control groups. Studies were not included if they did not contribute to the weight of evidence either because of inadequate documentation or because of poor quality. This section only covers some of the key studies and reviews. OSHA has also identified two case reports demonstrating the development of nasal irritation and nasal septum perforations, and these case reports are summarized as well. One case report shows how a worker can develop the nasal perforations from direct contact (i.e., touching the inner surface of the nose with contaminated fingers).

Lindberg and Hedenstierna examined the respiratory symptoms and effects of 104 Swedish electroplaters (Ex. 9–126). Of the 104 electroplaters, 43 were exposed to chromic acid by inhalation. The remaining 61 were exposed to a mixture of chromic acid and nitric acid, hydrochloric acid, boric acid, nickel, and copper salts. The workers were evaluated for respiratory symptoms, changes in the nasal septum, and lung function. All workers were asked to fill out a detailed questionnaire on their history of respiratory symptoms and function. Physicians performed inspections of the nasal passages of each worker. Workers were given a pulmonary function test to assess lung function. For those 43 workers exposed exclusively to chromic acid, the median exposure time was 2.5 years, ranging from 0.2 to 23.6 years. The workers were divided into two groups, a low exposure group (19 workers exposed to eight-hour time weighted average levels below 2 $\mu g/m^3$) and a high exposure group (24 workers exposed to eight-hour time weighted average levels above 2 $\mu g/m^3$). Personal air sampling was conducted on 11 workers for an entire week and at stations close to the chrome baths to evaluate peak exposures and variations in exposure on different days over the week. Nineteen office employees were not exposed to Cr(VI) used as controls for nose and throat symptoms, and 119 auto mechanics (no car painters or welders) whose lung function had been evaluated using similar techniques to those used on Cr(VI) exposed workers were used as controls for lung function.

The investigators reported nasal ulcerations and perforations in a group of workers exposed at the highest peak exposure levels (ranging from 20 $\mu g/m^3$/day to peak levels of 46 $\mu g/m^3$/day) to chromic acid as Cr(VI); prevalence of ulceration/perforation was statistically higher than the control group. Of the 14 individuals in the 20–46 $\mu g/m^3$ exposure group, seven developed nasal ulcerations. In addition to nasal ulcerations, 2 of the 7 also had progressed to nasal perforations. Furthermore, three individuals developed nasal perforations only, at the same exposure levels. At average exposure levels from 2 $\mu g/m^3$ to 20 $\mu g/m^3$, half of the workers complained of "constantly running nose," "stuffy nose," or "there was a lot to blow out." (Authors do not provide details of each complaint). Atrophy, which is a precursor to ulcerations and perforations, was only observed in occupationally exposed workers at relatively low peak levels ranging from 2.5 $\mu g/m^3$ to 11 $\mu g/m^3$. No one exposed to levels below 1 $\mu g/m^3$ (time-weighted average, TWA) complained of respiratory symptoms or developed lesions.

The authors also reported that in the exposed workers, both forced vital capacity and forced expiratory volume in one second were reduced by 0.2 L, when compared to controls. The forced mid-expiratory flow diminished by 0.4 L/second from Monday morning to Thursday afternoon in workers exposed to chromic acid as Cr(VI) daily TWA average levels of 2 $\mu g/m^3$ or higher. The effects were small, not outside the normal range and transient (recovery after 2 days). There was no difference between the control and exposed group after the weekend. The workers exposed to lower levels (2 $\mu g/m^3$ or lower, TWA) showed no significant changes.

Kuo *et al.* evaluated nasal septum ulcerations and perforations in 189 electroplaters in 11 electroplating factories (three factories used chromic acid, six factories used nickel-chromium, and two factories used zinc) in Taiwan (Ex. 35–10). Of the 189 workers, 26 used Cr(VI), 129 used nickel-chromium, and 34 used zinc. The

control group consisted of electroplaters who used nickel and zinc. All workers were asked to fill out a questionnaire and were given a nasal examination including a lung function test by a certified otolaryngologist. The authors determined that 30% of the workers (8/26) that used chromic acid developed nasal septum perforations and ulcerations and 38% (10/26) developed nasal septum ulcers. Using the Mantel Extension Test for Trends, the authors also found that chromium electroplaters had an increased likelihood of developing nasal ulcers and perforations compared to electroplating workers using nickel-chromium and zinc. Personal sampling of airborne Cr(VI) results indicated the highest levels (32 $\mu g/m^3 \pm 35$ $\mu g/m^3$, ranging from 0.1 $\mu g/m^3$ – 119 $\mu g/m^3$) near the electroplating tanks of the Cr(VI) electroplating factories (Ex. 35–11). Much lower personal sampling levels were reported in the "other areas in the manufacturing area" and the "administrative area" (TWA 0.16 ± 0.10 $\mu g/m^3$) of the Cr(VI) electroplating plant. The duration of sampling was not indicated. The results of the lung function tests showed significantly lower values among Cr(VI) electroplaters compared to the other two exposure groups in regards to vital capacity, forced vital capacity, and forced expiratory volume in one second.

Cohen *et al.* examined respiratory symptoms of 37 electroplaters following inhalation exposure to chromic acid (Ex. 9–18). The mean length of employment for the 37 electroplaters was 26.9 months (range from 0.3 to 132 months). Fifteen workers employed in other parts of the plant were randomly chosen for the control group (mean length of employment was 26.1 months; range from 0.1 to 96). All workers were asked to fill out a questionnaire on their respiratory history, including providing details on their symptoms. An otolaryngologist then examined each individual's nasal passages and identified ulcerations and perforations. Air samples to measure Cr(VI) were collected for electroplaters. The air sampling results of chromic acid as Cr(VI) concentrations for electroplaters was a mean of 2.9 $\mu g/m^3$ (range from non-detectable to 9.1 $\mu g/m^3$). The authors found that 95% of the electroplaters developed pathologic changes in nasal mucosa. Thirty-five of the 37 workers, who were employed for more than 1 year had nasal tissue damage. None of these workers reported any previous job experience involving Cr(VI) exposure. Four workers developed nasal perforations, 12 workers developed ulcerations and crusting of the septal mucosa, 11 workers developed discoloration of the septal mucosa, and eight workers developed shallow erosion of septal mucosa. The control group consisted of 15 workers who were not exposed to Cr(VI) at the plant. All but one had normal nasal mucosa. The one individual with abnormal finding was discovered to have a previous Cr(VI) exposure while working in a garment manufacturing operation as a fabric dyer for three years. In addition to airborne exposure, the authors observed employees frequently wiping their faces and picking their noses with contaminated hands and fingers. Many did not wear any protective gear, such as gloves, glasses, or coveralls.

Lucas and Kramkowsi conducted a Health Hazard Evaluation (HHE) on 11 chrome platers in an industrial electroplating facility (Ex. 3–84). The electroplaters worked for about 7.5 years on average. Physicians evaluated each worker for chrome hole scars, nasal septum ulceration, mucosa infection, nasal redness, perforated nasal septum, and wheezing. Seventeen air samples for Cr(VI) exposure were collected in the chrome area. Cr(VI) air concentrations ranged from 1 to 20 $\mu g/m^3$, with an average of 4 $\mu g/m^3$. In addition to airborne exposure, the authors observed workers being exposed to Cr(VI) by direct "hand to nose" contact, such as touching the nose with contaminated hands. Five workers had nasal mucosa that became infected, two workers had nasal septum ulcerations, two workers had atrophic scarring (author did not provide explanation), possibly indicative of presence of past ulcerations, and four workers had nasal septum perforations.

Gomes evaluated 303 employees from 81 electroplating operations in Sao Paulo, Brazil (Ex. 9–31). Results showed that more than two-thirds of the workers had nasal septum ulcerations and perforations following exposure to chromic acid at levels greater than 100 $\mu g/m^3$, but less than 600 $\mu g/m^3$ (precise duration of exposure was not stated). These effects were observed within one year of employment.

Lin et al. examined nasal septum perforations and ulcerations in 79 electroplating workers from seven different chromium electroplating factories in Taipei, Taiwan (Ex.35–13). Results showed six cases of nasal septum perforations, four having scar formations, and 38 cases of nasal septum ulcerations following inhalation exposure to chromic acid. Air sampling near the electroplating tanks had the highest range of chromic acid as Cr(VI) (mean of 28 $\mu g/m^3$; range from 0.7 to 168.3 $\mu g/m^3$). In addition to airborne exposures, the authors also observed direct "hand to nose" contact where workers placed contaminated fingers in their nose. The authors attributed the high number of cases to poor industrial hygiene practices in the facilities. Five of the seven factories did not have adequate ventilation systems in place. Workers did not wear any PPE, including respirators.

Bloomfield and Blum evaluated nasal tissue damage and nasal septum perforations in 23 workers employed at six chromium electroplating plants (Ex. 9–13). They found that daily exposure to chromic acid as Cr(VI) at levels of 52 $\mu g/m^3$ or higher can lead to nasal tissue damage. Three workers developed nasal ulcerations, two workers had nasal perforations, nine workers had nose bleeds, and nine workers had inflamed mucosa.

Kleinfeld and Rosso found seven cases out of nine of chrome electroplaters having nasal septum ulcerations (Ex. 9–41). Workers were exposed to chromic acid as Cr(VI) by inhalation at levels ranging from 93 $\mu g/m^3$ to 728 $\mu g/m^3$. Duration of exposure varied from two weeks to one year. Nasal septum ulcerations were noted as early as one month of employment in some workers.

Royle, using questionnaire responses, reported a significant increase in the prevalence of nasal ulcerations among 997 British electroplaters exposed to chromic acid with an increasing prevalence the longer the worker was exposed to chronic acid (*e.g.*, from 14 cases with exposure less than one year to 62 cases with exposure over five years) (Ex. 7–50). In all but 2 cases, air samples revealed chromic acid was at concentrations of 0.03 mg/m^3 (i.e., 30 $\mu g/m^3$)..

Gibb *et al.* reported nasal irritations, nasal septum bleeding, nasal septum ulcerations and perforations among a cohort of 2,350 chrome production workers in a Baltimore plant (Ex. 31–22–12). A description of the cohort is provided in detail in the cancer health effects section V.B. of this preamble. The authors found that more than 60% of the cohort had experienced nasal ulcerations and irritations, and that the workers developed these effects for the first time within the first three months of being hired (median). Gibb *et al.* found the median exposure to Cr(VI) during first diagnosis of irritated and/or ulcerated nasal septum was 10 $\mu g/m^3$. About 17% of the cohort had reported nasal perforations. Based on historical data, the authors believe that the nasal findings are attributed to Cr(VI) exposure.

Gibb *et al.* also used a Proportional Hazard Model to evaluate the relationship between Cr(VI) exposure and first occurrence of each of the clinical findings. Cr(VI) data was entered into the model as a time dependent variable. Other explanatory variables were calendar year of hire and age of hire. Results of model indicated that airborne Cr(VI) exposure was associated with the occurrence of nasal septum ulceration ($p = 0.0001$). The lack of an association of airborne Cr(VI) exposure to nasal perforation and bleeding nasal septum may reflect the fact that Cr(VI) concentrations used in the model represent annual averages for the job, in which the worker was involved in at the time of the findings, rather than a short-term average. Annual averages do not factor in day-to-day fluctuations or extreme episodic occurrences. Also, the author believes poor housekeeping and hygiene practices may have contributed to these health effects as well as Cr(VI) airborne concentrations.

Based on their hazard model, Gibb *et al.* estimated the relative risks for nasal septum ulcerations would increase 1.2 for each 52 µg of Cr(VI)/m^3 increase in Cr(VI) air levels. They saw a reduction in the incidence of nasal findings in the later years. They found that workers from the earlier years who did not wear any PPE had a greater risk of developing respiratory problems. They believe that the reduction in ulcerations was possibly due to an increased use of respirators and protective clothing and improved industrial hygiene practices at the facility.

The U.S. Public Health Service conducted a study of 897 chrome production workers in seven chromate-producing plants in the early 1950s (Ex. 7–3). The findings of this study were used in part as justification for the current OSHA PEL. Workers were exposed by inhalation to various water soluble chromates and bichromate compounds. The total mean exposure to the workers was a TWA of 68 µg/m^3. Of the 897 workers, 57% (or 509 workers) were found to have nasal septum perforations. Nasal septum perforations were observed even in workers during their first year on the job.

Case reports provide further evidence that airborne exposure to direct "hand to nose" contact of Cr(VI) compounds lead to the development of nasal irritation and nasal septum perforations.

For example, a 70-year-old man developed nasal irritation, incrustation, and perforation after continuous daily exposure by inhalation to chromium trioxide (doses were not specified, but most likely quite high given the nature of his duties). This individual inhaled chromium trioxide daily by placing his face directly over an electroplating vessel. He worked in this capacity from 1934 to 1982. His symptoms continued to worsen after he stopped working. By 1991, he developed large perforations of the nasal septum and stenosis (or constriction) of both nostrils by incrustation (Ex. 35–8).

Similarly, a 30-year-old female jigger (a worker who prepares the items prior to electroplating by attaching the items to be plated onto jigs or frames) developed nasal perforation in her septum following continuous exposure (doses in this case were not provided) to chromic acid mists. She worked adjacent to the automated Cr(VI) electroplating shop. She was also exposed to chromic acid from direct contact when she placed her contaminated fingers in her nose. Her hands became contaminated by handling wet components in the jigging and de-jigging processes (Ex. 35–24).

Evidence of nasal septum perforations has also been demonstrated in experimental animals. Adachi exposed 23 C57BL mice to chromic acid by inhalation at concentrations of 1.81 mg Cr(VI)/m^3 for 120 minutes per day, twice a week and 3.63 mg Cr(VI)/m^3 for 30 minutes per day, two days per week for up to 12 months (Ex. 35–26). Three of the 23 mice developed nasal septum perforations in the 12-month exposure group.

Adachi *et al.* also exposed 50 ICR female mice to chromic acid by inhalation at concentrations of 3.18 mg Cr(VI)/m^3 for 30 minutes per day, 2 days per week for 18 months (Ex. 35–26–1). The authors used a miniaturized chromium electroplating system to mimic electroplating processes and exposures similar to working experience. Nasal septum perforations were found in six mice that were sacrificed after 10 months of exposure. Of those mice that were sacrificed after 18 months of exposure, nasal septum perforations were found in three mice.

2. Occupational Asthma

Occupational asthma is considered "a disease characterized by variable airflow limitation and/or airway hyper responsiveness due to causes and conditions attributable to a particular occupational environment and not to stimuli encountered outside the workplace" (Ex. 35–15). Asthma is a serious illness that can damage the lungs and in some cases be life threatening. The common symptoms associated with asthma include heavy coughing while exercising or when resting after exercising, shortness of breath, wheezing sound, and tightness of chest. Many workers develop an asthmatic attack. An attack may be triggered by particles in the air (Ex. 35–3; Ex. 35–6). It is not clear what occupational exposure levels of Cr(VI) compounds would lead to the development of occupational asthma.

The strongest evidence of occupational asthma has been demonstrated in four case reports. OSHA chose to focus on these four case reports because the data from other occupational studies do not exclusively implicate Cr(VI), even though the studies generally show an increased prevalence of workers having difficulty breathing and other asthmatic-related symptoms following inhalation of multiple chemicals. The four case reports have the following in common: (1) The worker has a history of occupational exposure exclusively to Cr(VI); (2) a physician has confirmed a diagnosis that the worker has symptoms consistent with occupational asthma; and (3) the worker exhibits functional signs of air restriction (*e.g.*, low forced expiratory volume in one second or low peak expiratory flow rate) upon bronchial challenge with Cr(VI) compounds. These case reports demonstrate, through challenge tests, that exposure to Cr(VI) compounds can cause asthmatic responses. The other general case reports below did not use challenge tests to confirm that Cr(VI) was responsible for the asthma; however, these reports were among workers similarly exposed to Cr(VI) such that Cr(VI) is likely to have been a contributing factor in the development of their asthmatic symptoms.

DaReave reported the case of a 48-year-old cement floorer who developed asthma from inhaling airborne Cr(VI) (Ex. 35–7). This worker had been exposed to Cr(VI) as a result of performing cement flooring activities for more than 20 years. The worker complained of dyspnea, shortness of breath, and wheezing after work, especially after working in enclosed spaces. The Cr(VI) content in cement was about 12 ppm. A bronchial challenge test with potassium dichromate produced a 50% decrease in forced expiratory volume in one second. The occupational physician concluded that the worker's asthmatic condition triggered by exposure to Cr(VI) caused the worker to develop bronchial constriction.

LeRoyer reported a case of a 28-year-old roofer who developed asthma from breathing dust while sawing material made of corrugated fiber cement containing Cr(VI) for nine years (Ex. 35–12). This worker demonstrated

symptoms such as wheezing, shortness of breath, coughing, rhinitis, and headaches while working. Skin prick tests were all negative. Several inhalation challenges were performed by physicians and immediate asthmatic reactions were observed after inhaling nebulization of potassium dichromate. A reduction (by 20%) in the forced expiratory volume in one second after exposure to fiber cement dust was noted.

Novey *et al.* reported a case of a 32-year-old electroplating worker who developed asthma from working with chromium sulfate and nickel salts (Ex. 35–16). He began experiencing coughs, wheezing, and dyspnea within the first week of exposure. Inhalation challenge tests given by physicians using chromium sulfate and nickel salts, in separate challenges, both resulted in positive reactions. The worker immediately had difficulty breathing and started wheezing in both challenges. The forced expiratory volume in 1 second decreased by 22% and the forced expiratory volume in 1 second/forced vital capacity ratio also decreased from 74.5% to 60.4%. The author believes the worker's bronchial asthma was induced from inhaling chromium sulfate and nickel salts, individually. Similar findings were reported in a different individual by Sastre (Ex. 35–20).

Shirakawa and Morimoto reported a case of a 50-year-old worker who developed asthma while working at a metal-electroplating plant (Ex. 35–21). Bronchial challenge by physicians produced positive results when using potassium bichromate, followed by a rapid recovery within 5 minutes, when given no exposures. The worker's forced expiratory volume in 1 second dropped by 37% after inhalation of potassium bichromate. The individual immediately began wheezing, coughing with dyspnea, and recovered without treatment within five minutes. The author believes that the worker developed his asthma from inhaling potassium bichromate.

In addition to the case reports confirming that Cr(VI) is responsible for the development of asthma using inhalation challenge tests, the following are several other case reports of Cr(VI) exposed workers having symptoms consistent with asthma where the symptoms were never confirmed by using inhalation challenge tests.

Lockman reported a case of a 41-year old woman, who was occupationally exposed to potassium dichromate during leather tanning (Ex. 35–14). The worker developed an occupational allergy to potassium dichromate. This allergy involved both contact dermatitis and asthma. The physicians considered other challenge tests using potassium dichromate as the test agent (*i.e.*, peak expiratory flow rate, forced expiratory volume in 1 second and methacholine or bronchodilator challenge), but the subject changed jobs before the physicians could administer these tests. Once the subject changed jobs, all her symptoms disappeared. It was not confirmed whether the occupational exposure to Cr(VI) was the cause of the asthma.

Williams reported a 23-year old textile worker who was occupationally exposed to chromic acid. He worked near two tanks of chromic acid solutions (Ex. 35–23). He inhaled fumes while frequently walking through the room with the tanks. He developed both contact dermatitis and asthma. He believes the tank was poorly ventilated and was the source of the fumes. He stopped working at the textile firm on the advice of his physician. After leaving, his symptoms improved greatly. No inhalation bronchial challenge testing was conducted to confirm that chromic acid was causing his asthmatic attacks. However, as noted above, chromic acid exposure has been shown to lead to occupational asthma, and thus, chromic acid was likely to be a causative agent in the development of asthma.

Park *et al.* reported a case of four workers who worked in various occupations involving exposure to either chromium sulfate or potassium dichromate (Ex. 35–18). Two worked in a metal electroplating factory, one worked at a cement manufacturer, and the other worked in construction. All four developed asthma. One individual had a positive response to bronchial provocation test (with chromium sulfate as the test agent). This individual developed an immediate reaction upon given chromium sulfate as the test agent. He experienced wheezing, coughing and dyspnea. Peak expiratory flow rate decreased by about 20%. His physician determined that exposure to chromium sulfate was contributing to his asthma condition. Two had positive reactions to prick skin tests with chromium sulfate as the test agent. Two had positive responses to patch tests using potassium dichromate as the testing challenge agent. Only one out of four underwent inhalation bronchial challenge testing (with a positive result to chromium sulfate) in this report.

3. Bronchitis

In addition to nasal ulcerations, nasal septum perforations, and asthma, there is also limited evidence from reports in the literature of bronchitis associated with Cr(VI) exposure. It is not clear what occupational exposure levels of Cr(VI) compounds would lead to the development of bronchitis.

Royle found that 28% (104/288) of British electroplaters developed bronchitis upon inhalation exposure to chromic acid, as compared to 23% (90/299) controls (Ex. 7–50). The workers were considered to have bronchitis if they had symptoms of persistent coughing and phlegm production. In all but two cases of bronchitis, air samples revealed chromic acid at levels of 0.03 mg/m^3. Workers were asked to fill out questionnaires to assess respiratory problems. Self-reporting poses a problem in that the symptoms and respiratory health problems identified were not medically confirmed by physicians. Workers in this study believe they were developing bronchitis, but it is not clear from this study whether the development of bronchitis was confirmed by physicians. It is also difficult to assess the bronchitis health effects of chromic acid from this study because the study results for the exposed (28%) and control groups (23%) were similar.

Alderson *et al.* reported 39 deaths of chromate production workers related to chronic bronchitis from three chromate producing factories (Bolton, Eaglescliffe, and Rutherglen) from 1947 to 1977 (Ex. 35–2). The specific Cr(VI) compound, extent, and frequency that the workers were exposed to were not specified. However, workers at all three factories were exposed to sodium chromate, chromic acid, and calcium chromate at one time or another. The authors did not find an excess number of number of bronchitis related deaths at the Bolton and Eaglescliffe factories. At Rutherglen, there was an excess number of deaths (31) from chronic bronchitis with a ratio of observed/expected of 1.8 ($p<0.001$). It is difficult to assess the respiratory health effects of Cr(VI) compounds from this study because there are no exposure data, there are no data on smoking habits, nor is it clear on the extent, duration, and amount of specific Cr(VI) compound the workers were exposed to during the study.

While the evidence for bronchitis is limited, evidence from experimental animals demonstrate that Cr(VI) compounds can cause lung irritation, inflammation in the lungs, and possibly lung fibrosis at various exposure levels. Glaser *et al.* examined the effects of inhalation exposure of chromium (VI) on lung inflammation and alveolar macrophage function in rats (Ex. 31–18–9). Twenty, 5-week old male TNO–W–74 Wistar rats were exposed via

inhalation to 25–200 μg Cr(VI)/m³ as sodium dichromate for 28 days or 90 days for 22 hours per day, 7 days per week in inhalation chambers. Twenty, 5-week old male TNO–W–74 Wistar rats also served as controls. All rats were killed at the end of the inhalation exposure period. The authors found increased lung weight in the 50–200 μg/m³ groups after the 90-day exposure period. They also found that 28-day exposure to levels of 25 and 50 μg/m³ resulted in "activated" alveolar macrophages with stimulated phagocytic activities. A more pronounced effect on the activation of alveolar macrophages was seen during the 90-day exposure period of 25 and 50 μg/m³.

Glaser *et al.* exposed 150 male, 8-week old Wistar rats (10 rats per group) continuously by inhalation to aerosols of sodium dichromate at concentrations of 50, 100, 200, and 400 μg Cr(VI)/m³ for 22 hours per day, 7 days a week, for continuous exposure for 30 days or 90 days in inhalation chambers (Ex. 31–18–11). Increased lung weight changes were noticeable even at levels as low as 50 and 100 μg Cr(VI)/m³ following both 30 day and 90 day exposures. Significant accumulation of alveolar macrophages in the lungs was noted in all of the exposure groups. Lung fibrosis occurred in eight rats exposed to 100 μg Cr(VI)/m³ or above for 30 days. Most lung fibrosis disappeared after the exposure period had ceased. At 50 μg Cr(VI)/m³ or higher for 30 days, a high incidence of hyperplasia was noted, possibly in response to Cr(VI)—induced damage to the lung and respiratory tract. The total protein in bronchoalveolar lavage (BAL) fluid, albumin in BAL fluid, and lactate dehydrogenase in BAL fluid were significant at elevated levels of 200 and 400 μg Cr(VI)/m³ in both the 30 day and 90 day exposure groups (as compared to the control group). These responses are indicative of severe injury in the lungs of animals exposed to these Cr(VI) dose levels. At levels of 50 and 100 μg Cr(VI)/m³, the responses are indicative of inflammatory changes in the lungs. The authors concluded that these results suggest that the severe inflammatory reaction may lead to more chronic and obstructive lesions in the lung, and that inflammation is essential for the induction of most effects observed following inhalation exposure.

4. Summary

Overall, there is convincing evidence to indicate that Cr(VI) exposed workers can develop nasal irritation, nasal ulcerations, nasal perforations, and asthma. There is also some limited evidence that bronchitis may occur when exposed to Cr(VI) compounds at high levels. Most of the studies involved exposure to water-soluble Cr(VI) compounds. It is very clear that workers may develop nasal irritations, nasal ulcerations, and nasal perforations at levels below the current PEL of 52 μg/m³. However, it is not clear what occupational exposure levels lead to disorders like asthma and bronchitis.

There are numerous studies in the literature showing nasal irritations, nasal perforations, and nasal ulcerations resulting from Cr(VI) inhalation exposure. It also appears that direct hand-to-nose contact (*i.e.*, by touching inner nasal surfaces with contaminated fingers) can contribute to the incidence of nasal damage. Additionally, some studies show that workers developed these nasal health problems because they did not wear any PPE, including respiratory protection. Inadequate area ventilation and sanitation conditions (lack of cleaning, dusty environment) probably contributed to the adverse nasal effects.

There are numerous well documented case reports in the literature describing occupational asthma specifically triggered by Cr(VI) in sensitized workers. However, OSHA is not aware of any data from the literature to determine a Cr(VI) dose in the work place that leads to the asthmatic condition or to determine how many people may be affected by such Cr(VI) exposure.

The evidence that workers breathing Cr(VI) can develop respiratory disease that involve inflammation, such as asthma and bronchitis is supported by experimental animal studies. The 1985 and 1990 Glaser *et al.* studies show that animals experience irritation and inflammation of the lungs following repeated exposure by inhalation to water-soluble Cr(VI) at air concentrations near the current PEL.

D. Dermal Effects

Occupational exposure to Cr(VI) is a well-established cause of adverse health effects of the skin. The effects are the result of two distinct processes: (1) Irritant reactions, such as skin ulcers and irritant contact dermatitis, and (2) delayed hypersensitivity (allergic) reactions. Some evidence also indicates that exposure to Cr(VI) compounds may cause conjunctivitis.

The mildest skin reactions consist of erythema (redness), edema (swelling), papules (raised spots), vesicles (liquid spots), and scaling (Ex. 35–313, p. 295). The lesions are typically found on exposed areas of the skin, usually the hands and forearms (Exs. 9–9; 9–25). These features are common to both irritant and allergic contact dermatitis, and it is generally not possible to determine the etiology of the condition based on histopathologic findings (Ex. 35–314). Allergic contact dermatitis can be diagnosed by other methods, such as patch testing (Ex. 35–321, p. 226). Patch testing involves the application of a suspected allergen to the skin, diluted in petrolatum or some other vehicle. The patch is removed after 48 hours and the skin examined at the site of application to determine if a reaction has occurred.

Cr(VI) compounds can also have a corrosive, necrotizing effect on living tissue, forming ulcers, or "chrome holes" (Ex. 35–315). This effect is apparently due to the oxidizing properties of Cr(VI) compounds (Ex. 35–318, p. 623). Like dermatitis, chrome ulcers generally occur on exposed areas of the body, chiefly on the hands and forearms (Ex. 35–316). The lesions are initially painless, and are often ignored until the surface ulcerates with a crust which, if removed, leaves a crater two to five millimeters in diameter with a thickened, hardened border. The ulcers can penetrate deeply into tissue and become painful. Chrome ulcers may penetrate joints and cartilage (Ex. 35–317, p. 138). The lesions usually heal in several weeks if exposure to Cr(VI) ceases, leaving a flat, atrophic scar (Ex. 35–318, p.623). If exposure continues, chrome ulcers may persist for months (Ex. 7–3).

It is generally believed that chrome ulcers do not occur on intact skin (Exs. 35–317, p. 138; 35–315; 35–25). Rather, they develop readily at the site of small cuts, abrasions, insect bites, or other injuries (Exs. 35–315; 35–318, p. 138). In experimental work on guinea pigs, Samitz and Epstein found that lesions were never produced on undamaged skin (Ex. 35–315). The degree of trauma, as well as the frequency and concentration of Cr(VI) application, was found to influence the severity of chrome ulcers.

The development of chrome ulcers does not appear to be related to the sensitizing properties of Cr(VI). Edmundson provided patch tests to determine sensitivity to Cr(VI) in 56 workers who exhibited either chrome ulcers or scars (Ex. 9–23). A positive response to the patch test was found in only two of the workers examined.

Parkhurst first identified Cr(VI) as a cause of allergic contact dermatitis in 1925 (Ex. 9–55). Cr(VI) has since been confirmed as a potent allergen. Kligman (1966) used a maximization test (a skin test for screening possible contact allergens) to assess the skin sensitizing potential of Cr(VI) compounds (Ex. 35–

327). Each of the 23 subjects was sensitized to potassium dichromate. On a scale of one to five, with five being the most potent allergen, Cr(VI) was graded as five (i.e., an extreme sensitizer). This finding was supported by a guinea pig maximization test, which assigned a grade of four to potassium chromate using the same scale (Ex. 35–328).

1. Prevalence of Dermal Effects

Adverse skin effects from Cr(VI) exposure have been known since at least 1827, when Cumin described ulcers in two dyers and a chromate production worker (Ex. 35–317, p. 138). Since then, skin conditions resulting from Cr(VI) exposure have been noted in a wide range of occupations. Work with cement is regarded as the most common cause of Cr(VI)-induced dermatitis (Exs. 35–313, p. 295; 35–319; 35–320). Other types of work where Cr(VI)-related skin effects have been reported include chromate production, chrome plating, leather tanning, welding, motor vehicle assembly, manufacture of televisions and appliances, servicing of railroad locomotives, aircraft production, and printing (Exs. 31–22–12; 7–50; 9–31; 9–100; 9–63; 9–28; 9–95; 9–54; 35–329; 9–97; 9–78; 9–9; 35–330). Some of the important studies on Cr(VI)-related dermal effects in workers are described below.

a. *Cement Dermatitis.* Many workers develop cement dermatitis, including masons, tile setters, and cement workers (Ex. 35–318, p. 624). Cement, the basic ingredient of concrete, may contain several possible sources of chromium (Exs. 35–317, p.148; 9–17). Clay, gypsum, and chalk that serve as ingredients may contain traces of chromium. Ingredients may be crushed using chrome steel grinders that, with wear, contribute to the chromium content of the concrete. Refractory bricks in the kiln and ash residues from the burning of coal or oil to heat the kiln serve as additional sources. Trivalent chromium from these sources can be converted to Cr(VI) in the kiln (Ex. 35–317. p. 148).

Cement dermatitis can be caused by direct irritation of the skin, by sensitization to Cr(VI), or both (Ex. 35–317, p. 147). However, sensitization is considered to be of greater importance than irritation in causing cement dermatitis (Ex. 35–317, p. 147). Burrows (1983) combined the results of 16 separate studies to report that, on average, over 80% of cement dermatitis cases were found to be sensitized to Cr(VI) (Ex. 35–317, p. 148). Cement is alkaline, abrasive, and hydroscopic (water-absorbing), and it is likely that the irritant effect resulting from these properties interferes with the skin's defenses, permitting penetration and sensitization to take place more readily (Ex. 35–318, p. 624). Dry cement is considered relatively innocuous because it is not as alkaline as wet cement (Exs. 35–317, p. 147; 9–17). When water is mixed with cement the water liberates calcium hydroxide, causing a rise in pH (Ex. 35–317, p. 147).

Flyvholm *et al.* (1996) noted a correlation between the Cr(VI) concentration in the local cement and the frequency of allergic contact dermatitis (Ex. 35–326, p. 278). Because the Cr(VI) content depends partially upon the chromium concentration in raw materials, there is a great variability in the Cr(VI) content in cement from different geographical regions. In locations with low Cr(VI) content, the prevalence of Cr(VI)-induced allergic contact dermatitis was reported to be approximately one percent, while in regions with higher chromate concentrations the prevalence was reported to rise to between 9 to 11% of those exposed (Ex. 35–326, p. 278).

The relationship between Cr(VI) content in cement and the prevalence of Cr(VI)-induced allergic contact dermatitis is supported by the findings of Avnstorp (1989) in a study of Danish workers who had daily contact with wet cement during the manufacture of pre-fabricated concrete products (Ex. 9–131). Beginning in September of 1981, low concentrations of ferrous sulfate were added to all cement sold in Denmark to reduce Cr(VI) to trivalent chromium. Two hundred and twenty seven workers were examined in 1987 for Cr(VI)-related skin effects. The findings from these examinations were compared to the results from 190 workers in the same plants who were examined in 1981. The prevalence of hand eczema had declined from 11.7% to 4.4%, and the prevalence of Cr(VI) sensitization had declined from 10.5% to 2.6%. Both of these results were statistically significant. There was no significant change in the frequency of skin irritation.

b. *Dermatitis Associated With Cr(VI) From Sources Other Than Cement.* In 1953 the U.S. Public Health Service reported on hazards associated with the chromium-producing industry in the United States (Ex. 7–3). Workers were examined for skin effects from Cr(VI) exposure. Workers' eyes were also examined for possible effects from splashes of Cr(VI)-containing compounds that had been observed in the plants. Of the 897 workers examined, 451 had skin ulcers or scars of ulcers. Seventeen workers were reported to have skin lesions suggestive of chrome dermatitis. The authors noted that most plants provided adequate washing facilities, and had facilities for providing clean work clothes. A statistically significant increase in congestion of the conjunctiva was also reported in Cr(VI)-exposed workers when compared with non-exposed workers (38.7% vs. 25.8%).

In the Baltimore, Maryland chromate production plant examined by Gibb *et al.* (2000), a substantial number of workers were reported to have experienced adverse skin effects (Ex. 31–22–12). The authors identified a cohort of 2,357 workers first employed at the plant between 1950 and 1974. Clinic and first aid records were examined to identify findings of skin conditions. These clinical findings were identified by a physician as a result of routine examinations or visits to the medical clinic by members of the cohort. Percentages of the cohort with various clinical findings were as follows:

Irritated skin: 15.1%
Dermatitis: 18.5%
Ulcerated skin: 31.6%
Conjunctivitis: 20.0%

A number of factors make these results difficult to interpret. The reported findings are not specifically related to Cr(VI) exposure. They may have been the result of other workplace exposures, or non-workplace factors. The report also indicates the percentage of workers who were diagnosed with a condition during their tenure at the plant; however, no information is presented to indicate the expected incidence of these conditions in a population that is not exposed to Cr(VI).

Measurements of Cr(VI) air concentrations by job title were used to estimate worker exposures. Based on these estimates, the authors used a proportional hazards model to find a statistically significant correlation ($p=0.004$) between ulcerated skin and airborne Cr(VI) exposure. Statistically significant correlations between year of hire and findings of ulcerated skin and dermatitis were also reported. Exposures to Cr(VI) in the plant had generally dropped over time. Median exposure to Cr(VI) at the time of occurrence for most of the findings was said to be about 10 $\mu g/m^3$ Cr(VI) (reported as 20 $\mu g/m^3$ CrO^3). It is unclear, however, what contribution airborne Cr(VI) exposures may have had to dermal effects. Direct dermal contact with Cr(VI) compounds in the plant may have been a contributing factor in the development of these conditions.

Mean and median times on the job prior to initial diagnosis were also

reported. The mean time prior to diagnosis of skin or eye effects ranged from 373 days for ulcerated skin to 719 days for irritated skin. Median times ranged from 110 days for ulcerated skin to 221 days for conjunctivitis. These times are notable because many workers in the plant stayed for only a short time. Over 40% worked for less than 90 days. Because these short-term workers did not remain in the workplace for the length of time that was typically necessary for these effects to occur, the results of this study may underestimate the incidence that would occur with a more stable worker population.

Lee and Goh (1988) examined the skin condition of 37 workers who maintained chrome plating baths and compared these workers with a group of 37 control subjects who worked in the same factories but were not exposed to Cr(VI) (Ex. 35–316). Mean duration of employment as a chrome plater was 8.1 (SD±7.9) years. Fourteen (38%) of the chrome platers had some occupational skin condition; seven had chrome ulcers, six had contact dermatitis and one had both. A further 16 (43%) of the platers had scars suggestive of previous chrome ulcers. Among the control group, no members had ulcers or scars of ulcers, and three had dermatitis.

Where ulcers or dermatitis were noted, patch tests were administered to determine sensitization to Cr(VI) and nickel. Of the seven workers with chrome ulcers, one was allergic to Cr(VI). Of the six workers with dermatitis, two were allergic to Cr(VI) and one to nickel. The worker with ulceration and dermatitis was not sensitized to either Cr(VI) or nickel. Although limited by a relatively small study population, this report clearly indicates that Cr(VI)-exposed workers face an increased risk of adverse skin effects. The fact that the majority of workers with dermatitis were not sensitized to Cr(VI) indicates that irritant factors play an important role in the development of dermatitis in chrome plating operations.

Royle (1975) also investigated the occurrence of skin conditions among workers involved in chrome plating (Ex. 7–50). A questionnaire survey completed by 997 chrome platers revealed that 21.8% had experienced skin ulcers, and 24.6% had suffered from dermatitis. No information was presented to indicate the expected incidence in a comparable population that was not exposed to Cr(VI). Of the 54 plants involved in the study, 49 used nickel, another recognized cause of allergic contact dermatitis.

The author examined the relationship between the incidence of these conditions and length of exposure. The plater population was divided into three groups: those with less than one year of Cr(VI) exposure, those with one to five years of Cr(VI) exposure, and those with over five years of Cr(VI) exposure. A statistically significant trend was found between length of Cr(VI) exposure and incidence of skin ulcers. The incidence of dermatitis, on the other hand, bore no relationship to length of exposure.

In 1973, researchers from NIOSH reported on the results of a health hazard investigation of a chrome plating establishment (Ex. 3–5). In the plating area, airborne Cr(VI) concentrations ranged from less than 0.71 up to 9.12 $\mu g/m^3$ (mean 3.24 $\mu g/m^3$; SD=2.48 $\mu g/m^3$). Of the 37 exposed workers who received medical examinations, five were reported to have chrome-induced lesions on their hands. Hygiene and housekeeping practices in this facility were reportedly deficient, with the majority of workers not wearing gloves, not washing their hands before eating or leaving the plant, and consuming food and beverages in work areas.

Gomes (1972) examined Cr(VI)-induced skin lesions among electroplaters in Sao Paulo, Brazil (Ex. 9–31). A clinical examination of 303 workers revealed 88 (28.8%) had skin lesions, while 175 (58.0%) had skin and mucus membrane lesions. A substantial number of employers (26.6%) also did not provide personal protective equipment to workers. The author attributed the high incidence of skin ulcers on the hands and arms to inadequate personal protective equipment, and lack of training for employees regarding hygiene practices.

Fleeger and Deng (1990) reported on an outbreak of skin ulcerations among workers in a facility where enamel paints containing chromium were applied to kitchen range parts (Ex. 9–97). A ground coat of paint was applied to the parts, which were then placed on hooks and transported through a curing oven. In some cases, small parts were places on hooks before paint application. Tiny holes in the oven coils apparently resulted in improper curing of the paint, leaving sharp edges and a Cr(VI)-containing residue on the hooks. Most of the workers who handled the hooks reportedly did not wear gloves, because the gloves were said to reduce dexterity and decrease productivity. As a result, cuts from the sharp edges allowed the Cr(VI) to penetrate the skin, leading to ulcerations (Ex. 9–97).

2. Prognosis of Dermal Effects

Cr(VI)-related dermatitis tends to become more severe and persistent with continuing exposure. Once established, the condition may persist even if occupational exposure ceases. Fregert followed up on cases of occupational contact dermatitis diagnosed over a 10-year period by a dermatology service in Sweden. Based on responses to questionnaires completed two to three years after treatment, only 7% of women and 10% of men with Cr(VI)-related allergic contact dermatitis were reported to be healed (Ex. 35–322). Burrows reviewed the condition of patients diagnosed with work-related dermatitis 10–13 years earlier. Only two of the 25 cases (8%) caused by exposure to cement had cleared (Ex. 35–323).

Hogan *et al.* reviewed the literature regarding the prognosis of contact dermatitis, and reported that the majority of patients had persistent dermatitis (Ex. 35–324). Job changes reportedly did not usually lead to a significant improvement for most patients. The authors surveyed contact dermatitis experts around the world to explore their experience with the prognosis of patients suffering from occupational contact dermatitis of the hands. Seventy-eight percent of the 51 experts who responded to the survey indicated that chromate was one of the allergens associated with the worst possible prognosis.

Halbert *et al.* reviewed the experience of 120 patients diagnosed with occupational chromate dermatitis over a 10-year period (Ex. 35–320). The time between initial diagnosis and the review ranged from a minimum of six months to a maximum of nine years. Eighty-four (70%) of patients were reviewed two or more years after initial diagnosis, and 40 (33%) after five years or more. In the majority of cases (78, or 65%), the dermatitis was attributed to work with cement. For the study population as a whole, 76% had ongoing dermatitis at the time of the review.

When the review was conducted, 62 (58%) patients were employed in the same occupation as when initially diagnosed. Fifty-five (89%) of these workers continued to suffer from dermatitis. Fifty-eight patients (48%) changed occupations after their initial diagnosis. Each of these individuals indicated that they had changed occupations because of their dermatitis. In spite of the change, dermatitis persisted in 40 members of this group (69%).

Lips *et al.* found a somewhat more favorable outcome among 88 construction workers with occupational chromate dermatitis who were removed from Cr(VI) exposure (Ex. 35–325). Follow-up one to five years after removal indicated that 72% of the patients no longer had dermatitis. The

authors speculated that this result might be due to strict avoidance of Cr(VI) contact. Nonetheless, the condition persisted in a substantial portion of the affected population.

3. Thresholds for Dermal Effects

In a response to OSHA's RFI submitted on behalf of the Chrome Coalition, Exponent indicated that the findings of Fowler *et al.* (1999) and others provide evidence of a threshold for elicitation of allergic contact dermatitis (Ex. 31–18–1, p. 27). Exponent also stated that because chrome ulcers did not develop in the Fowler *et al.* study, "more aggressive" exposures appear to be necessary for the development of chrome ulcers.

The Fowler *et al.* study involved the dermal exposure of 26 individuals previously sensitized to Cr(VI) who were exposed to water containing 25 to 29 mg/L Cr(VI) as potassium dichromate (pH 9.4) (Ex. 31–18–5). Subjects immersed one arm in the Cr(VI) solution, while the other arm was immersed in an alkaline buffer solution as a control. Exposure lasted for 30 minutes and was repeated on three consecutive days. Based on examination of the skin, the authors concluded that the skin response experienced by subjects was not consistent with either irritant or allergic contact dermatitis.

The exposure scenario in the Fowler *et al.* study, however, does not mimic the occupational experience. While active dermatitis, scratches, and skin lesions served as criteria for excluding both initial and continuing participation in the study, it is reasonable to expect that individuals with these conditions will often continue to work. Cr(VI)-containing mixtures and compounds used in the workplace may also pose a greater challenge to the integrity of the skin than the solution used by Fowler *et al.* Wet cement, for example, may have a pH higher than 9.4, and may be capable of abrading or otherwise damaging the skin. As damaged skin is liable to make exposed workers more susceptible to Cr(VI)-induced skin effects, the suggested threshold is likely to be invalid. The absence of chrome ulcers in the Fowler *et al.* study is not unexpected, because subjects with "fissures or lesions" on the skin were excluded from the study (Ex. 31–18–5). As discussed earlier, chrome ulcers are not believed to occur on intact skin.

4. Preliminary Conclusions

OSHA believes that adverse dermal effects from exposure to Cr(VI), including irritant contact dermatitis, allergic contact dermatitis, and skin ulceration, have been firmly established. The available evidence is not sufficient to relate these effects to any given Cr(VI) air concentration. Rather, it appears that direct dermal contact with Cr(VI) is the most relevant factor in the development of dermatitis and ulcers. Based on the findings of Gibb *et al.* (Ex. 32–22–12) and U.S. Public Health Service (Ex. 7–3), OSHA also considers it likely that conjunctivitis can result from eye contact with Cr(VI).

OSHA does not believe that the available evidence is sufficient to establish a threshold concentration of Cr(VI) below which dermal effects will not occur in the occupational environment. This preliminary finding is supported not only by the belief that the exposure scenario of Fowler *et al.* is not consistent with occupational exposures, but by experience in the workplace as well. As summarized by Flyvholm *et al.* (1996), numerous reports have indicated that allergic contact dermatitis occurs in cement workers exposed to Cr(VI) concentrations below the threshold suggested by Fowler *et al.* (1999). OSHA considers the evidence of Cr(VI)-induced allergic contact dermatitis in these workers to indicate that the threshold for elicitation of response suggested by Fowler *et al.* (1999) is not applicable to the occupational environment.

E. Other Health Effects

OSHA has examined the possibility of health effect outcomes associated with Cr(VI) exposure in addition to such effects as lung cancer, nasal ulcerations and perforations, occupational asthma, and irritant and allergic contact dermatitis. Unlike the Cr(VI)-induced toxicities cited above, the data on other health effects do not definitively establish Cr(VI)-related impairments of health from occupational exposure at or below the current OSHA PEL.

There is some positive evidence that workplace inhalation to Cr(VI) results in gastritis and gastrointestinal ulcers, especially at high exposures (generally over OSHA's current PEL) (Ex. 7–12). This is supported by ulcerations in the gastrointestinal tract of mice breathing high Cr(VI) concentration for long periods (Ex. 10–8). Other studies reported positive effects but significant information was not reported or the confounders made it difficult to draw positive conclusions (Ex. 3–84; Sassi 1956 as cited in Ex. 35–41). Other studies reported negative results (Exs. 7–14; 9–135).

Likewise, several studies reported increases in renal proteins in the urine of chromate production workers and chrome platers (Exs. 35–107; 5–45; 35–105; 5–57). The Cr(VI) air levels recorded in these workers were usually below the current OSHA PEL (Exs. 35–107; 5–45). Workers with the highest urinary chromium levels tended to also have the largest elevations in renal markers (Ex. 35–107). One study reported no relationship between chromium in urine and renal function parameters, no relationship with age or with duration of exposure, and no relationship between the presence of chromium skin ulcers and chromium levels in urine or renal function parameters (Ex. 5–57). In most studies, the elevations renal protein levels were restricted to only one or two proteins out of several examined per study, generally exhibited small increases (Ex. 35–105) and the effects appeared to be reversible (Ex. 5–45). It has been stated that low molecular weight proteinuria can occur from other reasons and cannot by itself be considered evidence of chronic renal disease (Ex. 35–195). Other studies reported no changes in renal markers (Exs. 7–27; 35–104) and animal inhalation studies did not report kidney damage (Exs. 9–135; 31–18–11; 10–11; 31–18–10; 10–10). Some studies with Cr(VI) administered by drinking water or gavage were positive for increases in renal markers, and some cell and tissue damage (Exs. 9–143; 11–10). However, it is not clear how to extrapolate such findings to workers exposed to Cr(VI) via inhalation. Well designed studies of effects in humans via ingestion were not found.

OSHA did not find information to clearly and sufficiently demonstrate that exposures to Cr(VI) result in significant impairment to the hepatic system. Two European studies, positive for an excess of deaths from cirrhosis of the liver and hepatobiliarity disorders, were not able to separate chromium exposures from exposures to the many other substances present in the workplace. The authors also could not rule out the role of alcohol use as a possible contributor to the disorder (Ex. 7–92; Sassi as cited in Ex. 35–41). Other studies did not report any hepatic abnormalities (Exs. 7–27; 10–11).

The reproductive studies showed mixed results. Some positive reproductive effects occurred in some welding studies. However, it is not clear that Cr(VI) is the causative agent in these studies (Exs. 35–109; 35–110; 35–108; 35–202; 35–203). Other positive studies were seriously lacking in information. Information was not given on exposures, the nature of the reproductive complications, or the women's tasks (Shmitova 1980, 1978 as cited in Ex. 35–41, p. 52). ATSDR states that because these studies were

generally of poor quality and the results were poorly reported, no conclusions can be made on the potential for chromium to produce adverse reproductive effects in humans (Ex. 35–41, p.52). In animal studies, where Cr(VI) was administered through drinking water or diet, positive developmental effects occurred in offspring (Exs. 9–142; 35–33; 35–34; 35–38). However, the doses administered in drinking water or given in the diet were high (i.e., 250, 500, and 750 ppm). Furthermore, strong studies showing reproductive or developmental effects in other situations where employees were working exclusively with Cr(VI) were not found. In fact, the National Toxicology Program (NTP) (Exs. 35–40; 35–42; 35–44) conducted an extensive multigenerational reproductive assessment by continuous breeding where the chromate was administered in the diet. The assessment yielded negative results (Exs. 35–40; 35–42; 35–44). Animal inhalation studies were negative (Exs. 35–199; 9–135; 10–10; Glaser 1984 as cited in Ex. 31–22–33;). Thus, it cannot be concluded that Cr(VI) is a reproductive toxin for normal working situations.

VII. Preliminary Quantitative Risk Assessment

A. Introduction

The Occupational Safety and Health (OSH) Act and some landmark court cases have led OSHA to rely on quantitative risk assessment, where possible, to support the risk determinations required to set a permissible exposure limit (PEL) for a toxic substance in standards under the OSH Act. Section 6(b)(5) of the Act states that "The Secretary [of Labor], in promulgating standards dealing with toxic materials or harmful agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life." (29 U.S.C. 651 *et seq.*)

In a further interpretation of the risk requirements for OSHA standard setting, the United States Supreme Court, in the 1980 "benzene" decision, (*Industrial Union Department, AFL–CIO* v. *American Petroleum Institute,* 448 U.S. 607 (1980)) ruled that the OSH Act requires that, prior to the issuance of a new standard, a determination must be made that there is a significant risk of material impairment of health at the existing PEL and that issuance of a new standard will significantly reduce or eliminate that risk. The Court stated that "before he can promulgate any permanent health or safety standard, the Secretary is required to make a threshold finding that a place of employment is unsafe in the sense that significant risks are present and can be eliminated or lessened by a change in practices' [448 U.S. 642]. The Court also stated "that the Act does not limit the Secretary's power to require the elimination of significant risks" [488 U.S. 644]. While the Court indicated that the use of quantitative risk analysis was an appropriate means to establish significant risk, they made clear that "OSHA is not required to support its finding that a significant risk exists with anything approaching scientific certainty."

Although the Court in the Cotton Dust case, (*American Textile Manufacturers Institute* v. *Donovan,* 452 U.S. 490 (1981)) rejected the use of cost-benefit analysis in setting OSHA standards, it reaffirmed its previous position in the "benzene" case that a risk assessment is not only appropriate but should be used to identify significant health risk in workers and to determine if a proposed standard will achieve a reduction in that risk. Although the Court did not require OSHA to perform a quantitative risk assessment in every case, the Court implied, and OSHA as a matter of policy agrees, that assessments should be put into quantitative terms to the extent possible.

The determining factor in the decision to perform a quantitative risk assessment is the availability of suitable data for such an assessment. As reviewed in section VI.B. on Carcinogenic Effects, there are a substantial number of occupational cohort studies that reported excess lung cancer mortality in workers exposed to Cr(VI) in several industrial operations. Many of these found that workers exposed to higher levels of airborne Cr(VI) for a longer period of time had greater standardized mortality ratios (SMRs) for lung cancer. OSHA believes two recently studied occupational cohorts have the strongest data sets on which to quantify lung cancer risk from cumulative Cr(VI) exposure (i.e., air concentration x exposure duration). Using a linear relative risk model on these data to predict excess lifetime risk, OSHA preliminarily estimates that the lung cancer risk from a 45 year occupational exposure to Cr(VI) at an 8-hour TWA at the current PEL of 52 μg/m^3 is 106 to 334 excess deaths per 1000. Quantitative lifetime risk estimates from a working lifetime exposure at several lower alternative PELs under consideration by the Agency are also estimated. For example, the projected risk at 0.5 μg/m^3 Cr(VI) is 1.1 to 4.3 per 1000. The sections below discuss the selection of the appropriate data sets and risk models, the estimation of lung cancer risks based on the selected data sets and models, the uncertainty in the risk estimates, the key issues that arise as result of the quantitative risk assessment as well as a summary describing comments from an expert peer review and the OSHA response.

In contrast to the more extensive occupational cohort data on Cr(VI) exposure-response, data from experimental animal studies are less suitable for quantitative risk assessment of lung cancer than human studies. Besides the obvious species difference, most of the animal studies administered Cr(VI) to the respiratory tract by less relevant routes, such as instillation or implantation. The few available inhalation studies in animals were limited by a combination of inadequate exposure levels, abbreviated durations, and small numbers of animals per dose group. Despite these limitations, the animal data do provide semi-quantitative information with regard to the relative carcinogenic potency of different Cr(VI) compounds. A more detailed discussion can be found in section VI.B.7.

The data that relate non-cancer health impairments, such as damage to the respiratory tract and skin, to Cr(VI) exposure are also not well suited for quantitative assessment. There are some data from cross-sectional studies and worker surveys that group the prevalence and severity of nasal damage by contemporary time-weighted average (TWA) Cr(VI) air measurements. However, there are no studies that track either incidence or characterize exposure over time. Nasal damage is also more likely influenced by shorter-term peak exposures that have not been as well characterized. While difficult to quantitate, the data indicate that the risk of damage to the nasal mucosa would be significantly reduced by lowering the current PEL, discussed further in section VIII on Significance of Risk.

There are even less suitable exposure-response data to assess risk for other Cr(VI)-induced impairments (*e.g.*, mild renal damage, gastrointestinal ulceration). With the possible exception of respiratory tract effects (*e.g.*, nasal damage, occupational asthma), the risk of non-cancer adverse effects that result from inhaling Cr(VI) are expected to be very low except as a result of long-term regular airborne exposure around or above the current PEL (52 μg/m^3). Since

the non-cancer effects occur at relatively high Cr(VI) air concentrations, OSHA believes that lowering the PEL to reduce the risk of developing lung cancer over a working lifetime would also eliminate or reduce the risk of developing these other health impairments. As discussed in section VI.E., adverse effects to the skin primarily result from dermal rather than airborne exposure.

B. Study Selection

The more than 40 occupational cohort studies reviewed in Section VI.B on carcinogenic effects were evaluated to determine the adequacy of the exposure-response information for the quantitative assessment of lung cancer risk associated with Cr(VI) exposure. The key criteria were data that allowed for estimation of input variables, specifically levels of exposure and duration of exposure (*e.g.*, cumulative exposure in $mg/m^3 - yr$); observed numbers of cancers (deaths or incident cases) by exposure category; and expected (background) numbers of cancer deaths by exposure category.

Additional criteria were applied to evaluate the strengths and weaknesses of the available epidemiological data sets. Studies needed to have well-defined cohorts with identifiable cases. Features such as cohort size and length of follow-up affect the ability of the studies to detect any possible effect of Cr(VI) exposure. Potential confounding of the responses due to other exposures was considered. Study evaluation also considered whether disease rates from an appropriate reference population were used to derive expected numbers of lung cancers. One of the most important factors in study evaluation was the ascertainment and use of exposure information (i.e., well-documented historical exposure data). Both level and duration of exposure are important in determining cumulative dose, and studies are often deficient with respect to the availability or use of such information. Evidence of exposure-response relationship was also important.

Two recently studied cohorts of chromate production workers were found to be the strongest data sets for quantitative assessment (Exs. 31–22–11; 33–10). Of the various studies, these two had the most extensive and best documented Cr(VI) exposures spanning three or four decades. Both cohort studies characterized observed and expected lung cancer mortality and reported a statistically significant positive association between lung cancer risk and cumulative Cr(VI) exposure. Four other cohorts had less satisfactory data for quantitative assessments of lung cancer risk (Exs. 7–11; 23; 7–14; 7–120; 31–16–3). While the lung cancer response in these cohorts was stratified across multiple exposure groups, there were limitations to these data that affected the certainty of the risk projections. The cohorts include chromate production workers, stainless steel welders, and aerospace manufacturing workers. Risk estimates from these lesser cohorts were used to examine the robustness of the more precise estimates from the Gibb and Luippold cohorts. The strengths and weaknesses of all six cohorts in terms of their use in exposure-response analysis are discussed in more detail below. Emphasis has been placed on the quantitative information available for each cohort.

Three other cohort studies that were used in the past to develop crude risk estimates from worker exposure to Cr(VI) are not being relied upon in the present assessment and therefore are not reviewed below (Exs. 7–37; 7–62; 7–95). In these cohorts, risk estimates were determined from background lung cancer rates and excess lung cancer mortality associated with a single, rather than multiple Cr(VI) exposure levels. There were also a number of other limitations to the study data that required the use of unsupported assumptions and raised uncertainties in the risks. The exposure-response data from the three studies and the resulting assessments are discussed in the 1995 report from the K.S. Crump Division (Ex. 13–5). OSHA believes the recent availability of several higher quality cohort studies cited above eliminates the need to rely on these more problematic cohorts to assess lung cancer risk from occupational Cr(VI) exposure.

1. Gibb Cohort

The Gibb et al. study was one of the stronger studies for quantitative risk assessment, especially in terms of cohort size, historical exposure data, and evidence of exposure-response (Exs. 31–22–11; 33–11). Gibb et al. studied an updated cohort from the same Baltimore chromate production plant previously studied by Hayes et al. (see section VII.B.4). The cohort consisted of 2357 male workers (white and non-white) first employed between 1950 and 1974. Follow-up was through the end of 1992 for a total of 70,736 person-years and an average length of 30 years per member. Smoking status at the start of employment was available for 91% of the cohort members.

A significant advantage of the Gibb data was the sizable amount of personal and area sampling measurements from a variety of locations and job titles collected concurrently over the years during which the cohort members were exposed (from 1950 to 1985, when the plant closed). Using these concentration estimates as the basis, a job exposure matrix was constructed giving annual average exposures by job title. Based on the job exposure matrix and work histories for the cohort members, Gibb et al. computed the person-years of observation, the observed numbers of lung cancer deaths, and the expected numbers of lung cancer deaths categorized by cumulative Cr(VI) exposure and age of death. They found that cumulative Cr(VI) exposure was a significant predictor of lung cancer risk over the exposure range of 0 to 2.76 (mean±SD = 0.70±2.75) mg/m^3 - yr, even with models that accounted for the smoking data at hire. This included a greater than expected number of premature lung cancer deaths in some workers. For example, chromate production workers between 40 and 50 years of age with mean cumulative Cr(VI) exposure of 0.41 mg CrO_3/m^3 - yr (equivalent to 0.21 mg $Cr(VI)/m^3$ - yr) were about four times more likely to die of lung cancer than a State of Maryland resident of similar age (Ex. 31–22–11, Table V).

The detailed reporting of the cumulative exposure, including mean values for four categories defined by the quartiles of cumulative exposure versus age, was another significant advantage. This level of documentation reduced some of the uncertainty associated with the estimation of cumulative exposure. Moreover, the cross-classification of cumulative exposure with age allowed the application of more elaborate models that consider the effect of age on lung cancer risk.

Since the publication of Gibb et al., the data file containing the demographic, exposure, and response data for the individual cohort members was made available (Ex. 295). These data have been used in a recent reanalysis (see subsection VII.C.1). The advantages of the study mentioned above are even greater now that the detailed cohort data can be accessed. Among other things, the exposure groups can be defined in alternative ways, the effect of considering different reference populations can be examined, and additional models can be applied in the dose-response analysis.

2. Luippold Cohort

The other well-documented exposure-response data set comes from a second cohort of chromate production workers. Luippold *et al.* studied a cohort of 482 predominantly white, male employees

who started work between 1940 and 1972 at the same Painesville, Ohio plant studied earlier by Mancuso (Ex. 33–10) (see subsection VII.B.3). Mortality status was followed through 1997 for a total of 14,048 person-years and an average length of 30 years. While the Luippold cohort was smaller and less racially diverse than the Gibb cohort, the workforce contained fewer transient, short-term employees. The Luippold cohort consisted entirely of workers employed over one year. Fifty-five percent worked for more than five years. In comparison, 65 percent of the Gibb cohort worked for less than a year and 15 percent for more than five years at the Baltimore plant. There was more limited information about the smoking behavior (smoking status available for only 35 percent of members) of the Luippold cohort than the Gibb cohort.

One aspect that the Luippold cohort had in common with the Gibb cohort was extensive and well-documented air monitoring of Cr(VI). Cr(VI) exposures for the Luippold cohort were based on 21 industrial hygiene surveys conducted at the plant between 1943 and 1971, yielding a total of more than 800 area samples (Ex. 35–61). A job exposure matrix was computed for 22 exposure areas for each month starting in 1940 and, coupled with detailed work histories available for the cohort members, cumulative exposures were calculated for each person-year of observation. The cumulative Cr(VI) exposures, which ranged from 0.003 to 23 (mean±SD = 1.58±2.50) mg Cr(VI)/m^3 − yr, were generally higher but overlapped those of the Gibb cohort.

Luippold *et al.* found significant dose-related trends for lung cancer SMRs as a function of year of hire, duration of employment, and cumulative Cr(VI) exposure. The data on exposure-response for this cohort are relatively strong. The use of individual work histories to define exposure categories and presentation of mean cumulative doses in the exposure groups provided a strong basis for a quantitative risk assessment. The higher cumulative exposure range and the longer work duration of the Luippold cohort serve to complement quantitative data available on the Gibb cohort. Risk assessments on the Luippold *et al.* study data performed by Crump *et al.* had access to the individual data and, therefore, had the best basis for analyses of this cohort (Exs. 31–18–1; 35–205; 35–58).

3. Mancuso Cohort

Mancuso (Ex. 7–11) studied the lung cancer incidence of an earlier cohort of 332 white male employees drawn from the same plant in Painesville, Ohio that was evaluated by the Luippold group. The Mancuso cohort was first employed at the facility between 1931 and 1937 and followed up through 1972, when the plant closed. Mancuso (Ex. 23) later extended the follow-up period through 1993, yielding a total of 12,881 person-years of observation for an average length of 38.8 years and a total of 66 lung cancer deaths. Since the Mancuso workers were first employed in the 1930s and the Luippold workers were first employed after 1940, the cohorts consisted of a completely different set of individuals.

A major limitation of the Mancuso study is the uncertainty of the exposure data. Mancuso relied exclusively on the air monitoring reported by Bourne and Yee (Ex. 7–98) conducted over a single short period of time during 1949. Bourne and Yee presented monitoring data as airborne insoluble chromium, airborne soluble chromium, and total airborne chromium by production department at the Painesville plant. The insoluble chromium was probably Cr(III) compounds with some slightly water-soluble and insoluble chromates. The soluble chromium was probably highly water-soluble Cr(VI). Mancuso (Exs. 7–11; 23) calculated cumulative exposures (mg/m^3 − yr) for each cohort member based on the 1949 mean chromium concentrations, by production department, under the assumption that those levels reflect exposures during the entire duration of employment for each cohort member, even though employment may have begun as early as 1931 and may have extended to 1972. Due to the lack of air measurements spanning the full period of worker exposure and the lack of adequate methodology to distinguish chromium valence states i.e., Cr(VI) vs. Cr(III)), the exposure data associated with the Mancuso cohort were not as well characterized as data from the Luippold or Gibb cohorts.

Mancuso presented observed lung cancer deaths and age-adjusted death rates stratified by age group and cumulative total, soluble and insoluble chromium exposure groups (Ex. 23). However, the study did not provide the expected numbers of lung cancers for the exposure groupings, making it more difficult to apply appropriate risk models to the data. Approaches that attempt to circumvent this limitation are discussed in subsection VII.E.1. Mancuso (Ex. 7–11; 23) reported cumulative exposure-related increases in age-adjusted lung cancer death rates for soluble, insoluble, or total chromium. Within a particular range of exposures to insoluble chromium, lung cancer death rates also tended to increase with increasing total cumulative chromium. However, the study did not report whether these tendencies were statistically significant, nor did it report the extent to which exposures to soluble and insoluble chromium were correlated. Thus, it is possible that the apparent relationship between insoluble chromium *e.g.*, primarily Cr(III)) and lung cancer may have arisen because both insoluble chromium concentrations and lung cancer death rates were positively correlated with Cr(VI) concentrations.

Although a 1995 risk assessment based on data from the 1975 Mancuso study was prepared for OSHA under contract (Ex. 13–5), it has been superseded by an updated assessment from the more complete 1997 Mancuso data (Ex. 33–15). Specific limitations with respect to quantitative risk estimation from the Mancuso cohort are discussed in section VII.E.1 on supporting risk assessments.

4. Hayes Cohort

Hayes *et al.* (Ex. 7–14) studied a cohort of employees at the same chromate production site in Baltimore examined by Gibb *et al.* The Hayes cohort consisted of 2101 male workers who were first hired between 1945 and 1974, excluding those employed for less than 90 days. The Gibb cohort had different date criteria for first employment (1950–1974) and no 90-day exclusion.

Hayes *et al.* reported SMRs for respiratory tract cancer based on workers grouped by time of hire, employment duration, and high or low exposure groups. Workers who had ever worked at an older plant facility and workers whose location of employment could not be determined were considered to have a high or questionable exposure. Workers known to have been employed exclusively at a newer renovated facility built in 1950 and 1951 were considered to have had low exposure. A dose-response was observed in the sense that higher SMRs for respiratory cancer were observed among long-term workers (workers who had worked for three or more years) than among short-term workers. Hayes *et al.* did not quantify occupational exposure to Cr(VI) at the time the cohort was studied.

Later on, Braver *et al.* (Ex. 7–17) estimated average cumulative soluble chromium, (presumed by the authors to be Cr(VI)) exposures for four subgroups of the Hayes cohort. The TWA Cr(VI) concentrations were determined from a total of 555 midget impinger air measurements that were collected at the older plant from 1945 to 1950. The

cumulative exposure for the subgroups were estimated from the yearly average Cr(VI) exposure for the entire plant and their average duration of employment rather than job-specific Cr(VI) concentrations and individual work histories. Such "group level" estimation of cumulative exposure is less appropriate than the estimation based on individual experiences as was done for the Gibb and Luippold cohorts. Another weakness is that exposures attributed to many workers (*e.g.*, those hired after 1950) were based on chromium measurements during an earlier period (i.e., 1949–1950).

Braver *et al.* (Ex. 7–17) discussed a number of other potential sources of uncertainty in the Cr(VI) exposure estimates, such as the possible conversion to Cr(III) during sample collection, the inability to measure insoluble forms of Cr(VI) even though soluble Cr(VI) compounds were primarily produced at the plant, and the likelihood that samples may have been collected mainly in potential problem areas. However, the biggest source of uncertainty was the assumption of rather high Cr(VI) air levels in the newly renovated facility at the Baltimore site throughout the 1950s based on measurements made 1945 to 1950 in an older facility, as explained in section VII.E.2.

5. Gerin Cohort

Gerin *et al.* (Ex. 7–120) developed a job exposure matrix that was used to quantify cumulative Cr(VI) exposures for male stainless steel welders who were part of the International Agency for Research on Cancer's (IARC) multi-center historical cohort study (Ex. 7–114). The IARC cohort included 11,092 welders for a total of 164,077 person-years. This resulted in an average of 14.8 person-years of risk for each member of the cohort. The number cohort members who were stainless steel welders, for which Cr(VI) exposures were estimated, could not be determined from their report. Gerin *et al.* used occupational hygiene surveys reported in the published literature to estimate typical eight-hour TWA Cr(VI) breathing zone concentrations for various combinations of welding processes and base metal. The resulting exposure matrix was then combined with information about individual work history, considering time and length of employment, type of welding, base metal, and ventilation status (*e.g.*, confined area, use of local exhaust ventilation, etc.) to estimate the cumulative Cr(VI) exposure.

Unfortunately, the industrial hygiene data used to develop the Gerin exposure matrix included measurements in the 1970s from only 8 of the 135 companies that employed welders in the cohort. Individual work histories were also not available for about 25 percent of the stainless steel welders. In these cases, information was assumed based on the average distribution of welding practices within the company. The lack of specific Cr(VI) air measurements and work practice information for this cohort raises questions concerning the accuracy of the exposure estimates.

Gerin *et al.* reported lung cancer mortality across four cumulative Cr(VI) exposure categories for two subcohorts of stainless steel welders; each accumulating between 7,000 and 10,000 person-years of observation. The welders were also known to be exposed to nickel, another potential lung carcinogen. There was no upward trend in lung cancer with respect to cumulative Cr(VI) exposure for either subcohort. Because of uncertainties in the exposure estimates, the lack of exposure-response, and possible confounding co-exposure to nickel, the Gerin cohort was not considered a featured data set for exposure-response assessment.

6. Alexander Cohort

Alexander *et al.* (Ex. 31–16–3) conducted a retrospective cohort study of 2429 aerospace workers employed in jobs entailing chromate exposure (*e.g.*, spray painting, sanding/polishing, chrome plating, etc.) between 1974 and 1994. The cohort included workers employed as early as 1940. Follow-up averaged a relatively short 8.9 years per cohort member.

Industrial hygiene data collected between 1974 and 1994 were used to classify jobs in categories of "high" exposure, "moderate" exposure, or "low" exposure to Cr(VI). The use of respiratory protection was accounted for when setting up the job exposure matrix. These exposure categories were assigned summary TWA concentrations and combined with individual job history records to estimate cumulative exposures for each person-year of observation. As further discussed in section VII.E.4, it was not clear from the study whether exposures are expressed in units of Cr(VI) or chromate (CrO_3). Exposures occurring before 1974 were assumed to be at TWA levels assigned to the interval from 1974 to 1985. The importance of the exposure assignments to the quantitative assessment of risk is further discussed in section VII.E.4.

Alexander *et al.* presented lung cancer incidence data for four cumulative chromate exposure categories based on worker duration and the three (high, moderate, low) exposure levels above. Lung cancer incidence rates were determined using a local cancer registry, part of the National Cancer Institute (NCI) Surveillance Epidemiology and End Results (SEER) program. There was no positive trend in lung cancer incidence with increasing Cr(VI) exposure. This cohort study was limited by the relatively young age of the cohort members, the short follow-up time, and lack of information on smoking. The available Cr(VI) air measurement data did not span the entire employment period of the cohort (*e.g.*, no data for 1940 to 1974) and was heavily grouped into a relatively small number of "summary" TWA concentrations that may not have fully captured individual differences in workplace exposures to Cr(VI). For the above reasons, the Alexander cohort was not considered as strong a data set for quantitative exposure-response analysis as the Gibb and Luippold cohorts.

7. Studies Selected for the Quantitative Risk Assessment

The epidemiologic database is quite extensive and contains several studies that have adequate data suitable for quantitative risk assessment. OSHA considers certain studies to be better suited for quantitative assessment than others. The Gibb and Luippold cohorts are considered the preferred sources for quantitative estimation because they have larger cohort sizes, extensive follow-up periods, fairly well documented historical Cr(VI) exposure levels, and because analysts have had access to the individual job histories and associated exposure matrices.

The Mancuso cohort and the Hayes cohort were derived from workers at the same plants as Luippold and Gibb, respectively, but have limitations associated with the reporting of quantitative information and exposure estimates that make them less suitable for a risk assessment. Similarly, the Gerin and Alexander cohorts are less suitable either because of the small size of the cohort, the shorter follow-up, or limitations with respect to exposure estimation. For example, the lung cancer status of the Alexander cohort had only been tracked for an average of nine years. This is in contrast to the Gibb, Luippold, and Mancuso cohorts that accumulated an average 30 or more years of observation. Long-term follow-up of cohort members is particularly important for determining the risk of lung cancer, which typically has an extended latency period of roughly twenty years. The Alexander cohort would need additional 20 years of

follow-up to achieve the person-years of observation accumulated by the Gibb cohort of about the same number of workers. The Guerin cohort is also limited by lack of follow-up, since the lung cancer status of the stainless steel welders are believed to have only been observed for an average of about 15 years.

Despite the limitations, the lesser studies each provide independent estimates of risk, albeit with more uncertainty, that can be compared to the estimates derived from the preferred data sets. OSHA believes evaluating consistency in risk among several different worker cohorts adds to the overall quality of the assessment. In light of the extensive worker exposure-response data, there is little additional value in deriving quantitative risk estimates from tumor incidence results in rodents, especially considering the concerns with regard to route of exposure and study design.

The following sections, describing the quantitative estimates of risk, start with the preferred Gibb and Luippold cohorts. The risk estimates from the supporting studies and previous risk assessments are then discussed. A discussion of remaining issues and uncertainties follows the quantitative presentation.

C. Quantitative Risk Assessments Based on the Gibb Cohort

Quantitative risk assessments have recently been performed on the exposure-response data from the Gibb cohort by three groups: Environ International (Exs. 33–15; 33–12) under contract with OSHA; the National Institute for Occupational Safety and Health (Ex. 33–13); and Exponent (Ex. 31–18–15–1) for the Chrome Coalition. All reported similar risks for Cr(VI) exposure over a working lifetime despite using somewhat different modeling approaches. The exposure-response data, risk models, statistical evaluation, and risk estimates reported by each group are discussed below.

1. Environ Risk Assessments

In 2002, Environ International (Environ) prepared a quantitative analysis of the association between Cr(VI) exposure and lung cancer (Ex. 33–15). The Environ analysis relied on a summary of the person-years of observation and observed and expected lung cancer deaths broken down by age and cumulative exposure (Ex. 31–22–11, Table V). These data are presented in Table VII–1. The job exposure matrix was the basis for the calculation of individual cumulative exposure estimates for all 2357 members of the cohort. The cumulative exposure estimates were lagged 5 years (i.e., at any point in time after exposure began, an individual's cumulative exposure would equal the product of chromate concentration and duration of exposure, summed over all jobs held up to five years prior to that point in time). An exposure lag is commonly used in the dose-response analysis of lung cancer since there is a long latency period between first exposure and the development of disease. Gibb et al. found that models using five- and ten-year lags provided better fit to the mortality data than lags of zero, two and twenty years (Ex. 31–22–11). The cross-classification of cumulative exposure with age allowed Environ to evaluate models that considered the effect of age on lung cancer risk. A total of 71,994 person-years summed up from Table V of the Gibb et al. study was slightly greater than the reported 70,736 cited in their publication (Ex. 31–22–11, p. 119).

TABLE VII–1.—DOSE-RESPONSE DATA FROM GIBB *et al.* (EX. 31–22–11): OBSERVED AND EXPECTED NUMBER OF LUNG CANCER DEATHS GROUPED BY AGE AND FOUR CUMULATIVE CR(VI) EXPOSURE CATEGORIES

Cumulative Cr(VI) exposure (μg/m³ – years)		Age						
		20–29	30–39	40–49	50–59	60–69	70–79	80+
0–0.77	Observed	0	1	0	14	8	2	1
	Expected	0.018	0.39	2.5	7.56	10.79	5	0.88
	Person-Years	5003	7684	6509	5184	3104	865	163
	Mean Exposure	0.21	0.21	0.27	0.28	0.26	0.24	0.21
0.78–4.6	Observed	0	0	2	10	10	4	2
	Expected	0.001	0.18	1.97	6.09	7.85	3.25	0.44
	Person-Years	349	3139	4643	3928	2183	558	79
	Mean Exposure	2.2	2.2	2.2	2.2	2.2	2.0	1.9
4.7–40	Observed	0	0	3	10	11	4	2
	Expected	0.002	0.19	1.93	5.7	7.66	3.26	0.38
	Person-Years	457	3520	4732	3720	2128	559	78
	Mean Exposure	16	16	16	16	15	15	14
40–2730	Observed	0	0	8	8	18	3	1
	Expected	0.001	0.17	1.82	5.63	6.71	2.48	0.18
	Person-Years	200	2874	4294	3663	1926	423	29
	Mean Exposure	110	170	210	270	330	410	450

A 5-year lag was used in the calculation of the cumulative exposures. The exposure estimates themselves have been converted from those shown in Gibb *et al.*, Table V, by multiplying by 0.52, to convert from chromate concentration to hexavalent chromium concentration and by 1000 to convert from mg/m³ - years to μg/m³–years

A set of "externally standardized" models was applied to the data in Table VII–1. These are externally standardized because they required estimates of expected lung cancer deaths from a standard reference population. The 2002 Environ analysis relied on expected lung cancer deaths from age-specific Maryland rates, as provided in Gibb *et al.* The observed numbers of cancer cases were assumed to have a Poisson distribution, with expected values corresponding to three different dose-related models. A Poisson distribution is assumed because it has been commonly used in statistics to describe the allocation of rare events that occur during a given time period. Regression techniques are then used to link explanatory variables (*e.g.*, cumulative exposure) to responses of interest (*e.g.*, lung cancer deaths).

The set of models used was mathematically described as follows:

E1. $N_i = C_0 * E_i * \exp\{kt_i\} * (1 + C_1D_i + C_2D_i^2)$

E2. $N_i = C_0 * E_i * (1 + C_1D_i * \exp\{kt_i\})$

E3. $N_i = C_0 * E_i + (PY_i * C_1D_i)$

where N_i is the predicted number of lung cancers in i^{th} group PY_i is the

number of person-years for group i; E_i is the expected number of lung cancers in that group, based on the reference population; D_i is the mean cumulative dose for that group; and C_0, C_1, C_2, and k are parameters to be estimated. In equations E1 and E2, t_i the mean age for group i.

Models E1 and E2 are relative risk models that differ with respect to the effect of age. In model E1, the background rates are adjusted for age whereas in E2 the dose coefficient is modified by the age. On the other hand, Model E3 is an additive risk model. In the case of additive risk models, the exposure-related estimate of risk is the same regardless of the age- and race-specific background rate of lung cancer. For relative risk models, a dose term is multiplied by the appropriate background rate of lung cancer to derive an exposure-related estimate of risk, so that excess risk is always relative to background.

Estimation of parameters (i.e., C_0, C_1, C_2, and k) was accomplished by maximum likelihood techniques. For the externally standardized models, likelihood ratio tests were used to determine which of the model parameters contributed significantly to the fit of the model. Parameters were sequentially added to the model, starting with C_1, when they contributed significantly ($p \geq 0.05$) to improving the fit. Parameters that did not contribute significantly were excluded from consideration.

Goodness-of-fit for each model was evaluated by considering the deviance, a likelihood-based statistic for which larger p-values indicate better model fit. In addition, the fits of different models were compared using the Akaike Information Criterion (AIC) value, a statistic based on the model's maximized likelihood and the number of parameters used. For the quadratic model E1, addition of a dose-squared term did not significantly improve the fit of model to the data (i.e., C_2 estimated to be zero) relative to a linear model. For models E1 and E2, the parameter k was not determined to be different from 0, and thus models E1 and E2 defaulted to the same linear relative risk model. The deviance-based test of fit suggested an adequate correspondence between model predictions and the observations ($p \geq 0.13$).

A second set of "internally standardized" models, which did not require estimation of the expected number of lung cancers, was also fit to the data in Table VII–1 (Ex. 33–15). Model parameters were estimated by the maximum likelihood procedures described above. The test for goodness-of-fit indicated that these models did not fit the data well ($p \leq 0.01$). The formulation and a more detailed description of these models can be found in the 2002 Environ report (Ex. 33–15).

Lifetable calculations were made of the number of extra lung cancers per 1000 workers exposed to Cr(VI), assuming a constant exposure from age 20 through a maximum of age 65. The lifetime probability of a lung cancer death was cumulated to age 100, resulting in a negligible loss of accuracy since the probability that a person will live longer than that is extremely small. Rates of lung cancer and other mortality for the lifetable calculations were based, respectively, on 1998 U.S. lung cancer and all-cause mortality rates for both sexes and all races.

The lifetable calculation of additional lifetime risk was completed for the maximum likelihood parameter estimates for each model. In addition, 95% confidence intervals for the additional lifetime risk were derived by a likelihood profile method. Details about the procedures used to estimate parameters, model fit, lifetable calculations, and confidence intervals are described in the 2002 Environ report (Ex. 33–15, p. 24–26).

Based on comparison of the models' AIC values, Environ indicated that the linear relative risk model (simplified E1/E2) was preferred over the E3 additive risk model. The relative risk model is also preferred over an additive risk model (fits being adequate in both cases) in the case of lung cancer because of its variable background rate with age. It may not be appropriate to assume, as an additive model does, that increased lung cancer risk at age 25, where background risk is relatively low, would be the same (for the same cumulative dose) as at age 50, where background rates are much higher.

The linear relative risk model predicted an excess lifetime risk of lung cancer associated with an occupational exposure of 45 years to 1 $\mu g/m^3$ Cr(VI) to be 6 per 1000 (95% CI: 0.8 to 14). The additive model predicted a slightly lower lifetime risk of 4.4 per 1000 (95% CI: 0.0 to 11). At the OSHA PEL (52 $\mu g/m^3$), the maximum likelihood estimate (MLE) using the linear relative risk model is 253 per 1000 (95% CI: 39 to 456).

Since the completion of the 2002 Environ analysis, individual data for the 2,357 men in the Gibb *et al.* cohort have become available. The new data included cumulative Cr(VI) exposure estimates, smoking information, date of birth, race, date of hire, date of termination, cause of death, and date of the end of follow-up for each individual (Ex. 35–295). The individual data allowed Environ to do several additional analyses that could not be done previously, including assessments based on (1) redefined exposure categories, (2) alternate background reference rates for lung cancer mortality, and (3) Cox proportional hazards modeling (Ex. 33–12). These are discussed below.

In the 2002 analysis, Environ used the same four-group categorization of cumulative exposure reported by Gibb *et al.* and presented in Table VII–1. The individual data allowed Environ to investigate alternate groupings of cumulative exposure categories. Environ presented two alternate groupings with ten cumulative Cr(VI) exposure groups each, six more than reported by Gibb *et al.* and used in the 2002 analysis. One alternative grouping was designed to divide the person-years of follow-up and, therefore, the expected numbers of lung cancers fairly evenly across groups. The other alternative allocated roughly the same number of observed lung cancers to each group. These two alternatives were designed to remedy the uneven distribution of observed and expected cases in the Gibb *et al.* categories, which may have caused parameter estimation problems due to the small number of cases in some groups. The new groupings assigned adequate numbers of observed and expected lung cancer cases to all groups and are presented in Table VII–2.

TABLE VII–2.—DOSE-RESPONSE DATA FROM ENVIRON (2003, EX. 33–12): OBSERVED AND EXPECTED LUNG CANCER DEATHS FOR GIBB COHORT GROUPED BY TEN CUMULATIVE CR(VI) EXPOSURE CATEGORIES

	Cumulative Cr(VI) exposure µg/m³-years)	Mean Cr(VI) exposure (µg/m³-yr)	Person-years	Observed lung cancers	Expected lung cancers	
					Maryland rates	Baltimore rates
Alternative 1: Roughly Equal Observed Cases per Group						
	0–0.151	0.0246	17982	12	10.3	13.37
	0.151–0.686	0.395	9314	12	13.0	16.80
	0.686–2.08	1.25	8694	12	10.3	13.55
	2.08–4.00	2.96	5963	12	7.38	9.42
	4.00–8.32	5.89	5102	12	5.63	7.32
	8.32–18.2	12.4	5829	13	7.09	9.21
	18.2–52	31.1	6679	13	6.83	9.05
	52–182	105	6194	12	5.77	7.73
	182–572	314	4118	12	5.79	7.66
	>572	979	945	12	2.07	2.62
Alternative 2: Roughly Equal Number of Person-Years per Group						
	0–0.052	0.00052	14282	4	5.08	6.63
	0.052–0.273	0.147	6361	11	9.05	11.58
	0.273–0.65	0.455	6278	7	8.71	11.33
	0.65–1.43	0.996	6194	11	7.30	9.58
	1.43–3.12	2.19	6395	12	8.17	10.52
	3.12–6.89	4.59	6207	11	6.90	8.95
	6.89–16.1	10.7	6296	17	7.77	10.05
	16.1–41.6	25.9	6230	12	6.50	8.57
	41.6–1.43	81.5	6287	10	5.56	7.52
	>143	384	6289	27	9.17	11.99
Total			70819.38	122	74.2	96.7

The lower bounds of the ranges are inclusive; the upper bounds are exclusive.

The 2003 Environ analysis also derived expected cases using lung cancer rates from alternative reference populations. In addition to the State of Maryland lung cancer rates that were used by Gibb *et al.*, Environ used age- and race-specific rates from the city of Baltimore, where the plant was located. Baltimore may represent a more appropriate reference population because most of the cohort members resided in Baltimore and Baltimore residents may be more similar to the cohort members than the Maryland or U.S. populations in their co-exposures and lifestyle characteristics, especially smoking habits and urban-related risk factors. On the other hand, Baltimore may not be the appropriate reference population if the elevated lung cancer rates primarily reflect extensive exposure to industrial carcinogens. This could lead to an under representation of relative risk attributable to Cr(VI) exposure.

The 2003 analysis used two externally standardized models, a quadratic relative risk model (model E1 from above, without the age factor) and a quadratic additive risk model (model E3 from above with the additional term $C_2D_i^2$) defined as follows:

E4. $N_i = C_0 * E_i + PY_i * (C_1D_i + C_2D_i^2)$.

The age factor was dropped from model E1 because the individual data obviated the need to rely on the cross-classifications of cumulative exposure. The availability of individual data also allowed a more refined approach to internally standardized modeling than employed in the 2002 assessment. Two Cox proportional hazards models were fit to the individual exposure-response data that incorporated the individual ages at death of all the lung cancer cases. The model forms were:

C1. $h(t;z;D) = h_0(t)*\exp(\beta_1 z + \beta_2 D)$

C2. $h(t;z;D) = h_0(t)*[\exp(\beta_1 z)][1 + \beta_2 D]$

where h is the hazard function, which expresses the age-specific rate of lung cancer among workers, as estimated by the model. In addition, t is age, z is a vector of possible explanatory variables other than cumulative dose, D is cumulative dose, $h_0(t)$ is the baseline hazard function (a function of age only), β_2 is the cumulative dose coefficient, and β_1 is a vector of coefficients for other possible explanatory variables (Ex. 35–57). Cox modeling is an approach that uses the experience of the cohort to estimate an exposure-related effect, irrespective of an external reference population or exposure categorization. Cox models can sometimes eliminate concerns about choosing an appropriate reference population and may be advantageous when the characteristics of the cohort under study are not well matched against reference populations for which age-related background rates have been tabulated. The two forms of the Cox models are consistent with those originally discussed by Cox. Model C1 assumes the lung cancer response is nonlinear with cumulative Cr(VI) exposure, whereas C2 assumes a linear lung cancer response with Cr(VI) exposure.

All externally standardized models provided a good fit to the data ($p \geq 0.40$). The choice of exposure grouping had little effect on the parameter estimates of either model E1 or E4. However, the choice of reference rates had some effect, notably on the "background" parameter, C_0, which was included in the models to adjust for differences in background lung cancer rates between cohort members and the reference population. Such an adjustment was necessary for the Maryland reference population (C_0 was significantly different from its default value, 1), but not for the Baltimore city reference population (C_0 was not significantly different from 1). The inclusion of the C_0 parameter allowed the model to fit the data and yielded a cumulative dose coefficient that reflected the effect of exposure and not the effect of differences in background rates. The model results indicated a relatively consistent cumulative dose coefficient, regardless of reference population. Details about the procedures used to estimate parameters, model fit, lifetable calculations, and confidence intervals

are described in the Environ report (Ex. 33–12, p. 8–9).

The coefficient for cumulative dose in the model ranged from 2.87 to 3.48 per mg/m^3-yr for the relative risk model, E1, and from 0.0061 to 0.0071 per mg/m^3-person-yr for the additive risk model, E4. These coefficients determine the slope of the linear cumulative Cr(VI) exposure-lung cancer response relationship. The cumulative dose coefficients for the relative risk model (E1) were only slightly greater than that obtained from model E1 in the 2002 Environ analysis. For the additive risk model (E4), the dose coefficients were approximately twice the value obtained from model E3 in the 2002 analysis (*i.e.*, 0.0033). In no case did the new analysis suggest that a quadratic model fit the data better than a linear model.

For the internally standardized Cox proportional hazards models, C1 and C2, the other possible explanatory variables considered were cigarette smoking status, race, and calendar year of death. For both models, addition of a term for smoking status significantly improved the fit of the models to the data ($p \leq 0.00001$). The experience with non-linear model C1 indicated that race ($p=0.15$) and year of death ($p=0.4$) were not significant contributors when cumulative dose and smoking status were included in the model. Based on results for model C1, race and year of death were not considered by Environ in the linear model C2. The cumulative dose coefficient, $\beta 2$, was 1.00 for model C1 and 2.68 for model C2. Model C2 provided a slightly better fit to the data than did model C1. A more complete description of the models and variables can be found in the 2003 Environ analysis (Ex. 33–12, p. 10).

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Table VII-3

Environ (2003, Ex. 33-12): Model Predictions of Excess Lung Cancer Deaths per 1000 Workers[a] Exposed to Various Cr(VI) Concentrations, by Model, Reference Population, and Exposure Grouping

Model	Reference Population	Exposure Grouping	Cr(VI) Concentration ($\mu g/m^3$) [95% Confidence Interval]						
			0.25	0.5	1.0	5	10	20	52
Relative Risk Model (E1)	Maryland State	Equal Cases/group	1.9 [0.9-3.6]	3.8 [1.8-7.2]	7.5 [3.7-14]	37 [18-69]	72 [36-132]	137 [57-240]	305 [168-471]
		Equal PYRs/group	2.0 [0.6-4.0]	4.0 [1.3-8.0]	8.0 [2.5-16]	39 [12-77]	76 [25-145]	144 [49-258]	318 [120-500]
	Baltimore City	Equal Cases/group	2.1 [1.0-3.6]	4.3 [1.3-8.0]	8.5 [4.1-14]	42 [20-68]	81 [40-130]	153 [78-237]	334 [186-467]
		Equal PYRs/group	2.3 [1.0-3.9]	4.6 [2.0-7.8]	9.1 [4.0-16]	45 [20-75]	86 [39-142]	163 [76-256]	351 [181-493]
Additive Risk Model (E4)	Maryland State	Equal Cases/group	2.4 [1.0-4.0]	4.7 [2.1-8.0]	9.4 [4.1-16]	46 [20-75]	89 [40-146]	170 [79-268]	373 [189-532]
		Equal PYRs/group	2.1 [0.7-3.7]	4.2 [1.5-7.5]	8.4 [3.0-15]	41 [15-72]	80 [29-137]	152 [58-253]	342 [141-511]
	Baltimore City	Equal Cases/group	2.4 [1.2-4.0]	4.8 [2.4-7.9]	10 [4.7-16]	47 [23-76]	92 [46-145]	174 [91-264]	380 [214-530]
		Equal PYRs/group	2.2 [1.0-3.8]	4.4 [2.0-7.5]	8.8 [3.9-15]	43 [19-72]	84 [38-138]	161 [74-254]	356 [181-513]
Cox Model C1	N/A	N/A	0.66 [0.3-0.9]	1.3 [0.6-1.9]	2.7 [1.3-3.8]	15 [6.7-21]	32 [14-49]	N/A	363 [110-606]
Cox Model C2	N/A	N/A	1.8 [0.7-3.4]	3.5 [1.4-6.8]	7.1 [2.7-14]	35 [13-66]	68 [27-125]	129 [52-229]	290 [128-456]

[a] The workers are assumed to start work at age 20 and continue to work for 45 years, at a constant exposure level.

Table VII–3 shows each model's predictions of excess lifetime lung cancer risk from various occupational exposures. The estimates are very consistent regardless of model, exposure grouping, or reference population. The model that appears to generate results least similar to the others is C1, which yielded one of the higher risk estimates at 52 $\mu g/m^3$, but estimated the lowest risks for exposure levels of 10 $\mu g/m^3$ or lower. The change in magnitude, relative to the other models, is a result of the nonlinearity of this model (the only nonlinear model among the set being considered). Confidence limits for all models, including C1, tend to overlap, suggesting a fair degree of consistency.

The estimates based on the individual data files were slightly greater than

those reported in the previous Environ analysis (Ex. 33–15). For example, the 2003 Environ analysis estimated additional lifetime risk from 45 years of exposure at the OSHA PEL to be between 290 and 380 per 1000, whereas the previous analysis estimated 253 per 1000 (Ex. 33–12, Table 9). This difference may be partly attributed to the availability of individual data, as opposed to data from summary tables, allowing a better definition of exposure categories. Some of the difference may be attributable to slightly different total person-years of follow-up reported by Gibb *et al.* in their summary table (71,994 from Table V, Ex. 31–22–11) and the total person-years accounted for in the individual data files (70,819 from Ex. 295). The reason for this variation in total person-years is unknown.

2. National Institute for Occupational Safety and Health (NIOSH) Risk Assessment

NIOSH (Ex. 33–13) developed a risk assessment from the Gibb cohort. The NIOSH analysis, like the 2003 Environ assessment, used the cohort individual data files to compute cumulative Cr(VI) exposure. However, NIOSH also explored some other exposure-related assumptions. For example, they performed the dose-response analysis with lag times in addition to the 5-year lag used by Environ. NIOSH also analyzed dose-response using as many as 50 exposure categories, although their report presents data in five cumulative Cr(VI) exposure groupings.

NIOSH incorporated information on the cohort smoking behavior in their quantitative assessments. They estimated (packs/day)-years of cumulative smoking for each individual in the cohort, using information from a questionnaire that was administered at the time of each cohort member's date of hire. To estimate cumulative smoking, NIOSH assumed that the cohort members maintained the level of smoking reported in the questionnaire from the age of 18 through the end of follow-up. Individuals with unknown smoking status were assigned a value equal to the average smoking level among all individuals with known smoking levels (presumably including non-smokers). Individuals who were known to smoke but for whom the amount was unknown were assigned a smoking level equal to the average of all smokers.

NIOSH considered six different relative risk models, fit to the data by Poisson regression methods. They did not consider additive risk models. The six relative risk models were externally standardized using age- and race-specific U.S. lung cancer rates. Their background coefficients, C_0, explicitly included smoking, race, and age terms to adjust for differences between the cohort and the reference population. These models are described as follows:

NIOSH1a: $N_i = C_0 * Ei * \exp(C_1 D_i)$
NIOSH1b: $N_i = C_0 * Ei * \exp(C_1 D_i ½)$
NIOSH1c: $N_i = C_0 * Ei * \exp(1 + C_1 D_i + C_2 D_i^2)$
NIOSH1d: $N_i = C_0 * Ei * (1 + D_i)\alpha$
NIOSH1e: $N_i = C_0 * Ei * (1 + C_1 D_i)$
NIOSH1f: $N_i = C_0 * Ei * (1 + C_1 D_i \alpha)$

where the form of the equation has been modified to match the format used in the Environ reports. In addition NIOSH fit Cox proportional hazard models (not specified) to the lung cancer mortality data using the individual cumulative Cr(VI) exposure estimates.

NIOSH reported that the linear relative risk model 1e generally provided a superior fit to the exposure-response data when compared to the various log linear models, 1a-d. Allowing some non-linearity (*e.g.*, model 1f) did not significantly improve the goodness-of-fit, therefore, they considered the linear relative risk model form 1e (analogous to the Environ model E1) to be the most appropriate for determining their lifetime risk calculations. A similar fit could be achieved with a log-linear power model (model 1d) using log-transformed cumulative Cr(VI) and a piece-wise linear specification for the cumulative smoking term.

The dose coefficient (C_1) for the linear relative risk model 1e was estimated by NIOSH to be 1.444 per mg CrO^3/m^3-yr. (Ex. 33–13, Table 4). If the exposures were converted to units of mg Cr(VI)/m^3-yr, the estimated cumulative dose coefficient would be 2.78 (95% CI: 1.04 to 5.44) per mg/m^3-yr. This value is very close to the estimates derived in the Environ 2003 analysis (maximum likelihood estimates ranging from 2.87 to 3.48 for model E1, depending on the exposure grouping and the reference population). Lifetime risk estimates based on the NIOSH-estimated dose coefficient and the Environ lifetable method using 2000 U.S. rates for lung cancer and all cause mortality are shown in Table VII–4. The values are very similar to the estimates predicted by the Environ 2003 analysis (Table VII–3). The small difference may be due to the NIOSH adjustment for smoking in the background coefficient. NIOSH found that excess lifetime risks for a 45-year occupational exposure to Cr(VI) predicted by the best-fitting power model gave very similar risks to the preferred linear relative risk model at TWA Cr(VI) concentrations between 0.52 and 52 µg/m^3 (Ex. 33–13, Table 5). Although NIOSH did not report the results, they stated that Cox modeling produced risk estimates similar to the Poisson regression. The consistency between Cox and Poisson regression modeling is discussed further in section VII.C.4.

Table VII-4

Model Predictions of Additional Lung Cancer Deaths per 1000 Workers[a] Exposed to Various Cr(VI) Concentrations Based on NIOSH-Estimated Parameters

Cr(VI) Concentration (µg/m^3) [95% Confidence Interval]							
0.25	0.5	1.0	2.5	5	10	20	52
1.8 [0.7-3.6]	3.7 [1.4-7.2]	7.3 [2.7-14]	18 [7-35]	36 [14-69]	70 [27-131]	133 [53-238]	297 [130-468]

[a] The workers are assumed to start work at age 20 and continue to work for 45 years, at a constant exposure level.

NIOSH reported a significantly higher dose-response coefficient for nonwhite workers than for white workers. That is, nonwhite workers in the Gibb cohort are estimated to have a higher excess risk of lung cancer than white workers, given equal cumulative exposure to Cr(VI). In contrast, no significant race difference was found in the Cox proportional hazards analysis reported by 2003 Environ.

3. Exponent Risk Assessment

In response to OSHA's Request For Information, Exponent (Ex. 31–18–15–1) prepared an analysis of lung cancer mortality from the Gibb cohort. Like 2003 Environ and NIOSH, the Exponent analysis relied on the individual worker data. Exponent performed their dose-response analyses based on three different sets of exposure categories using two reference populations and 70,808 person-years of follow-up. A total of four analyses were completed, using (1) Maryland reference rates and the four Gibb *et al.* exposure categories; (2) Baltimore reference rates and the four Gibb *et al.* exposure categories; (3) Baltimore reference rates and six exposure groups defined by Exponent; and (4) Baltimore City reference rates and five exposure categories, obtained by removing the highest of the six groups defined by Exponent from the dose-response analysis. A linear relative risk model without a background correction term, C_0, (as was used by Environ and NIOSH) was applied in all of these cases and cumulative exposures were lagged five years (as done by Environ and NIOSH). The analyses showed excess lifetime risk between 6 and 14 per 1000 for workers exposed to 1 μg/m³ Cr(VI) for 45 years.

The analysis using Maryland reference lung cancer rates and the Gibb *et al.* four-category exposure grouping yielded an excess lifetime risk of 14 per 1000. This risk, which is higher than the excess lifetime risk estimates by Environ and NIOSH for the same occupational exposure, probably results from the absence of a background rate coefficient in Exponent's model. As reported in the Environ 2002 and 2003 analyses, the Maryland reference lung cancer rates require a background rate coefficient greater than 1 to achieve the best fit to the exposure-response data. The unadjusted Maryland rates underestimate the cohort's background lung cancer rate, leading to overestimation of the risk attributable to cumulative Cr(VI) exposure.

The two analyses that used Baltimore reference rates and either Exponent's six-category exposure grouping or the Gibb *et al.* four-category grouping both resulted in an excess lifetime risk of 9 per 1000 for workers exposed to 1 μg/m³ Cr(VI) for 45 years. This risk is close to estimates reported by Environ using their relative risk model (E1) and Baltimore reference rates for the same occupational exposure (Table VII–3). The Environ analysis showed that, unlike the Maryland-standardized model discussed above, the Baltimore-standardized models had background rate coefficients very close to 1, the "default" value assumed by the Exponent relative risk model. This suggests that the Baltimore reference rates may more accurately represent the background lung cancer rate for this cohort.

The lowest excess lifetime risk for workers exposed to 1 μg/m³ Cr(VI) for 45 years reported by Exponent, at 6 per 1000, was derived from the analysis that excluded the highest of Exponent's six exposure groups. While this risk value is close to the Environ and NIOSH unit risk estimates, the analysis merits some concern. Exponent eliminated the highest exposure group on the basis that most cumulative exposures in this group were higher than exposures usually found in current workplace conditions. However, eliminating this group could exclude possible long-term exposures (*e.g.*, >15 years) below the current OSHA PEL (52 μg/m³) from the risk analysis. Moreover, no matter what current exposures might be, data on higher cumulative exposures are still relevant for understanding the dose-response relationships.

In addition, the Exponent six category cumulative exposure grouping may have led to an underestimate of the dose effect. The definition of Exponent's six exposure groups was not related to the distribution of cumulative exposure associated with individual person-years, but rather to the distribution of cumulative exposure among the workers at the end of their employment. This division does not result in either a uniform distribution of person-years or observed lung cancer cases among exposure categories. In fact, the six category exposure groupings of both person-years and observed lung cancers were very uneven, with a preponderance of both allocated to the lowest exposure group. This skewed distribution of person-years and observed cases puts most of the power for detecting significant differences from background cancer rates at low exposure levels, where these differences are expected to be small, and reduces the power to detect any significant differences from background at higher exposure concentrations.

Exponent conducted analyses to further explore the dose-response relationship in addition to the assessments described above (Ex. 31–18–1). Of particular interest was an examination of short-term workers' likely impact on the dose-response assessment and an SMR analysis based on peak exposure estimates. A substantial proportion of the Gibb cohort worked less than one year at the Baltimore plant. Inclusion of these workers in the exposure-response assessment could potentially bias the results, if, for example, these workers incurred unrecorded Cr(VI) exposures at other jobs. In brief, Exponent found that excluding these short-term workers would not likely impact the dose-response analysis.

Exponent reported that SMRs for workers with "peak" exposures less than 0.18 mg CrO_3/m³ (0.094 mg Cr(VI)/m³) were not significantly elevated and that this exposure level may represent a "threshold" (i.e., exposure below which the probability of cancer is zero), such that workers exposed to concentrations below the threshold may not have excess cancer risk (Ex. 31–18–1). However, the analysis used peak exposure estimates based on recorded average annual exposures. True peak exposures were unavailable for the Gibb cohort members. The use of the highest recorded average annual Cr(VI) air level as an exposure metric ignores any risk contribution from the duration of exposure. It assumes the same lung cancer risk regardless of whether the worker is exposed at a particular Cr(VI) concentration for one month or ten years. This is clearly inconsistent with the study results.

The validity of the "peak exposure" analysis also suffers from Exponent's problematic definition of exposure categories, which is similar to the six-part grouping used in the dose-response assessments. As with Exponent's cumulative exposure groups, the peak exposure grouping allocates most of the observed cancers and person-years to the lowest exposure groups, reducing the power to detect significant differences from background at more moderate exposure concentrations below 0.094 mg Cr(VI)/m³. The implication that the data indicate a "threshold" at 0.094 mg Cr(VI)/m³ is, therefore, misleading, and not considered a valid analysis for estimating risk of lung cancer to workers exposed to Cr(VI).

4. Summary of Risk Assessments Based on the Gibb Cohort

OSHA finds remarkable consistency among the risk estimates from the

various quantitative analyses of the Gibb cohort. The excess lifetime risks from cumulative Cr(VI) exposure were similar whether the analyses were based on the summary information reported by Gibb *et al.* or on the information provided in the individual data file.

Both Environ and NIOSH determined that linear relative risk models with respect to cumulative exposure generally provided a superior fit to the data when compared to other relative risk models. The Environ 2003 analysis further suggested that a linear additive risk model could adequately describe the observed dose-response data. The risk estimates for NIOSH and Environ's best-fitting models were statistically consistent (compare Tables VI–3 and VI–4).

The choice of reference population had little impact on the risk estimates. NIOSH used the entire U.S. population as the reference, but included adjustment terms for smoking, age and race in its models. The Environ 2003 analysis used both Maryland and Baltimore lung cancer rates, and included a generic background adjustment term. The adjustment was significant in the fitted model when Maryland rates were used for external standardization, but not when Baltimore rates were used. Since no adjustment in the model background term was required to better fit the exposure-response data using Baltimore City lung cancer rates, they may best represent the cohort's true background lung cancer incidence. OSHA considers the inclusion of such adjustment factors, whether specific to smoking, race, and age (as defined by NIOSH), or generic (as defined by Environ), to be appropriate and contribute to accurate risk estimation by helping to correct for confounding risk factors. The internally standardized Cox models, especially the linear Cox model, which also adjusted for smoking yielded risk estimates that were generally consistent with the externally standardized models.

Finally, the number of exposure categories used in the analysis had little impact on the risk estimates. When an appropriate adjustment to the background rates was included, the four exposure groups originally defined by Gibb *et al.* and analyzed in the 2002 Environ report, the six exposure groups defined by Exponent, the two alternate sets of ten exposure categories as defined in the 2003 Environ analysis, and the fifty groups defined and aggregated by NIOSH all gave essentially the same risk estimates. The robustness of the results to various categorizations of cumulative exposure adds to the validity of the risk projections.

Having reviewed the analyses described in this section, OSHA finds that the best estimates of excess lung cancer risk to workers exposed to the current PEL (52 μg Cr(VI)/m^3) for a working lifetime are about 300 to 400 per thousand based on data from the Gibb cohort. The best estimates of excess lung cancer risks to workers exposed to TWA exposure concentrations of 1 μg Cr(VI)/m^3 for a working lifetime range from 7.1 to 9.4 per 1000 with the lowest 95% confidence bound being 2.7, and the highest 95% confidence bound being 16 (Table VII–3). These estimates are consistent with predictions from Environ, NIOSH and Exponent models that applied linear relative and additive risk models based on the full range of cumulative Cr(VI) exposures experienced by the Gibb cohort and used appropriate adjustment terms for the background lung cancer mortality rates.

It is instructive to examine whether the excess lung cancer risk estimated from the mathematical modeling reasonably predicts the risk based on the mortality observed in the Gibb *et al.* study. There were 855 deaths in the Gibb cohort of which 122 were from cancer of the lung (Ex. 31–22–11, Table I). The expected number of lung cancer deaths from the age-, gender-, race-, and calendar year-adjusted reference population in Baltimore was 96.7 (Table VII–2). Therefore, there were about 25 lung cancer deaths (i.e., 122—96.7) presumably attributable to Cr(VI) exposure out of the 855 total deaths, or 29 per 1000 workers (i.e., 25/855 × 1000). If lung cancer were to continue to occur with the same proportionate mortality in this cohort (64 percent of the cohort were still living), their excess lifetime lung cancer risk would be close to three percent.

The mean cumulative exposure for the Gibb cohort was 0.134 mg CrO_3/m^3 - yr with a mean 3.1 years of work (Ex. 31–22–11, Table II). An approximate average Cr(VI) air level of 22.5 μg Cr(VI)/m^3 can be calculated after converting from CrO_3 to Cr(VI). Using the average Cr(VI) air concentration (22.5 μg/m^3), mean exposure duration (3.1 yr), and mean age of hire of 30 years of age (Ex. 31–22–11, Table III), the linear relative risk model E1 (equal PYRs per group, Table VII–3) predicts an excess lifetime lung cancer risk of 14.8 per 1000 (95% CI: 6.97 to 25.1 per 1000) for workers with the mean cumulative exposure of the Gibb cohort. These Cr(VI) levels are below the current PEL for considerably shorter than a full working lifetime.

The model-predicted lung cancer risk is about half the risk calculated from the observed mortality in the Gibb *et al.* study. This is probably due, in part, to the higher cumulative Cr(VI) exposure for the subset of workers who had already died. The mean Cr(VI) exposure of the lung cancer cases was slightly over two-fold higher (i.e., 0.294 mg CrO_3/m^3 - yr) than the cohort as a whole (Ex. 31–22–11, Table II). It also seems likely that the workers who already died of causes other than lung cancer would be older cohort members that may have experienced higher Cr(VI) exposure than the presumably younger cohort members hired more recently and still living. If their mean cumulative Cr(VI) exposure were more like that of the lung cancer cases than the total cohort group, the relative risk model would predict risks close to the three percent excess lung cancer risk derived from the observed mortality data.

D. Quantitative Risk Assessments Based on the Luippold Cohort

As discussed earlier, Luippold *et al.* (Exs. 35–204; 33–10) provided information about the cohort of workers employed in a chromate production plant in Painesville, Ohio. Follow-up for the 482 members of the Luippold cohort started in 1940 and lasted through 1997, with accumulation of person-years for any individual starting one year after the beginning of his first exposure. There were 14,048 total person-years of follow-up for the cohort. The person-years were then divided into five exposure groups that had approximately equal numbers of expected lung cancers in each group. Ohio reference rates were used to compute expected numbers of deaths. White male rates were used because the number of women was small (4 out of 482) and race was known to be white for 241 of 257 members of the cohort who died and for whom death certificates were available. The 1960–64 Ohio rates (the earliest available) were assumed to hold for the time period from 1940 to 1960. Rates from 1990–94 were assumed to hold for the period after 1994. For years between 1960 and 1990, rates from the corresponding five-year summary were used. There were significant dose-related trends for lung cancer SMR as a function of year of hire, duration of employment, and cumulative Cr(VI) exposure. Overall, there was significantly increased SMR for lung cancer deaths of 241 (95% CI: 180 to 317).

TABLE VII.–5—DOSE-RESPONSE DATA FROM LUIPPOLD COHORT AS CITED BY ENVIRON (2002, EX. 33–15): OBSERVED AND EXPECTED NUMBERS OF LUNG CANCER DEATHS GROUPED BY FIVE CUMULATIVE CR(VI) EXPOSURE CATEGORIES

Cumulative Cr(VI) exposure (mg/m^3 – yrs)[a]	Mean Cr(VI) exposure (mg/m^3 – yrs)[a]	Observed lung cancers	Expected lung cancers[b]	Person-years
< 0.20	0.10	3	4.5	2952
0.20 – 0.49	0.36	8	4.4	2369
0.49 – 1.05	0.74	4	4.4	3077
1.05 – 2.70	1.79	16	4.4	3220
2.70 – 27.8	4.81	20	4.3	2482

[a] Note that units mg/m^3 – yrs is 1000 times greater than $\mu g/m^3$ – yrs in data tables for Gibb cohort.
[b] Expected lung cancer deaths derived using Ohio state mortality rates.

Environ conducted a risk assessment based on the cumulative Cr(VI) exposure-lung cancer mortality data from Luippold *et al.* and presented in Table VII–5 (Ex. 33–15). Cumulative Cr(VI) exposures were categorized into five groups with about four expected lung cancer deaths in each group. In the absence of information to the contrary, Environ assumed Luippold *et al.* did not employ any lag time in determining the cumulative exposures. The calculated and expected numbers of lung cancers were derived from Ohio reference rates. Environ applied the relative and additive risk models, E1 and E3, to the data in Table VII–5. Model E1 was applied without the $\exp\{kt_i\}$ term, because no categorization by age was available. Addition of a quadratic term did not improve the fit over that of a linear relative risk model. Model E2 was not applied, because without the $\exp\{kt_i\}$ term model E2 is the same as E1. The background rate parameter, C_0, was assumed to be 1.0 in both models since other values did not significantly improve model fit.

Linear relative and additive risk models fit the Luippold cohort data adequately ($p \geq 0.25$). The maximum likelihood estimates for the Cr(VI) exposure-related parameter, C_1, of the linear relative and additive risk models were 0.88 per mg/m^3 – yr and 0.0014 per mg/m^3 – person-yr, respectively. The C_1 estimates based on the Luippold cohort data were about 2.5-fold lower than the parameter estimates based on the Gibb cohort data. The excess lifetime risk estimate calculated by Environ for a 45-year working-lifetime exposure to 1 μg Cr(VI)/m^3 for both models was 2.2 per 1000 workers (95% confidence intervals from 1.3 to 3.5 per 1000 for the relative risk model and 1.2 to 3.4 per 1000 for the additive risk model) using a lifetable analysis with 1998 U.S. mortality reference rates. These risks were 2.5 to 3-fold lower than the projected risks based on the Gibb data set for equivalent cumulative Cr(VI) exposures.

Crump *et al.* (Exs. 33–15; 35–58; 31–18) also performed an exposure-response analysis from the Painesville data. In a Poisson regression analysis, cumulative exposures were grouped into ten exposure categories with approximately two expected lung cancer deaths in each group. The observed and expected lung cancer deaths by Cr(VI) exposure category are shown in Table VII–6. Ohio reference rates were again used in calculating the expected lung cancer deaths and cumulative exposures were lagged 5 years.

TABLE VII–6.—DOSE-RESPONSE DATA FROM CRUMP *et al.* (EX. 35–58): OBSERVED AND EXPECTED NUMBERS OF LUNG CANCER DEATHS FOR LUIPPOLD COHORT GROUPED BY TEN CUMULATIVE CR(VI) EXPOSURE CATEGORIES

Cumulative Cr(VI) exposure (mg/m^3-yrs)[a]	Mean Cr(VI) exposure (mg/m^3-yrs)[a]	Observed lung cancers	Expected lung cancer[b]	Person-years
0–0.06	0.0098	0	2.09	3112
0.06–0.18	0.11	3	2.19	1546
0.18–0.30	0.23	3	2.21	1031
0.30–0.46	0.38	5	2.13	1130
0.46–0.67	0.56	0	2.22	1257
0.67–1.00	0.80	4	2.23	1431
1.00–1.63	1.25	12	2.23	1493
1.63–2.60	2.10	3	2.18	1291
2.60–4.45	3.27	10	2.18	1248
4.45–29.0	7.55	11	2.12	904

The lower bounds of the ranges are inclusive; the upper bounds are exclusive.
[a] Note that units mg/m^3-yrs is 1000 times greater than $\mu g/m^3$-yrs in data tables for Gibb cohort.
[b] Expected lung cancer deaths derived using Ohio state mortality rates.

The Crump *et al.* analysis used the same linear relative risk and additive risk models as Environ on the individual data categorized into the ten cumulative exposure groups (Ex. 35–58). Tests for systematic departure from linearity were non-significant for both models ($p \geq 0.11$). The cumulative dose coefficient determined by the maximum likelihood method was 0.79 (95% CI: 0.47 to 1.19) per mg/m^3-yr for the relative risk model and 0.0016 (95% CI: 0.00098 to 0.0024) per mg/m^3—person-yr for the relative and additive risk model, respectively. The authors noted that application of the linear models to five and seven exposure groups resulted in no significant difference in dose coefficients, although the data was not presented. The dose coefficients reported by Crump *et al.* were very

similar to those obtained by Environ above, even though different exposure groups were used and the lag for the cumulative exposure calculation was slightly different. The authors noted that the linear models did not fit the exposure data grouped into ten categories very well (goodness-of-fit $p \leq 0.01$) but fit the data much better with seven exposure groups ($p > 0.3$) after eliminating the nonmonotonic (i.e., not progressively increasing with exposure) scatter contributed by the many lower exposure categories where there are few observed and expected cancers. This nonmonotonic pattern is avoided by using more stable exposure groupings with greater number of cancers. The reduction in number of exposure groups did not significantly change the dose coefficient estimates.

The maximum likelihood estimate for the cumulative dose coefficient using the linear Cox regression model (i.e., model C2) was 0.66 (90% CI: 0.11 to 1.21), which was similar to the linear [Poisson regression] relative risk model. When the Cox analysis was restricted to the 197 workers with known smoking status and a smoking variable in the model, the dose coefficient for Cr(VI) was nearly identical to the estimate without controlling for smoking. This led the authors to conclude that "the available smoking data did not suggest that exposure to Cr(VI) was confounded with smoking in this cohort, or that failure to control for smoking had an appreciable effect upon the estimated carcinogenic potency of Cr(VI)" (Ex. 35–58, p.1156).

Crump *et al.* also presented benchmark dose estimates (EC_{10}s) of 52 $\mu g/m^3$ (95 percent lower confidence bound, LEC_{10}, of 37 $\mu g/m^3$) and 49 $\mu g/m^3$ (LEC_{10} of 35 $\mu g/m^3$) for the relative risk and additive risk models, respectively. The EC_{10} is an estimate of the dose associated with a ten percent, or 100 in 1000, risk. The EC_{10} and its LEC_{10} are being considered by the U.S. EPA, under certain circumstances, as a reasonable point of departure for extrapolation modeling below the biologically observable range (Ex. 35–53, p. 3–12 to 3–15). These results are very consistent with those predicted by Environ (Ex. 33–15) for the Luippold *et al.* cohort (*e.g.*, approximately 100 lung cancer cases per 1000 workers from estimated working lifetime at the OSHA PEL of 52 $\mu g/m^3$). There were only minor non-significant changes in benchmark dose estimates when exposure lags were varied from 5 to 20 years using Poisson or Cox linear regression models.

Given the similarity in results, OSHA believes it is reasonable to use the dose coefficients reported by Exponent based on their groupings of the individual cumulative exposure data to estimate excess lifetime risk from the Luippold cohort. Table VII–7 presents the excess risk for a working lifetime exposure to various TWA Cr(VI) levels as predicted by the relative and additive risk models using a lifetable analysis with 2000 U.S. rates for all causes and lung cancer mortality. The maximum likelihood estimates and 95 percent confidence limits from the Luippold cohort indicate that working lifetime exposures to the current Cr(VI) PEL would entail excess lifetime lung cancer risks around 100 per 1000 and that risks of 1.2 to 3.3 per 1000 would be expected from TWA exposures of 1 μg Cr(VI)/m^3 for a working lifetime.

Table VII-7

Model Predictions of Additional Lung Cancer Deaths per 1000 Workers[a] Exposed to Various Concentrations of Cr(VI) Based on the Luippold Cohort and Crump Dose Coefficients

Model	Cr(VI) Concentration ($\mu g/m^3$) [95% Confidence Interval]							
	0.25	0.5	1.0	2.5	5	10	20	52
Relative Risk	0.52 [0.31 –0.79]	1.0 [0.62–1.6]	2.1 [1.2–3.1]	5.2 [3.1 – 7.8]	10 [6.2–15]	21 [12– 31]	41 [21-60]	101 [62 -147]
Additive Risk	0.55 [0.36– 0.82]	1.1 [0.67–1.6]	2.2 [1.3–3.3]	5.5 [3.4 – 8.2]	11 [6.7–16]	22 [13– 32]	43 [27-64]	108 [67 – 155]

[a] The workers are assumed to start work at age 20 and continue to work for 45 years, at a constant exposure level.
Maximum likelihood estimates and 95% confidence intervals are shown.
These estimates were derived from the Environ risk models using the dose coefficients reported in preamble section VII.D. and a lifetable representing 2000 U.S. mortality rates for all causes and lung cancer.

The excess lung cancer risk predicted from the mathematical modeling can be compared with the risk expected based on the actual mortality experience of the Luippold cohort. There were 303 observed deaths in the cohort of which 51 were from cancer of the lung (Ex. 33–10, Table 2). The expected number of lung cancer deaths from the age-, gender-, race-, and calendar year-adjusted reference population from Ohio was 21.2. Therefore, there were about 30 lung cancer deaths (51–21.2) presumably attributable to Cr(VI) exposure out of 303 total deaths, or 98 per 1000 workers ($29.8/303 \times 1000$). If lung cancer were to continue to occur with the same proportionate mortality in this cohort (37 percent of the cohort was still living), their excess lifetime lung cancer risk would be about ten percent.

The mean cumulative exposure for the Luippold cohort was 1.58 mg Cr(VI)/

m^3-yr (Ex. 33–10, Table 1), which is about twenty-three times the mean exposure for the Gibb cohort (i.e., 0.0697 mg Cr(VI)/m^3-yr). Although the mean length of employment of the Luippold cohort was not reported, a crude distribution of the years employed is consistent with an average of about ten years (Ex. 33–10, Table 1). If the cohort were exposed an average ten years then their average Cr(VI) air level would be roughly 158 μg Cr(VI)/m^3 (1.58 × 10 yr÷ 1000 μg/mg). Using this Cr(VI) air concentration (158 μg/m^3), the estimated mean exposure duration (10 yr), and the mean age of hire of 34 years of age (Ex. 33–10, Table 1), the linear relative risk model E1 predicts an excess lifetime lung cancer risk of 74 per 1000 (95% CI: 46 to 110 per 1000). This is slightly lower than the 98 per 1000 excess lung cancer deaths attributable to Cr(VI) determined from the observed study data. The Luippold cohort workers were exposed to mean Cr(VI) levels about three-fold higher than the current PEL for an average duration that was slightly less than a quarter of a full 45 year working lifetime.

As previously explained, it is not surprising that the relative risk model may underpredict the excess risks calculated from study mortality data. The risk model predicts the probability of lung cancer risk in an individual or set of workers, all with the same cumulative Cr(VI) exposure. The excess lung cancer risk calculated from the observed mortality data were for a group of workers with a wide range of Cr(VI) exposures. Like the Gibb study, the lung cancer cases had a mean cumulative Cr(VI) that was twice that of the entire cohort. Therefore, their risk may be somewhat higher than predicted for the cohort as a whole. Since most of the Luippold cohort had died (i.e., 63 percent), the model-derived lung cancer risk based on the mean exposure of the entire Luippold cohort may better predict the mortality-derived excess risk estimate than was the case for the Gibb cohort, which had a lower percentage of deaths (i.e., 36 percent).

Crump *et al.* reported on tests of trend and of excess lung cancer mortality by highest reported monthly TWA Cr(VI) concentration and cumulative Cr(VI) exposure for the workers in the Luippold cohort. The former analysis examined air concentration irrespective of exposure duration, even though there was a significant positive trend for excess lung cancer mortality with duration of employment (Ex. 33–10, Table 3). They found that a statistically significant excess mortality was not observed in workers exposed to less than the current OSHA PEL (i.e., 52 μg/m^3). An analysis of cumulative Cr(VI) exposure found that a statistically significant exposure-related trend in lung cancer mortality only occurred if cumulative Cr(VI) exposure estimates above 1.0 mg/m^3-yr were included. Crump *et al.* acknowledged that their analysis had limited statistical power (i.e., the magnitude of excess mortality needed to achieve statistical significance) to detect increases in excess mortality at the lower cumulative Cr(VI) exposures (Ex. 35–58, p. 1147).

The lack of statistical significance for the subset of 103 workers in the Luippold cohort whose highest monthly TWA exposure was less than the OSHA PEL is readily explained by a further examination of the data. The highest monthly TWA exposures of those workers averaged 27 μg/m^3 for an average duration of 34 months (Ex. 31–18–3, Table 8). Using the dose coefficient from the linear relative risk model based on cumulative exposure fit to the full Luippold data set in a lifetable analysis, where workers were exposed to this Cr(VI) air concentration and duration starting at age 34 (the average starting age for the Luippold cohort), the additional lifetime risk is predicted to be 4.5 per 1000. This means that less than one additional lung cancer case would be projected for the Luippold subcohort of approximately 100 workers whose highest reported eight-hour TWA (i.e., average 27 μg/m^3) was below the PEL using a linear model without a threshold.

Exponent suggested that the lack of a statistically significant increase in lung cancer mortality observed among workers whose reported average monthly TWA Cr(VI) was not above the PEL was evidence of an absence of increased risk at this level (Ex. 31–18–1). This assertion is not supported by the data. As explained above, the Crump *et al.* analysis lacks the statistical power to support this conclusion. Since exposure at the highest reported TWA accounts for almost all of the cumulative exposure experienced by those workers (Ex. 31–18–3, Table 8), the lack of an observed increase in the lung cancer SMR is entirely consistent with a small, but significant, lung cancer risk as predicted by a linear, non-threshold relative risk model.

E. Supporting Quantitative Risk Assessments

In addition to the preferred data sets analyzed above, there are four other cohorts with available data sets for estimation of additional lifetime risk of lung cancer. These are the Mancuso cohort, the Hayes cohort, the Gerin cohort, and the Alexander cohort. Environ (Ex. 33–15) recently did quantitative risk assessments on study data for all but the Hayes cohort. Several years earlier, the K.S. Crump Division (Ex. 13–5) did quantitative assessments on data from the Mancuso and Hayes cohort, under contract with OSHA. The U.S. EPA (Exs. 19–1; 35–52) developed quantitative risk assessments from the Mancuso cohort data for its Integrated Risk Information System (IRIS). The California EPA (Ex. 35–54), Public Citizen Health Research Group (Ex. 1), and the U.S. Air Force Armstrong Laboratory (AFAL) for the Department of Defense (Ex. 35–51) performed assessments from the Mancuso data using the 1984 U.S. EPA risk estimates as their starting point. The U.S. EPA also published a supporting risk assessment based on the Hayes cohort data (Ex. 7–102). Until the cohort studies of Gibb *et al.* and Luippold *et al.* became available, these earlier assessments provided the most current projected cancer risks from airborne exposure to Cr(VI). While the risk estimates from these data sets are associated with a greater degree of uncertainty, it is nevertheless valuable to compare them to the risk estimates from the preferred Gibb and Luippold cohorts. The cohort data sets and the analyses conducted on them are discussed below.

The Mancuso and Hayes cohorts worked at the Painesville and Baltimore chromate production plants, respectively. Even though the entry date requirements, other cohort selection criteria, and the studied site facilities were different, the lung cancer risk estimated from the Hayes data set may not be completely independent from that estimated from the Gibb data set. A similar situation exists between the Mancuso and Luippold data sets. Unlike the Mancuso and Hayes cohorts, the Gerin and Alexander cohorts were not chromate production workers and lung cancer mortality did not show a statistically significant positive trend with cumulative Cr(VI) exposure. Environ performed quantitative assessments on these data sets to determine if the predicted lung cancer risks had statistical precision that was compatible with those estimated from the preferred Gibb and Luippold cohorts.

1. Mancuso Cohort

As described in subsection VII.B.3, the Mancuso cohort was initially defined in 1975 and updated in 1997. The cohort members were hired between 1931 and 1937 and worked at the same Painesville facility as the Luippold cohort workers. However,

there was no overlap between the two cohorts since all Luippold cohort workers were hired after 1939. The quantitative risk assessment by Environ used data reported in the 1997 update (Ex. 23, Table XII) in which lung cancer deaths and person-years of follow-up were classified into four groups of cumulative exposure to soluble chromium, assumed to represent Cr(VI) (Ex. 33–15). The mortality data and person-years were further broken down by age of death in five year increments starting with age interval 40 to 44 years and going up to >75 years. However, no expected numbers of lung cancers were computed, either for the cohort as a whole or for specific groups of person-years. Environ used two methods for dealing with the lack of expected numbers in order to complete the risk assessment based on this cohort.

In the first method, Environ used the recorded median age and year of entry into the cohort to estimate the calendar years that corresponded to the middle of the age categories for which expected numbers of lung cancers were needed. Data in the Mancuso study indicated that the median age at entry into the cohort was somewhere between 25 and 29 years and that the median year of entry into the cohort was in 1933 or 1934 (Ex. 23). Person-years of observation for the 40–44 age category would have been centered around 1948–49 (i.e., 15 years after 1933–34, where 15 is the difference between the age group under consideration and the median age at entry into the cohort, equal to 40–25 or 44–29). Similar calculations were made for the other age categories. Expected numbers were then derived from the U.S. lung cancer mortality rates for years as close to the target years as could be obtained.

The exposure-response data with the resulting expected number of lung cancer deaths are reported in Table 3 of the 2002 Environ report (Ex. 33–15, p. 39). The mean cumulative exposures to soluble Cr(VI) were assumed to be equal to the midpoints of the tabulated ranges. No lag was assumed for calculating the cumulative exposures. Environ applied three externally standardized models (see models E1–E3 in subsection VII.C.1) to these data. Unlike other data sets modeled by Environ, the age-related parameter k for the Mancuso data set was estimated to be different from 0, so that models E1 and E2 had different dose coefficients (Ex. 33–15, Table 6, p. 42). The quadratic term (i.e., C_2 in model E1) did not significantly improve model fit, so E1 was linear with respect to cumulative exposure.

Since the expected numbers of lung cancers for the Mancuso cohort could only be approximated, Environ also applied a set of internally-standardized models that did not require estimation of expected number of lung cancers to the exposure-response data (Ex. 33–15, p. 24–25). While both externally- and internally-standardized models provided adequate fit to the data ($p \geq 0.13$), the AIC procedure indicated that model E2, the linear relative risk model with an age-dependent exposure term, provided a superior fit over the other models. The next best fitting models, E1 and I2, presented other problems. Model E1 estimated risk predictions that were apparent outliers and the confidence intervals around risk predictions from model I2 were unusually wide (Ex. 33–15, Table 8, p. 43). Further explanation for the inherent instability of these models can be found in the 2002 Environ report (Ex. 33–15, p. 28–29).

The excess risk of lung cancer from a working lifetime exposure to Cr(VI) at the current OSHA PEL using the preferred model E2 is 293 per 1000 workers (95% CI: 188 to 403). The maximum likelihood estimate from working lifetime exposure to 1.0 $\mu g/m^3$ Cr(VI) is 7.0 per 1000 workers (95% CI: 4.1 to 11 per 1000). These estimates are close to those predicted from the Gibb cohort but are higher than predicted from the Luippold cohort. This result indicates that the non-overlapping Painesville worker cohorts (i.e., Mancuso and Luippold cohorts) probably generate independent estimates of risk, even though they were drawn from the same plant.

There are uncertainties associated with both the exposure estimates and the estimates of expected numbers of lung cancer deaths for the 1997 Mancuso data set. The estimates of exposure were derived from a single set of measurements obtained in 1949 (Ex. 7–98). Although little prior air monitoring was available, it is thought that the 1949 air levels probably understate the Cr(VI) concentrations in the plant during some of the 1930s and much of the 1940s when chromate production was high to support the war. The sampling methodology used by Bourne and Yee only measured soluble Cr(VI), but it is believed that the chromate production process employed at the Painesville plant in these early years yielded slightly soluble and insoluble Cr(VI) compounds that would not be fully accounted for in the sampling results (Ex. 35–61). This would imply that risks would be overestimated by use of concentration estimates that were biased low. However, it is possible that the 1949 measurements may not have underestimated the Cr(VI) air levels in the early 1930s prior to the high production years. Some older cohort members were also undoubtedly exposed to less Cr(VI) in the 1950s than measured in 1949 survey.

Another uncertainty in the risk assessment for the Mancuso cohort is associated with the post-hoc estimation of expected numbers of lung cancer deaths. The expected lung cancers were derived based on approximate summaries of the ages and assumed start times of the cohort members. Several assumptions were dictated by reliance on the published groupings of results (*e.g.*, ages at entry, calendar year of entry, age at end of follow-up, etc.) as well as by the particular choices for reference mortality rates (*e.g.*, U.S. rates, in particular years close to the approximated time at which the person-years were accrued). Since the validity of these assumptions could not be tested, the estimates of expected numbers of lung cancer deaths are uncertain.

There is also a potential healthy worker survivor effect in the Mancuso cohort. The cohort was identified as workers first hired in the 1930s based on employment records surveyed in the late 1940s (Ex. 2–16). The historical company files in this time period were believed to be sparse and more likely to only identify employees still working at the plant in the 1940s (Ex. 33–10). If there was a sizable number of unidentified short-term workers who were hired but left the plant in the 1930s or who may have died before 1940 prior to systematic death registration, then there may have been a selection bias (i.e., healthy worker survivor effect) toward longer-term, healthier individuals (Ex. 35–60). Since the mortality of these long-term "survivors" is often more strongly represented in the higher cumulative exposures, it can negatively confound the exposure-response and lead to an underestimation of risk, particularly to shorter-term workers (Ex. 35–63). This may be an issue with the Mancuso cohort, although the magnitude of the potential underestimation is unclear.

Several earlier quantitative risk assessments were done on cohort data presented in the 1975 Mancuso report (Ex. 7–11). These assessments did not have access to the 20 additional years of follow-up nor did they have age-grouped lung cancer mortality stratified by cumulative *soluble chromium* (presumed Cr(VI)) exposure), which was presented later in the 1997 update. Instead, age-grouped lung cancer mortality was stratified by cumulative exposure to *total chromium* that

included not only carcinogenic Cr(VI) but substantial amounts of non-carcinogenic Cr(III).

The 1995 risk analysis by K.S. Crump Division, under contract with OSHA, estimated cumulative Cr(VI) exposures by multiplying cumulative total chromium exposure by an adjustment factor of 0.4 (Ex. 13–5). This factor is roughly the average contribution of soluble chromium to the total chromium exposure levels measured across departments in the Painesville plant by Bourne and Yee in 1949 (Ex. 7–98). The K.S. Crump Division used the lung cancer mortality data cross-classified by the eight exposure categories and three age groups reported in Table IX of the 1975 Mancuso report (Ex. 7–11). They estimated the expected number of lung cancer deaths in a manner similar to the Environ assessments in 2002. The median age at entry for the cohort was estimated to be 28.5 years from the 1975 Mancuso study with an estimated median start date of 1934. Average values for cumulative exposure in each group were estimated by the arithmetic mean of the endpoints defining the group.

An externally standardized linear relative risk model was used to fit the exposure-response data. A sensitivity analysis was used to examine the impact of different average cumulative exposure estimates to represent the highest exposure group (>3.0 mg-yr/m^3) since an arithmetic average could not be calculated for this category. The maximum likelihood estimates for the dose coefficient were relatively constant over a wide range of assumed average exposures. However, the best fit occurred when the high-exposure group was excluded from the analysis (p=0.49). This was because the lung cancer mortality ratios observed for workers with the highest cumulative chromium exposure in the Mancuso data set tended to be lower than predicted by linear projections based on the lung cancer mortality data from workers exposed to lower cumulative exposures. The excess lung cancer risks for a working lifetime at the current OSHA PEL (52 µg/m^3) for Cr(VI) range from 246 to 342 per 1000 workers using the different assumptions about the highest exposure group (Ex. 13–5, Table 8). The excess risk estimates from a working lifetime exposures to 0.5 µg/m^3 Cr(VI) ranged from 2.9 to 4.4 per 1000 workers. This was similar to the risk estimated by Environ using the more updated Mancuso data set.

Like Environ, the K.S. Crump Division explored another method of Poisson regression that internally controlled for age, and which consequently alleviated the need to estimate background rates from an external control population. The dose coefficients estimated for the internally standardized linear relative risk model were similar to those from the externally controlled model. However, sensitivity analysis indicated that the internally standardized model may lead to less stable risk estimates, in that relatively minor changes in average exposure assumptions led to bigger changes in the risk estimates.

The U.S. EPA also used exposure-response data presented in Table IX of the 1975 Mancuso report (Ex. 7–11) as the primary data source for calculating its unit risk estimate . The unit risk refers to an incremental lifetime cancer risk over background occurring in a hypothetical population in which all individuals are exposed continuously throughout life to a concentration of 1 µg Cr(VI)/m^3 in the air that they breathe. Like the K.S. Crump Division, the EPA relied on the observed lung cancer deaths cross-classified by age group and cumulative exposure to total chromium. However, rather than estimate the year of cohort death based on age at entry into the study, the EPA chose to determine expected number of lung cancers for the entire cohort, regardless of age at death, using lung cancer mortality statistics for 1964. They estimated that a large proportion of lung cancer deaths in the cohort probably occurred around that year.

The U.S. EPA assessment did not adjust the total cumulative chromium exposure estimates of Mancuso for the contribution of Cr(VI). While the EPA acknowledged that the resulting overestimation of dose would likely lead to an underestimation of risk, they judged that this would be potentially balanced by two factors that tend to overestimate the risk of lung cancer. One factor was the likelihood that the airborne Cr(VI) levels in the 1930s and 1940s were higher than measured by Bourne and Yee in 1949, as mentioned previously. EPA also suggested the possibility that the Mancuso cohort may have smoked more than the general population so that the expected numbers of lung cancer deaths associated with Cr(VI) exposure would be low and the relative risk overestimated for the cohort.

The 1984 U.S. EPA assessment employed an exposure-dependent multistage model of additive risk to fit the 1975 Mancuso cohort data that relied on average chromium exposure, rather than the cumulative workplace exposure (Ex. 19–1). In their review of the U.S. EPA assessment, the K.S. Crump Division pointed out potential flaws in the EPA conversion of cumulative workplace exposure to their "continuous exposure equivalent" that resulted in high average chromium exposure estimates and a correspondingly low unit risk (Ex. 13–5, p. 19–21). The U.S. EPA determined that the maximum likelihood estimate of additional lung cancer risk associated with continuous lifetime exposure to 1 µg/m^3 of Cr(VI) was 0.012 (i.e., 12 per 1000). More recently, the EPA corrected its dose conversion for the Mancuso cohort which yielded a higher unit risk estimate of 0.016 per µg Cr(VI)/m^3 (Ex. 35–52).

In 1985, the California Department of Health Services (CDHS) estimated a cancer potency factor for Cr(VI) in support of its Toxic Air Contaminants Program (Ex. 35–54, p. 210–215). They estimated the relative lung cancer risks and continuous total chromium exposure equivalents for the 1975 Mancuso data set using the same assumptions and procedures as the 1984 EPA assessment. An average relative risk and average total chromium exposure level, weighted by the person-years per age and exposure category, were calculated for all groups combined. The average total chromium exposure level was multiplied by one-seventh (0.142) as an assumed adjustment for the fraction of total chromium present as Cr(VI). A linear relative risk model was then used to calculate a "crude" approximation of the excess risk from continuous exposure to 1 µg/m^3 of Cr(VI) for a lifetime. The CDHS chose the 95 percent upper confidence limit of 0.15 per µg Cr(VI)/m^3 as their cancer potency factor which is about an order of magnitude greater than the EPA unit risk estimate.

The Public Citizen Health Research Group (PCHRG) attempted to estimate the magnitude of lung cancer risks associated with occupational exposure to Cr(VI) from the 1984 U.S. EPA unit risk for continuous lifetime exposure (Ex. 1). They reported that the excess lung cancer risk from a working lifetime exposure to Cr(VI) at the OSHA PEL (52 µg/m^3) was 220 per 1000 workers. As described in the 1995 report by K.S. Crump Division (Ex. 13–5, p. 27–29), there were several errors in the PCHRG analysis and the correctly calculated excess occupational risk at the OSHA PEL using the EPA unit risk method is 80 cases per 1000 workers. This risk is lower than the estimate from Environ and the K.S. Crump Division, probably as a result of the EPA conversion of occupational cumulative chromium exposure to a continuous average Cr(VI) exposure for an individual lifetime.

The U.S. Air Force Armstrong Laboratory (AFAL) estimated lung cancer risks to U.S. Navy workers from Cr(VI) exposures as a result of welding, abrasive blasting, spray painting, and other operations (Ex. 35–51). They used a cancer potency factor of 41 per mg Cr(VI)/kg-day derived from the 1984 EPA unit risk adjusted for an average breathing rate of 20 m^3/day and body weight of 70 kg. They also reduced their measured airborne Cr(VI) dust concentrations by an assumed respirable fraction of 0.23. The estimated excess lifetime risk from a 45-year occupational exposure to an eight hour TWA 0.5 µg/m^3 using the AFAL methodology and assumptions is about 0.2 per 1000 workers. This is lower than the Environ and K.S Crump Group estimates due to the lower EPA potency factor and the added adjustment for the respirable fraction.

OSHA believes that the Environ quantitative risk assessment is the most credible analysis from the Mancuso cohort. It relied on the updated cohort mortality data and cumulative exposure estimates derived directly from air measurements of soluble chromium. The other assessments used older cohort mortality data with fewer years of follow-up and more problematic exposure estimates and calculations.

2. Hayes Cohort

The K.S. Crump Division (Ex. 13–5) and Gibb *et al.* (Ex. 7–102) assessed risk based on the exposure-response data reported in Table IV by Braver *et al.* (Ex. 7–17) for the cohort studied by Hayes *et al.* (Ex. 7–14). The Hayes cohort overlapped with the Gibb cohort. The Hayes cohort included 734 members, not part of the Gibb cohort, who worked at an older facility from 1945 to 1950 but did not work at the newer production facility built in August 1950. The Hayes cohort excluded 990 members of the Gibb cohort who worked less than 90 days in the new production facility after August 1950. As noted in section VII.B.4, Braver *et al.* derived a single cumulative soluble Cr(VI) exposure estimate for each of four subcohorts of chromate production workers categorized by duration of employment and year of hire by Hayes *et al.* Thus, exposures were not determined for individual workers using a more comprehensive job exposure matrix procedure, as was done for the Gibb and Luippold cohorts. In addition, the exposures were estimated from air monitoring conducted only during the first five of the fifteen years the plant was in operation. Unlike the Mancuso cohort, Hayes *et al.* did not stratify the observed lung cancer deaths by age group. The expected number of lung cancer deaths for each subcohort was based on the mortality statistics from Baltimore.

The K.S. Crump Division applied the externally standardized linear relative risk approach to fit the exposure-response data (Ex. 13–5). The maximum likelihood estimate for the dose coefficient (*e.g.*, projected linear slope of the Cr(VI) exposure-response curve) was 0.75 per mg Cr(VI)/m^3-yr with a 90% confidence bound of between 0.45 and 1.1 per mg Cr(VI)/m^3-yr. These confidence bounds are consistent with the dose coefficient estimate obtained from modeling the Luippold cohort data (0.83, 95% CI: 0.55 to 1.2) but lower than that from the Gibb cohort data (3.5, 95% CI: 1.5 to 6.0). The later result indicates that the two Baltimore chromate production cohorts (i.e., Hayes and Gibb cohorts) probably generate independent estimates of risk, even though they were drawn from facilities at the same site for overlapping periods of time. The linear relative risk model fit the Hayes cohort data well (p=0.50). The K.S. Crump Division predicted the excess risk from occupational exposure to Cr(VI) for a 45 year working lifetime at the OSHA PEL (52 µg/m^3) to be 88 lung cancer cases per 1000 workers (95% CI: 61 to 141). For 1 µg/m^3, about 2 excess lung cancer deaths per 1000 (95% CI: 1.2 to 3.0) were predicted for the same duration of occupational exposure. These estimates are somewhat lower than the corresponding estimates based on the Gibb cohort data, probably because of the rather high average soluble Cr(VI) level (218 µg/m^3) assumed by Braver *et al.* for plant workers throughout the 1950s. If these assumed air levels led to an overestimate of worker exposure, the resulting risks would be underestimated.

Gibb *et al.* provided a risk assessment for the U.S. EPA of the same Braver exposure-response data used by the K.S. Crump Division (Ex. 7–102). In order to determine the EPA unit risk, the cumulative occupational exposures were converted to average lifetime concentration (as discussed in section VII.E.2) and an average age of 55 was assumed at the end of follow-up for members of the Hayes cohort. Gibb *et al.* used the additive risk model E3 with the default value of 1 for C_0, to fit the data. They reported that the maximum likelihood estimate for the dose coefficient was 0.13 per mg/m^3-yr and it yields a unit risk similar to that derived by the EPA from the 1975 Mancuso cohort (Ex. 19–1). Since the excess lung cancer risk from lifetime occupational exposure to Cr(VI) at the OSHA PEL was 80 cases per 1000 workers based on the EPA unit risk from the Mancuso cohort, a similar occupational risk estimate is likely from the Gibb *et al.* unit risk based on the Hayes cohort. This would be consistent with the occupational risk (*e.g.*, 88 cases per 1000 workers) at the OSHA PEL projected from the assessments of the K.S. Crump Division.

3. Gerin Cohort

Environ (Ex. 33–15) did a quantitative assessment of the observed and expected lung cancer deaths in stainless steel welders classified into four cumulative Cr(VI) exposure groups reported in Tables 2 and 3 of Gerin *et al.* (Ex. 7–120). The lung cancer data come from a large combined multi-center welding study in which a statistically significant excess lung cancer risk was observed for the whole cohort and non-statistically significant elevated lung cancer mortality was found for the stainless steel welder subcohorts (Ex. 7–114). A positive relationship with time since first exposure was also observed for the stainless steel welders (the type of welding with the highest exposure to Cr(VI)) but not with duration of employment.

The exposure-response data from the Gerin study was only presented for those stainless steel welders with at least five years employment. Workers were divided into "ever stainless steel welders" and "predominantly stainless steel welders" groups. The latter group were persons known to have had extended time welding stainless steel only or to have been employed by a company that predominantly worked stainless steel. As mentioned in section VII.B.5, the cumulative exposure estimates were not based on Cr(VI) air levels specifically measured in the cohort workers, and therefore are subject to greater uncertainty than exposure estimates from the chromate production cohort studies. Environ restricted their analysis to the "ever stainless steel welders" since that subcohort had the greater number of eligible subjects and person-years of follow-up, especially in the important lower cumulative exposure ranges. The person-years, observed numbers of lung cancers, and expected numbers of lung cancers were computed starting 20 years after the start of employment. Gerin *et al.* provided exposure-response data on welders with individual work histories (about two-thirds of the workers) as well as the entire subcohort. Regardless of subcohort examined, there was no obvious indication of a Cr(VI) exposure-related effect on lung cancer mortality. This may be explained by the

uncertainties in the exposure estimates and presence of co-exposures discussed in section VII.B.5.

Environ used their externally standardized models, E1 to E3, to fit the data (Ex. 33–15). They assumed that the cumulative Cr(VI) exposure for the workers was at the midpoint of the reported range. A value of 2.5 mg/m^3-yr was assumed for the highest exposure group (*e.g.*, >0.5 mg/m^3-yr), since Gerin *et al.* cited it as the mean value for the group, which they noted to also include the "predominantly stainless steel welders". All models fit the data adequately (p>0.28) with dose coefficients considerably lower than for the Gibb or Luippold cohorts (Ex. 33–15, Table 6). In fact, the maximum likelihood estimates for the dose coefficients were not statistically different from 0 at the p=0.05 significance level, which would be expected when there is no exposure-related trend.

Environ chose the linear relative risk model, E2, as the best fitting model based on the AIC value. The projected excess risk of lung cancer from a working lifetime exposure to Cr(VI) at the current OSHA PEL using the preferred model E2 was 46 (95% CI: 0 to 130) cases per 1000 workers. The maximum likelihood estimates of excess risk from working lifetime exposure to 1.0 µg Cr(VI)/m^3 was 0.9 (95% CI: 0 to 2.8) cases per 1000 workers, respectively. The rather large 95 percent confidence interval around the maximum likelihood estimate reflects the greater statistical uncertainty associated with risk estimates from the Gerin cohort. The confidence interval overlaps that for equivalent risk estimates from the Luippold cohort but not the Gibb cohort.

4. Alexander Cohort

Environ (Ex. 33–15) did a quantitative assessment of the observed and expected lung cancer incidence in aerospace workers exposed to Cr(VI) classified into four cumulative chromate exposure groups, reported in Table 4 of Alexander *et al.* (Ex. 31–16–3). The lung cancer data come from a retrospective study with a small number (15) of observed lung cancers in a young cohort (median age of 42 years at end of follow-up) with a relatively short follow-up period (median nine years per member). The authors stated that they derived "estimates of exposure to chromium [VI]" based on the TWA measurements, but later on referred to "the index of cumulative total *chromate* exposure (italics added) reported as µg/m^3 chromate TWA-years" (Ex. 31–16–3, p. 1254). For their analysis, Environ assumed that the cumulative exposures were expressed in µg/m^3-yr of Cr(VI), rather than chromate (CrO_4^{-2}) or chromic acid (CrO_3).

Alexander *et al.* grouped the lung cancer data by cumulative exposure with and without a ten year lag period (Ex. 31–16–3). They found no statistically significant elevation in lung cancer incidence among the chromate-exposed workers or clear trend with cumulative chromate exposure. Environ used the externally standardized linear relative risk model to fit the unlagged data (Ex. 33–15). The additional risk model, E3, could not be applied because no person-years of observation were presented by Alexander *et al.* Environ assumed workers were exposed to a cumulative Cr(VI) exposure at the midpoint of the reported ranges. For the open-ended high exposure category, Environ assumed a cumulative exposure 1.5 times greater than the lower limit of 0.18 mg/m^3 - yr. The model did not fit the data particularly well (p=0.04) and the dose coefficient was considered to be 0 since positive values did not significantly improve the fit. This is not surprising considering the lack of a positive trend between lung cancer incidence and cumulative Cr(VI) exposure for this cohort. Possible reasons for the lack of a positive association between Cr(VI) exposure and lung cancer incidence in this cohort were previously discussed in section VII.B.6.

The best estimate of excess risk of lung cancer from the Alexander cohort was 0 for all exposures to Cr(VI) based on the default dose coefficient. The upper 95 percent confidence bound on the risk was estimated to be 212 cases per 1000 workers from a working lifetime exposure to Cr(VI) at the current OSHA PEL. The upper 95 percent confidence bound on risk from working lifetime exposure to 1.0 mg Cr(VI)/m^3 is 4.8 cases per 1000 workers. The confidence intervals around the risk estimates from the Alexander cohort are greater than those from the Gerin cohort reflecting greater statistical uncertainty. However, the 95 percent confidence intervals for the risk estimates from the Alexander cohort overlap those for equivalent risk estimates from both the Luippold and Gibb cohorts.

If the cumulative exposures from Alexander *et al.* are assumed to be cumulative chromate (CrO_4^{-2}) estimates, then exposures in terms of Cr(VI) would be calculated by dividing by 0.45. As a result, the upper confidence bound on risk would be higher by 1/.45 = 2.2-fold, which would also be statistically consistent with the risk estimates based on the Gibb and Luippold data sets.

F. Summary of Risk Estimates Based on Gibb, Luippold, and Supporting Cohorts

OSHA believes that the best estimates of excess lifetime lung cancer risks are derived from the Gibb and Luippold cohorts. These two cohorts have accumulated a substantial number of lung cancer deaths that were extensively examined in terms of cumulative Cr(VI) exposure. Cohort exposures were reconstructed from air measurements and job histories over three or four decades. The linear relative risk model adequately fitted the Gibb and Luippold data sets, as well as several other supporting data sets. Environ and NIOSH explored a variety of nonlinear dose-response forms, but none provided a statistically significant improvement over the linear relative risk model.

The maximum likelihood estimates from a linear relative risk model fitted to the Gibb data are three-to five-fold higher than estimates based on the Luippold data at equivalent cumulative Cr(VI) exposures and the confidence limits around the projected risks from the two data sets do not overlap. This indicates that the maximum likelihood estimates derived from one data set are unlikely to describe the lung cancer mortality observed in the other data set. Despite this statistical inconsistency between the risk estimates, the differences between them are not unreasonably great given that the cohorts worked in different chromate production facilities and the potential uncertainties involved in estimating cancer risk from the data (see section VII.G). Since the analyses based on these two cohorts are each of high quality and their projected risks are reasonably close (*e.g.*, well within an order of magnitude), OSHA believes the excess lifetime risk of lung cancer from occupational exposure to Cr(VI) is best represented by the range of risks that lie between maximum likelihood estimates of the Gibb and Luippold data sets.

TABLE VII–8.—OSHA ESTIMATES OF EXCESS LUNG CANCER CASES PER 1000 WORKERS[a] EXPOSED TO VARIOUS EIGHT HOUR TWA CR(VI) WITH 95 PERCENT CONFIDENCE INTERVAL COMPARISONS BY COHORT

Cr(VI) (μg/m³)	Best estimates of risk[b]	95% confidence interval on risk estimates by cohort[c]					
		Featured cohorts		Supporting cohorts			
		Gibb	Luippold	Mancuso	Hayes	Guerin	Alexander
0.25	0.52–2.3	1.0–3.9	0.31–0.79	1.0–2.7	0.31–0.75	0.0–0.7	0.0–1.2
0.5	1.0–4.6	2.0–7.8	0.62–1.6	2.0–5.4	0.62–1.5	0.0–1.4	0.0–2.4
1.0	2.1–9.1	4.0–16	1.2–3.1	4.1–11	1.2–3.0	0.0–2.8	0.0–4.8
2.5	5.2–23	10–37	3.1–7.8	10–27	3.1–7.5	0.0–6.9	0.0–12
5.0	10–45	20–75	6.2–15	20–52	6.1–15	0.0–14	0.0–24
10	21–86	39–142	12–31	n/a	12–30	0.0–29	0.0–50
20	41–163	76–256	21–60	n/a	24–51	0.0–54	0.0–91
52	101–351	181–493	62–147	188–403	61–141	0.0–130	0.0–212

[a] The workers are assumed to start work at age 20 and continue to work for 45 years, at a constant exposure level. All estimates were recalculated using year 2000 U.S. reference rates, all races, both sexes, for lung cancer and all causes, except for those from Mancuso, for which 1998 rates were used.

[b] OSHA preliminarily finds that the estimates of risk best supported by the scientific evidence are the ranges bounded by the maximum likelihood estimates from the linear relative risk models presented in Table VII–3 (Baltimore reference population/exposure grouping with equal person-years) for the Gibb cohort and Table VII–7 for the Luippold cohort.

[c] The confidence intervals for the Gibb and Luippold cohorts are from Tables VII–3 and VII–7. The confidence intervals for the Mancuso, Guerin and Alexander cohorts are derived from parameters reported by Environ (2002, Ex. 33–15). All are from the best fitting linear relative risk models and are 95% confidence intervals. The confidence interval for the Hayes cohort was calculated from the 90 percent confidence interval on the dose coefficient for the linear relative risk model reported by the K.S. Crump Division (1995, Ex. 13–5).

OSHA's best estimates of excess lung cancer cases from a 45-year working lifetime exposure to Cr(VI) are presented in Table VII–8. This range of projected risks lie between the maximum likelihood estimates derived from the Gibb and Luippold data sets. As previously discussed, several acceptable assessments of the Gibb data set were performed, with similar results. The 2003 Environ model E1, applying the Baltimore City reference population and ten exposure categories based on a roughly equal number of person-years per group, was selected to represent the range of best risk estimates derived from the Gibb cohort, in part because this assessment employed an approach most consistent with the exposure grouping applied in the Luippold analysis (see Table VII–7). To characterize the statistical uncertainty of OSHA's risk estimates, Table VII–8 also presents the 95% confidence limits associated with the maximum likelihood risk estimates from the Gibb cohort and the Luippold cohort. The confidence interval on the risk estimates from the Luippold data set is smaller (i.e., just over a two-fold range) than those for the Gibb data set (i.e., about a 3.5-fold range) but the Gibb cohort is larger. Therefore, it appears reasonable to consider both analyses jointly in providing estimates of lung cancer risk.

OSHA finds that the most likely lifetime excess risk at the current PEL of 52 μg/m³ Cr(VI) lies between 101 per 1000 and 351 per 1000, as shown in Table VII–8. That is, OSHA predicts that between 101 and 351 of 1000 workers occupationally exposed for 45 years at the current PEL would develop lung cancer as a result of their exposure. The wider range of 62 per 1000 (lower 95% confidence bound, Luippold cohort) to 493 per 1000 (upper 95% confidence bound, Gibb cohort) illustrates the range of risks considered statistically plausible, based on these cohorts and, thus, represents the statistical uncertainty in the estimates of lung cancer risk. This range of risks roughly falls proportionally with exposure so that estimates at 5 μg/m³ are about 10 to 45 cases per 1000 workers and estimates at 0.5 μg/m³ are about 1 to 4.5 cases per 1000 workers.

The 95 percent confidence limits on estimates of risk for the four supporting cohort data sets are also presented in Table VII–8. As discussed previously, the exposure-response data from supporting cohorts are not as strong as those from the two featured cohorts. The cumulative Cr(VI) exposure reconstructions in these data sets were based on more limited air measurements and were frequently not linked to cohort workers on an individual basis. Some of the cohort data sets were weaker in terms of either number of workers, length of follow-up, documented mortality data, and possibility of co-exposures or a healthy worker survivor effect. These features may have introduced bias into the estimates of risk determined from the studies. However, observed lung cancers were grouped across multiple exposure groups in these more problematic cohorts that allowed quantitative assessments to be done and compared against the stronger Gibb and Luippold cohorts.

OSHA believes the supplemental assessments support the range of projected excess lung cancer risks from the Gibb and Luippold cohorts. This is illustrated by the 95 percent confidence intervals shown in Table VII–8. The confidence interval encompasses those risk estimates that are consistent with the cohort data to a certainty of 95 percent. The confidence intervals tend to be smaller for the larger data sets and better model fits. OSHA's range of best risk estimates for a given occupational Cr(VI) exposure overlap the 95 percent confidence bands for each of the four supporting cohorts. This indicates that the range of best estimates includes risks with a statistical precision that is compatible with all the exposure-response data sets, including the smaller Gerin and Alexander cohorts where the lung cancers did not show a clear positive trend with cumulative Cr(VI) exposure.

The 95 percent confidence intervals from the four supporting cohorts overlap those of either the Gibb or Luippold cohorts (or both). The confidence intervals for estimates of the Mancuso cohort overlap with those of the Gibb cohort but are higher than those of the Luippold cohort. The risks projected from the Mancuso data set are likely overestimated because they depend on air monitoring conducted near the end of the study period when exposures were likely lower and because the sampling method only captured highly soluble Cr(VI) compounds. The Mancuso cohort was also probably exposed to significant

amounts of the more potent slightly soluble and insoluble chromates (*e.g.*, calcium chromate). The relative potency of Cr(VI) compounds is further discussed in section VII.G.4. The confidence intervals for estimates from the Hayes cohort overlap the Luippold cohort but are lower than those of the Gibb cohort. The risks projected from the Hayes cohort may be low because the cumulative exposure estimates rely on air monitoring near the beginning of the study period when Cr(VI) levels were likely higher. The confidence intervals for estimates from the Gerin cohort also overlap those from the Luippold but not the Gibb cohort. The confidence intervals for estimates from the Alexander cohort overlap those from both featured cohorts.

While there is statistical consistency between the range of best risk estimates based on the primary studies and those estimated from the supporting data sets, the risk analysis does not account for potential bias introduced by the lack of exposure data, inadequate follow-up and other limitations in these weaker studies. Unfortunately, the magnitude and direction of this potential bias cannot be reasonably assessed and, thus, the impacts on the risk estimates are unclear.

It would be difficult to formally combine the data or the results (*e.g.*, parameter estimates) from the six studies considered for quantitative analysis. The inclusion criteria (*e.g.*, duration of employment required for entry into the cohorts) differed from study to study. Moreover, the reported cumulative exposure categories were based on different lag periods before accumulation of exposure began. Nevertheless, the lung cancer risks derived from all the data sets, as a group, support the range of best estimates derived from the two featured cohorts.

G. Issues and Uncertainties

The risk estimates presented in the previous sections include confidence limits that reflect statistical uncertainty. This statistical uncertainty concerns the limits of precision for statistical inference, given assumptions about the input parameters and risk models (*e.g.*, exposure estimates, observed lung cancer cases, expected lung cancer cases, linear dose-response). However, there are uncertainties with regard to the above input and assumptions, not so easily quantified, that may impact the degree of confidence in the OSHA risk estimates. Some of these uncertainties are discussed below.

1. Uncertainty With Regard to Worker Exposure to Cr(VI)

The uncertainty that may have the greatest impact on risk estimates relates to the assessment of worker exposure. Even for the Gibb cohort, whose exposures were estimated from roughly 70,000 air measurements over a 35-year period, the calculation of cumulative exposure is inherently uncertain. The methods used to measure airborne Cr(VI) did not characterize particle size that determines deposition in the respiratory tract (see section VI.A.). Workers differ from one another with respect to working habits and they may have worked in different areas in relation to where samples are taken. Inter-individual (and intra-facility) variability in cumulative exposure can only be characterized to a limited degree, even with extensive measurement. The impact of such variability is likely less for estimates of long-term average exposures when there were more extensive measurements in the Gibb and Luippold cohorts in the 1960s through 1980s, but could affect the reliability of estimates in the 1940s and 1950s when air monitoring was done less frequently. Exposure estimates that rely on annual average air concentrations are also less likely to reliably characterize the Cr(VI) exposure to workers who are employed for short periods of time. This may be particularly true for the Gibb cohort in which a sizable fraction of cohort members were employed for only a few months.

Like many retrospective cohort studies, the frequency and methods used to monitor Cr(VI) concentrations may also be a source of uncertainty in reconstructing past exposures to the Gibb and Luippold cohorts. Exposures to the Gibb cohort in the Baltimore plant from 1950 until 1961 were determined based on periodic collection of samples of airborne dust using high volume sampling pumps and impingers that were held in the breathing zone of the worker for relatively short periods of time (*e.g.*, tens of minutes) (Ex. 31–22–11). High volume sampling with impingers to collect Cr(VI) samples may have underestimated exposure since the accuracy of these devices depended on an air flow low enough to ensure efficient Cr(VI) capture, the absence of agents capable of reducing Cr(VI) to Cr(III), the proper storage of the collected samples, and the ability of short-term collections to accurately represent full-shift worker exposures. Further, impingers would not adequately capture any insoluble forms of Cr(VI) present, although other survey methods indicated minimal levels of insoluble Cr(VI) were produced at Baltimore facility (Ex. 13–18–14).

In the 1960s, the Baltimore plant expanded its Cr(VI) air monitoring program beyond periodic high volume sampling to include extensive area monitoring in 27 exposure zones around the facility. Multiple short-term samples were collected (*e.g.*, twelve one-hour or eight three-hour samples) on cellulose tape for an entire 24 hour period and analyzed for Cr(VI). Studies have shown that Cr(VI) can be reduced to Cr(III) on cellulose filters under certain circumstances so there is potential for underestimation of Cr(VI) using this collection method. Gibb *et al.* reported that the full set of monitoring data records was not accessible prior to 1971. The area monitoring was supplemented by routine full-shift personal monitoring of workers starting in 1977. The 24-hour area sampling supplemented with personal monitoring was continued until plant closure in 1985.

The Exponent critique of the Gibb cohort suggested that the tape samplers used in the Baltimore plant from the mid-1960s to 1985 resulted in reduction of Cr(VI) to Cr(III) and that Braver *et al.* excluded these measurements from their analyses because of concerns about underestimation of Cr(VI) concentration (Ex. 31–18–14). While there may be some potential for Cr(VI) reduction on these tape samplers, Gibb *et al.* reported that the tape measurements did not significantly differ from personal breathing zone air measurements "for approximately two-thirds of the job titles with sufficient number of samples to make the comparison" (Ex. 31–22–11, p. 118). Furthermore, Gibb *et al.* reported that exposure estimates from the area tape sampling system were adjusted to an equivalent personal exposure estimate using job-specific ratios of the mean area and personal breathing estimates determined during the 1978–1985 time period when both were in operation (Ex. 31–22–11, p. 117). Any potential exposure underestimation of Cr(VI) by the tape sampling system should be minimized by this correction procedure. Braver *et al.* considered the usual post-1960 Cr(VI) exposures of 31 ug/m3 to be "less credible because they were very low" compared to prior time periods (*e.g.*, pre-1950s) and, therefore, excluded workers exposed after 1960 from their exposure assessment (Ex. 7–17, p. 372). However, this exposure level turned out to be very consistent with the more extensive Cr(VI) concentrations later reported by Gibb *et al.* (Ex. 31–22–11) and Proctor *et al.* (Ex. 35–61) for

chromate production plants in the 1960s and 1970s.

Some of the same uncertainties exist in reconstructing exposures from the Luippold cohort. Exposure monitoring from operations at the Painesville plant in the 1940s and early 1950s was sparse and consisted of industrial hygiene surveys conducted by various groups (Ex. 35–61). The United States Public Health Service (USPHS) conducted two industrial hygiene surveys (1943 and 1951), as did the Metropolitan Life Insurance Company (1945 and 1948). The Ohio Department of Health (ODH) conducted surveys in 1949 and 1950. The most detailed exposure information was available in annual surveys conducted by the Diamond Alkali Company (DAC) from 1955 to 1971. Exponent chose not to consider the ODH data in their analysis since the airborne Cr(VI) concentrations reported in these surveys were considerably lower than values measured at later dates by DAC. Excluding the ODH survey data in the exposure reconstruction process may have led to higher worker exposure estimates and lower predicted lung cancer risks.

There were uncertainties associated with the early Cr(VI) exposure estimates for the Painesville cohort. Like the monitoring in the Baltimore plant, Cr(VI) exposure levels were determined from periodic short-term, high volume sampling with impingers that may have underestimated exposures (Ex. 35–61). Since the Painesville plant employed a "high-lime" roasting process to produce soluble Cr(VI) from chromite ore, a significant amount of slightly soluble and insoluble Cr(VI) was formed. It was estimated that up to approximately 20 percent of the airborne Cr(VI) was in the less soluble form in some areas of the plant prior to 1950 (Ex. 35–61). The impingers were unlikely to have captured this less soluble Cr(VI) so some reported Cr(VI) air concentrations may have been slightly underestimated for this reason.

The annual air monitoring program at the Painesville plant was upgraded in 1966 in order to evaluate a full 24 hour period (Ex. 35–61). Unlike the continuous monitoring at the Baltimore plant, twelve area air samples from sites throughout the plant were collected for only 35 minutes every two hours using two in-series midget impingers containing water. The more frequent monitoring using the in-series impinger procedure may be an improvement over previous high-volume sampling and is believed to be less susceptible to Cr(VI) reduction than cellulose filters. While the impinger collection method at the Painesville plant may have reduced one source of potential exposure uncertainty, another source of potential uncertainty was introduced by failure to collect air samples for more than 40 percent of the work period. Also, personal monitoring of workers was not conducted at any time.

Another type of uncertainty is associated with extrapolation from one exposure pattern to another (*e.g.*, different combinations of exposure duration and Cr(VI) air concentrations). Both Gibb *et al.* and Luippold *et al.* found that lung cancer mortality showed a significant trend with cumulative Cr(VI) exposure, which is being employed by OSHA as the exposure metric of choice in its quantitative risk assessments. However, the Cr(VI) exposure levels experienced by the cohorts were higher (*e.g.*, 5 to 10,000 $\mu g/m^3$) than for some of the lower exposure scenarios (*e.g.*, 0.25 to 2.5 $\mu g/m^3$) of interest to OSHA. The cohorts were also exposed for a considerably shorter duration than a 45-year working lifetime. Uncertainties arise when extrapolating risks for Cr(VI) concentrations and exposure durations outside the experience of the cohort data, even when cumulative exposures are similar.

There are several examples in which an increasing relative risk of chronic disease has been observed to attenuate (*e.g.*, the slope of the exposure-response lessens) at high cumulative exposures (Ex. 35–55). A variety of reasons can cause this behavior including the healthy worker survivor effect previously discussed, a limit on the relative risk that can be achieved for diseases with a high background rate (*e.g.*, lung cancer), and misclassification of exposure. Since the cumulative exposure for a full working lifetime at the current OSHA PEL is higher than observed in almost all workers from the Gibb cohort and most of the Luippold cohort, it is possible that a linear relative risk model might overpredict the excess risk at this exposure if there were a significant attenuation in the slope of the exposure-response.

In order to evaluate the likelihood of an attenuated relative risk of lung cancer at high cumulative Cr(VI) exposures, Environ fit the Gibb and Luippold data sets to a power model of the form:

$$\text{Relative Risk} = E(1 + bd^c)$$

where E was the expected number of lung cancer deaths, d is the cumulative exposure, and b and c were parameters to be estimated (Ex. 36–2). The parameter, c, was allowed to be less than 1, which would accommodate a decreasing slope in the exposure-response with increasing cumulative exposure. Of course, the power model assumes a linear shape, if c = 1. The power model fit to the two primary data sets produced maximum likelihood estimates of 0.61 and 0.66 for the Gibb and Luippold data sets, respectively. However, the power models did not significantly improve the fit compared to the linear model ($p = 0.41$ and 0.14 for Gibb and Luippold, respectively). This is consistent with the conclusions of NIOSH and Exponent who also reported that departure from linearity in the exposure-response was not significant for these data sets (Exs. 33–13; 33–12). In light of the above analyses, OSHA does not find adequate reason to believe a linear relative risk model overpredicts the lung cancer risk for a full working lifetime at the OSHA PEL. This is especially true since this Cr(VI) exposure is well within the range of cumulative exposures experienced by workers in the Luippold cohort.

While the cumulative Cr(VI) exposure estimates determined from the Gibb and Luippold cohorts are much more extensive than usually available for a cancer cohort, they are still a primary source of uncertainty in the assessment of risk. As occurs in many retrospective cancer epidemiologic studies, it was difficult to reconstruct worker exposure in the 1950s from the limited air monitoring data available from the Painesville and Baltimore plants. It appears that the usual airborne Cr(VI) exposure levels in some chromate production and processing areas at these facilities dropped five to ten-fold from the late 1940s to the mid-1960s with little documentation in the intervening years. This required more indirect methods to complete the job-exposure matrices for these cohorts. The need to reconstruct cohort exposure in the absence of extensive air measurements combined with the different procedures used to collect air samples at the two plants could partially explain the slight but statistically different exposure-specific risks between the Gibb and Luippold cohorts. Finally, some uncertainty in risk is introduced when extrapolating cohort exposures to higher Cr(VI) levels for shorter periods to an equivalent cumulative exposure of lower intensity for a longer duration (*e.g.*, 45 year exposure to 0.25 $\mu g/m^3$). Despite the uncertainties, the exposure estimates from the Gibb *et al.* and Luippold *et al.* studies are derived from the best available data and better than is generally found in retrospective cohort studies. They are more than adequate to assess occupational risk to

Cr(VI) and OSHA does not believe the potential inaccuracies in the exposure assessment for either cohort are large enough to result in serious overprediction or underprediction of risk.

2. Model Uncertainty, Exposure Threshold, and Dose Rate Effects

The models used to fit the observed data may also introduce uncertainty into the quantitative predictions of risk. Linear and non-linear risk models based on a Poisson distribution were applied to the exposure-response data sets. Both Environ (Ex. 33–12) and NIOSH (Ex. 33–13) evaluated nonlinear models among the suite of models fit to the Gibb *et al.* cohort data. These included quadratic, log-linear, log-square-root, and log-quadratic models as well as models that included cumulative dose raised to some power. Cox proportional hazard models were also applied to the data. Linear models generally fit the exposure-response data better than the nonlinear models. For most data sets, there was no indication that any model more elaborate than a linear model was necessary to describe the exposure-response patterns observed in these cohorts.

The linear relative risk model was used to estimate excess lung cancer risks at cumulative Cr(VI) exposures in the range of 0.01 to 2.3 mg/m^3 – yr (*i.e.*, 0.25 – 52 µg/m^3 for 45 years) which, to a large extent, overlap the cumulative exposures experienced of workers in either the Gibb or Luippold cohorts. Certainly, cumulative exposures above 0.1 mg/m^3 – yrs (*e.g.*, 2.5 µg/m^3 for 45 years) are within the exposure range of both studies. Since risks were estimated at cumulative exposures generally within the range of the data represented in the preferred cohorts, they are less susceptible to dose-extrapolation uncertainties and less susceptible to model misspecification. Thus, OSHA believes that the use of a linear model is a reasonable and appropriate basis on which to calculate lung cancer risks at the cumulative occupational exposures of interest, especially given the consistency in the results from fitting the linear model across most of the studies.

In their response to the OSHA Request For Information regarding occupational exposure to Cr(VI), the Chrome Coalition submitted comments, prepared by Exponent, suggesting that a threshold dose-response model is an appropriate approach to estimate lung cancer risk from Cr(VI) exposures (Ex. 31–18–1). Their arguments rely on: (1) The lack of a statistically significant increased lung cancer risk for workers exposed below a cumulative Cr(VI) exposure of 1.0 mg/m^3 – yr (*e.g.*, roughly equivalent to 20 µg/m^3 TWA for a 45 year working lifetime) and below "a highest reported eight hour average" Cr(VI) concentration of 52 µg/m^3 (*i.e.*, OSHA PEL); (2) the presumed existence of "an overall reducing capacity" within the lung for extracellular reduction of Cr(VI) to Cr(III) that must be exceeded before Cr(VI) can damage cellular DNA, and (3) a reported dose rate effect for lung tumor development in rats exposed to Cr(VI) by long-term, repeated intratracheal instillations.

The lack of a statistically significant result for a subset of the entire cohort should not be construed to imply a threshold. As pointed out in an earlier discussion (section VII.D) and by Crump *et al.*, the Luippold data set does not have the statistical power to detect small increases in risk that may be associated with the lower cumulative exposures in the cohort (Ex. 35–58). In their report, Exponent acknowledges that the non-significant increase in lung cancer deaths in the Luippold cohort below 1.25 mg Cr(VI)/m^3 – yr cumulative exposure is consistent with predictions from a linear relative risk model (Ex. 31–18–1, p.25).

The Chrome Coalition characterized the work of De Flora *et al.* as providing convincing support for the existence of a threshold exposure (*i.e.*, exposure below which the probability of disease is zero) for Cr(VI) carcinogenicity. De Flora *et al.* determined the amount of soluble Cr(VI) reduced to Cr(III) *in vitro* by human bronchioalveolar fluid and pulmonary alveolar macrophage fractions over a short period (Ex. 31–18–7). These specific activities were used to estimate an "overall reducing capacity" of 0.9–1.8 mg Cr(VI) and 136 mg Cr(VI) per day per individual for the two preparations, respectively. As discussed in Health Effects section VI.A., cell membranes are permeable to Cr(VI) but not Cr(III), so only Cr(VI) enters cells to any appreciable extent. De Flora *et al.* interpreted these data to mean that high levels of Cr(VI) would be required to "overwhelm" the reduction capacity before significant amounts of Cr(VI) could enter lung cells and damage DNA, thus creating a biological threshold to the exposure-response (Ex. 31–18–8).

There are several problems with the threshold interpretation of De Flora *et al.* The *in vitro* reducing capacities were determined in the absence of cell uptake. Cr(VI) uptake into lung cells happens concurrently and in parallel with its extracellular reduction, so it cannot be concluded from the De Flora data that a threshold reduction capacity must be exceeded before uptake occurs. The rate of Cr(VI) reduction to Cr(III) is critically dependant on the presence of adequate amounts of reductant, such as ascorbate or GSH (Ex. 35–65). It has not been established that sufficient amounts of these reductants are present throughout the thoracic and alveolar regions of the respiratory tract to create a biological threshold. Moreover, the *in vitro* activity of Cr(VI) reduction in epithelial lining fluid and alveolar macrophages was shown to be highly variable among individuals (Ex. 31–18–7, p. 533). It is possible that Cr(VI) is not rapidly reduced to Cr(III) in some workers or some areas of the lung. Finally, even if there was an exposure threshold created by extracellular reduction, the De Flora data do not establish the dose range in which the putative threshold would occur. It has already been shown that a physiological concentration of ascorbate substantially reduces, but may not eliminate, the uptake in cells treated with low M concentrations of Cr(VI) for 24 hours (Ex. 35–68). OSHA does not believe that there is sufficient scientific evidence to support the Chrome Coalition conclusion that the De Flora data "suggest a linear, non-threshold model to predict cancer risk at low exposure levels [at least, those being considered by OSHA] is overly conservative and inappropriate" (Ex. 31–18–1, p.2).

The Chrome Coalition has stated that the intratracheal instillation study in rats by Steinhoff *et al.* "suggests that there is likely a threshold exposure level below which there is no increase in lung cancer risk, and that the threshold is compound-specific." (Ex. 31–18–1, p. 2). The Steinhoff study is discussed in detail in section VI.B. on carcinogenic effects. Briefly, the study showed that rats intratracheally administered 1.25 mg/kg of soluble sodium dichromate or slightly soluble calcium chromate once a week for 30 months developed significant increases (about 17 percent incidence) in lung tumors (Ex. 11–7). The same total dose administered more frequently (*e.g.*, five times weekly) at a five-fold lower dose level did not increase lung tumor incidence in the sodium dichromate-treated rats and significantly increased lung tumor incidence (about 7.5 percent) in the calcium chromate-treated rats by only about half as much as rats that received the greater dose level.

OSHA does not believe that the accelerated tumor development at the high Cr(VI) dose levels in the Steinhoff *et al.* study "clearly support that there is a threshold for Cr(VI) exposures" or indicate that "peak exposures high enough to overload the reductive capacity of the lung may be a better

predictor of lung cancer risk than lifetime cumulative exposure" as stated by Chrome Coalition (Ex. 31–18–1, p. 31). Rather, OSHA believes these findings should be interpreted to suggest that Cr(VI)-induced carcinogenesis is influenced not only by the total Cr(VI) dose retained in the respiratory tract but also by the rate at which the dose is administered. For example, the highest dose level (i.e., 1.25 mg/kg) in the study was reported to cause moderate to severe lung damage, including inflammation and hyperplasia. It is likely that these effects caused a proliferative stimulus that accelerated the neoplastic transformation and expansion of initiated (i.e., genetically altered) cells. The Steinhoff *et al.* study also suggests that lung damage is not an absolute requirement for Cr(VI)-induced tumorigenesis. This is illustrated by the significant, but smaller, increased tumor incidence in the animals receiving a lower dose level (i.e., 0.25 mg/kg) of Cr(VI), as calcium chromate, that caused relatively minor non-neoplastic changes in the lungs.

OSHA believes that the existence of dose rate effects is supported by the available scientific evidence and may introduce uncertainty when projecting lung cancer risk based on workers exposed to higher Cr(VI) concentrations for shorter durations to workers exposed to the same cumulative exposure but at substantially lower Cr(VI) concentrations for substantially longer periods. However, the Steinhoff *et al.* study instilled the Cr(VI) compounds directly on the trachea rather than introduce the test compound by inhalation and was only able to characterize a significant dose rate effect at one cumulative dose level (*e.g.*, 1.25 mg/kg). For these reasons, OSHA considers the data inadequate to reliably determine the human exposures where a dose rate effect might occur and to confidently predict its magnitude.

OSHA solicits comment on the whether the linear relative risk model is the most appropriate approach on which to estimate risk associated with occupational exposure to Cr(VI). OSHA is particularly interested in whether there is convincing scientific evidence of a non-linear exposure-response relationship and, if so, whether there are sufficient data to develop a non-linear model that would provide more reliable risk estimates than the linear approach being used in the preliminary assessment.

3. Influence of Smoking, Race, and the Healthy Worker Survivor Effect

A common confounder in estimating lung cancer risk to workers from exposure to a specific agent such as Cr(VI) is the impact of cigarette smoking. First, cigarette smoking is known to cause lung cancer. Ideally, lung cancer risk attributable to smoking among the Cr(VI)-exposed cohorts should be controlled or adjusted for in characterizing exposure-response. Secondly, cigarette smoking may interact with the agent (i.e., Cr(VI)) or its biological target (i.e., susceptible lung cells) in a manner that enhances or even reduces the risk of developing Cr(VI)-induced lung cancer from occupational exposures, yet is not accounted for in the risk model.

OSHA believes its risk estimates have adequately accounted for the potential confounding effects of cigarette smoking in the underlying exposure-lung cancer response data, particularly for the Gibb cohort. One of the key issues in this regard is whether or not the reference population utilized to derive the expected number of lung cancers appropriately reflects the smoking behavior of the cohort members. The risk analyses of the Gibb cohort by NIOSH and Environ indicate that cigarette smoking was properly controlled for in the exposure-response modeling. NIOSH applied a smoking-specific correction factor that included a cumulative smoking term for individual cohort members (Ex.33–13). Environ applied a generic correction factor and used lung cancer mortality rates from Baltimore City as a reference population that was most similar to the cohort members with respect to smoking behavior and other factors that might affect lung cancer rates (Ex. 33–12). Environ also used internally standardized models that did not require use of a reference population and included a smoking-specific (yes/no) variable. All these models predicted very similar estimates of risk over a wide range of Cr(VI) exposures. There was less information about smoking status for the Luippold cohort. However, regression modeling that controlled for smoking indicated that it was not a significant confounding factor when relating Cr(VI) exposure to the lung cancer mortality (Ex. 35–58).

Smoking has been shown to interact in a synergistic manner (i.e., combined effect of two agents are greater than the sum of either agent alone) with some lung carcinogens, most notably asbestos (Ex. 35–114). NIOSH reported a slightly negative but nonsignificant interaction between cumulative Cr(VI) exposure and smoking in a model that had separate linear terms for both variables (Ex. 33–13). This means that, at any age, the smoking and Cr(VI) contributions to the lung cancer risk appeared to be additive, rather than synergistic, given the limited smoking information in the Gibb cohort along with the cumulative smoking assumptions of the analysis. In their final linear relative risk model, NIOSH included smoking as a multiplicative term in the background rate in order to estimate lifetime lung cancer risks attributable to Cr(VI) independent of smoking. Although this linear relative risk model makes no explicit assumptions with regard to an interaction between smoking and Cr(VI) exposure, the model does assume a multiplicative relationship between the background rate of lung cancer in the reference population and Cr(VI) exposure. Therefore, to the extent that smoking is a predominant influence on the background lung cancer risk, the linear relative risk model implicitly assumes a multiplicative (*e.g.*, greater than additive and synergistic, in most situations) relationship between cumulative Cr(VI) exposure and smoking. Since current lung cancer rates reflect a mixture of smokers and non-smokers, it is reasonable to expect that the excess lung cancer risks from Cr(VI) exposure predicted by the linear relative risk model to overestimate the risks to non-smokers to some unknown extent. By the same token, the model may underestimate the risk from Cr(VI) exposure to a heavy smoker. Because there were so few non-smokers in the study cohorts (*e.g.*, approximately 15 percent of the exposed workers and four lung cancer deaths in the Gibb cohort), it was not possible to reliably estimate risk for this subpopulation.

Although OSHA is not aware of any convincing evidence of a specific interaction between cigarette smoking and Cr(VI) exposure, prolonged cigarette smoking does have profound effects on lung structure and function that may indirectly influence lung cancer risk from Cr(VI) exposure . Cigarette smoke is known to cause chronic irritation and inflammation of the respiratory tract. This leads to decreases in airway diameter that could result in an increase in Cr(VI) particulate deposition. It also leads to increased mucous volume and decreased mucous flow, that could result in reduced Cr(VI) particulate clearance. Increased deposition and reduced clearance would mean greater residence time of Cr(VI) particulates in the respiratory tract and a potentially greater probability of developing bronchogenic cancer. Chronic cigarette

smoking also leads to lung remodeling and changes in the proliferative state of lung cells that could influence susceptibility to neoplastic transformation. While the above effects are plausible consequences of cigarette smoking on Cr(VI)-induced carcinogenesis, the likelihood and magnitude of their occurrence have not been firmly established and, thus, the impact on risk of lung cancer in workers is uncertain.

Differences in lung cancer incidence with race may also introduce uncertainty in risk estimates. Gibb *et al.* reported differing patterns for the cumulative exposure-lung cancer mortality response between whites and non-whites in their cohort of chromate production workers (Ex. 31–22–11). In the assessment of risk from the Gibb cohort, NIOSH reported a strong interaction between cumulative Cr(VI) exposure and race, such that nonwhites had a higher cumulative exposure coefficient (i.e., higher lung cancer risk) than whites based on a linear relative risk model (Ex. 33–13). If valid, this might explain the slightly lower risk estimates in the predominantly white Luippold cohort. However, Environ found that including race as an explanatory variable in the Cox proportional hazards model C1 did not significantly improve model fit (p=0.15) once cumulative Cr(VI) exposure and smoking status had been considered (Ex. 33–12).

NIOSH suggested that exposure or smoking misclassification might plausibly account for the Cr(VI) exposure-related differences in lung cancer by race seen in the Gibb cohort (Ex. 33–13, p. 15). It is possible that such misclassification might have occurred as a result of systematic differences between whites and non-whites with respect to job-specific Cr(VI) exposures at the Baltimore plant, unrecorded exposure to Cr(VI) or other lung carcinogens when not working at the plant, or in smoking behavior. Unknown racial differences in biological processes critical to Cr(VI)-induced carcinogenesis could also plausibly account for an exposure-race interaction. However, OSHA is not aware of evidence that convincingly supports any of these possible explanations.

Another source of uncertainty that may impact the risk estimates is the healthy worker survivor effect. Studies have consistently shown that short-term employed workers have higher mortality rates than workers with long-term employment status. This is possibly due to a higher proportion of ill individuals and those with a less healthy lifestyle (Ex. 35–60). As a result, exposure-response analyses based on mortality of long-term healthy workers will tend underestimate the risk to short-term workers and vice versa, even when their cumulative exposure is similar. This might partially explain the higher risk estimates from the Gibb data set relative to the Luippold data set for the same cumulative exposures using similar risk models. The Gibb cohort contained a higher proportion of workers with short duration of employment, lower cumulative Cr(VI) exposure, and is arguably more prone to mortality. On the other hand, the Luippold cohort consisted of longer-term workers at higher cumulative exposures that may be more prone to negative confounding as a result of the survivor effect. The healthy worker survivor effect is thought to be less of a factor in diseases with a multifactorial causation and long onset, such as cancer.

4. Potency Considerations of Different Cr(VI) Compounds

An issue that needs to be addressed is whether the excess lung cancer risks derived from epidemiologic data for chromate production workers are representative of the risks for other Cr(VI)-exposed workers (*e.g.*, plating, painting, welding operations). Typically, OSHA has used epidemiologic studies from one industry to estimate risk for other industries. In many cases, this approach is acceptable because it is exposure to a common agent of concern that is the primary determinant of risk and not some other factor unique to the workplace. However, in the case of Cr(VI), workers in different industries are exposed to various Cr(VI) compounds that differ in carcinogenic potency depending to a large extent on water solubility. The chromate production workers in the Gibb and Luippold cohorts were primarily exposed to certain highly water-soluble chromates. As more fully described in section VI.B. of the Cancer Effects section and summarized below, the scientific evidence indicates that the carcinogenic potency of the highly water-soluble chromates is likely lower than the potency of other less water-soluble Cr(VI) compounds. Therefore, OSHA believes that the lung cancer risk of workers in other industries exposed to equivalent levels of Cr(VI) will be of similar magnitude, or possibly even greater in the case of some workers exposed to certain Cr(VI) compounds, than the risks projected from chromate production workers in the Gibb and Luippold cohorts.

The primary operation at the plants in Painesville and Baltimore was the production of the water-soluble sodium dichromate from which other primarily water-soluble chromates such as sodium chromate, potassium dichromate, and chromic acid could be made (Exs. 7–14; 35–61). Therefore, it is likely that the Gibb and Luippold cohorts were principally exposed to water-soluble Cr(VI). The Painesville plant used a high-lime process known to form some less water-soluble Cr(VI) compounds (Ex. 35–61). Less water-soluble chromates is a designation that refers to all chromates not considered to be highly water soluble and readily captured by an aqueous impinger sampling device. These would include both slightly water-soluble chromates, such as calcium and strontium chromate and the more water-insoluble chromates, such as zinc and lead chromate. The 1953 USPHS survey confirmed that approximately 20 percent of the total Cr(VI) in the roasting residue at the Painesville plant consisted of the less water-soluble chromates (Ex. 2–14). The Painesville plant subsequently reduced and eliminated exposure to Cr(VI) roasting residue through improvements in the production process. The high-lime process was not used at the Baltimore plant and the 1953 USPHS survey detected minimal levels of less soluble Cr(VI) at this facility (Ex. 7–17). Proctor *et al.* estimated that a proportion of the Luippold cohort prior to 1950 were probably exposed to the less water-soluble Cr(VI) compounds, but that it would amount to less than 20 percent of their total Cr(VI) exposure (Ex. 35–61). A small proportion of workers in the Special Products Division of the Baltimore plant may also have been exposed to less water-soluble Cr(VI) compounds during the occasional production of these compounds over the years.

As discussed in the preamble section VI.B on carcinogenic effects, both water-soluble and insoluble forms of Cr(VI) compounds are regarded as carcinogenic to the respiratory tract as a result of inhalation. This is not only supported by epidemiologic studies of the chromate production workers above, but also by studies of chromate pigment workers exposed primarily to the insoluble zinc and lead chromates (Exs. 7–36; 7–42; 7–49). The standardized lung cancer incidence and mortality ratios reported among these pigment workers were relatively high and clearly significant. Langard and Vigander found that the lung cancer incidence among a cohort of workers exposed primarily to zinc chromate, but also lead chromate, at a pigment production plant in

Norway was 44 times what would be expected from an age- and sex-adjusted Norwegian population (Ex. 7–36). The Davies study found from 2.2-($p<0.01$) to 5.6-fold ($p<0.001$) excess lung cancer mortality for various cohorts of pigment workers exposed to both zinc and lead chromate at two British factories (Ex. 7–42). Workers in jobs judged to involve the highest Cr(VI) exposure had the highest risk of lung cancer. A cohort study of workers exposed to the highly water-soluble chromic acid during electroplating operations also reported excess lung cancer mortality (Ex. 35–62). While the lung cancer mortality was significantly elevated in pigment and electroplating cohorts, there was inadequate exposure information for risk analysis.

The slightly water-soluble Cr(VI) compounds, calcium and strontium chromate, led to significant increases in tumors when instilled in the respiratory tract of experimental animals (Exs. 11–7; 11–2). Levy *et al.* reported a bronchial carcinoma incidence of 43 percent (43/99) and 25 percent (25/100) after a single 2 mg intrabronchial instillation of strontium chromate and calcium chromate, respectively (Ex. 11–2). This compares with the non-significant bronchial carcinoma incidence of one percent (1/100) in rats instilled with 2 mg of highly water-soluble sodium dichromate in the same study. Steinhoff *et al.* reported a 7.5 percent tumor incidence (6/80, $p<0.01$) following repeated intratracheal instillations of 0.25 mg/kg slightly water-soluble calcium chromate in rats (Ex. 11–7). The same dosing of the highly water-soluble sodium dichromate produced no tumor incidence (0/80) in the same study. This and other evidence led IARC to conclude that there was sufficient evidence for carcinogenicity in experimental animals of the less water-soluble strontium chromate, calcium chromate, zinc chromates, and lead chromates but only limited evidence for carcinogencity in experimental animals of the highly water-soluble chromic acid and sodium dichromate (Ex. 18–1, p. 213). Because the above animal studies either used an inadequate number of dose levels (*e.g.*, single dose level) or employed a less appropriate route of administration (*e.g.*, tracheal instillation), it was not possible to determine a reliable quantitative estimate of risk for human workers breathing these chromates during occupational exposure. IARC drew the overall conclusion that all Cr(VI) compounds are carcinogenic to humans based on the combined results of animal studies, human epidemiological evidence and other data relevant to the carcinogenic mode of action.

Other studies reported that insoluble Cr(VI) compounds are retained in the lung for longer periods and are considered a more persistent source of locally available Cr(VI) for uptake into lung cells than water-soluble Cr(VI) compounds. Bragt and Van Dura found that water-soluble sodium chromate is more rapidly absorbed and cleared from the lung than the highly insoluble lead chromate when intratracheally instilled in rats (Ex. 35–56). On day 50 after instillation, 13.8 percent of the initial lead chromate remained in the lungs as opposed to only 3.0 percent of the initial sodium chromate. Research at George Washington University Medical Center showed that treatment of embryo cells in culture with insoluble lead chromate particulates led to cell-enhanced dissolution and uptake of Cr(VI) resulting in DNA damage and neoplastic transformation (Exs. 35–104; 35–69; 35–132). Internalization, dissolution, and uptake of lead chromate and the resulting damage to DNA were later shown to also occur in normal human lung epithelial cells (Exs. 35–66; 35–327). Elias *et al.* showed that a wide range of insoluble lead and zinc chromate pigments could morphologically transform normal mammalian cells into neoplastic cells (Ex. 12–5). These studies have led the researchers to suggest that the less water-soluble Cr(VI) compounds may be more carcinogenic in the lung than the highly water-soluble Cr(VI) since these insoluble chromate particulates provide a persistent source of high Cr(VI) concentration within the immediate microenvironment of the lung cell surface (Exs. 35–67; 35–149).

Experts have evaluated the combined epidemiologic, animal, and mechanistic evidence and concluded that the less water-soluble chromates are likely more carcinogenic than highly water-soluble Cr(VI) compounds (Exs. 17–101; 17–5B). This is reflected in the lower recommended ACGIH TLVs for insoluble Cr(VI) compounds (i.e., 10 mg/m3) and certain slightly soluble Cr(VI) compounds (*e.g.*, 1 mg/m3 for calcium chromate; 0.5 mg/m3 for strontium chromate) than the recommended TLV for the water-soluble Cr(VI) compounds (*e.g.*, 50 mg/m3). For all the reasons cited above, OSHA believes the lung cancer risk for workers exposed to equivalent levels of Cr(VI) compounds other than sodium chromate and sodium dichromate over a working lifetime is likely to be similar in magnitude to the risks projected from the chromate production workers in the Gibb and Luippold cohorts, or possibly even greater in the case of inhaled slightly water-soluble and insoluble Cr(VI) particulates.

OSHA seeks comment on whether its preliminary assessment of risk based on the exposure-response data from the two cohorts of chromate production workers is reasonably representative of the risks expected from equivalent exposures to different Cr(VI) compounds encountered in other industry sectors. Of particular interest is whether there is convincing evidence that the preliminary risk estimates from worker cohorts primarily engaged in the production of the highly water soluble sodium chromate and sodium dichromate would substantially overpredict the lung cancer risk for workers exposed at the same level and duration to airborne Cr(VI) during welding operations, chromic acid aerosol in electroplating operations, the less water soluble Cr(VI) particulates encountered during pigment production and painting operations, or Cr(VI) exposure in other important industry sectors and job categories.

H. Expert Peer Review of the OSHA Draft Preliminary Quantitative Risk Assessment

OSHA contracted an independent organization known as Toxicology Excellence for Risk Assessment (TERA) to organize an external scientific peer review of the January 21, 2004 Draft Quantitative Risk Assessment (Exs. 36–1–1; 36–1–2). TERA selected three peer reviewers based on a high level of competence in occupational epidemiology and/or risk assessment. The reviewers were screened to ensure no apparent conflict of interest or involvement in the key studies that provided the basis for the OSHA assessment. OSHA did not participate in the selection process other than to examine reviewer credentials to confirm their qualifications. The three peer reviewers selected by TERA were Dr. David Gaylor, Dr. Allan Smith, and Dr. Irva Hertz-Picciotto. Curriculum Vitae of the three reviewers have been submitted to the docket (Ex. 36–1–3).

TERA provided the peer reviewers with a review package that consisted of the draft quantitative risk assessment, copies of the key studies, and a set of instructions and questions (Ex. 36–1–1). The reviewers were asked to comment on several aspects of the draft OSHA risk assessment including the suitability of the different data sets for exposure-response analysis, the choice of exposure metric and risk models, the appropriateness of the risk estimates, and the characterization of key issues and uncertainties. The peer reviewers filed written draft reports with TERA

which then reviewed the comments for completeness before passing the reports on to OSHA (Ex. 36–1–4). OSHA requested clarification in writing on some of the reviewer responses. These were addressed by the peer reviewers in their final peer review reports or answered in an attachment (Ex. 36–1–4–3). The clarification process with the reviewers was handled by TERA.

The three peer reviewers agreed that the results from six occupational cohorts under review were adequately evaluated as to their suitability for exposure-response analysis and concurred that the Gibb and Luippold cohorts provided the strongest data sets for quantitative assessment. There was general agreement among the peer reviewers that the risk models and statistical methodologies used in the OSHA assessment were appropriately applied. Dr. Smith remarked that "there is no question in my mind that relative risk models are superior to others when conducting quantitative cancer risk assessments on epidemiological data" (Ex. 36–1–4–2) and commended OSHA for supporting a relatively straightforward [linear] model widely used in epidemiology (Ex. 36–1–4–2). At his suggestion, OSHA expanded on reasons for using a linear relative risk model to fit the epidemiological data. The selection of the linear relative risk model was not solely based on mathematical fit. Relative risk models inherently adjust for age-related increases in cancer incidence. The linear relative risk model has been extensively and successfully used to analyze other cancer mortality data sets and is an accepted approach in carcinogen risk assessment.

The peer reviewers were also in general agreement that cumulative exposure based on time-weighted average air concentrations by job title and employment history was a reasonable exposure metric to use. Dr. Hertz-Picciotto stated "the use of cumulative exposure constructed in this way is currently the standard, and the use of individual job histories is the best available method at this time (Ex. 36–1–4–4)." She pointed out that the underlying assumption that exposure patterns and dose rate differences at equivalent cumulative exposures do not influence cancer risk is an uncertainty in the assessment. This is more fully explained in section VII.G.1 on uncertainties with regard to worker exposure.

Dr. Smith raised another limitation to the cumulative exposure metric as it relates to relative risk. It has been shown, in some instances, that relative risk of chronic disease will not continue to rise at high cumulative exposure but will tend to stabilize or attenuate. In the case of a significant attenuation, the excess risk at high Cr(VI) exposures (*e.g.*, working lifetime at the current OSHA PEL) could be overestimated by a linear relative risk model. Environ examined this possibility by fitting the Gibb and Luippold data sets to a power model that requires the exposure-response to rise steeply at low exposure and level out at high exposure (Ex. 36–2). The power model did not significantly improve the fit compared to the linear relative risk model for either data set. This analysis would not support a significant attenuation in the relative risk of lung cancer with increasing cumulative Cr(VI) exposure. Therefore, OSHA does not find adequate reason to believe its linear relative risk model would overpredict the lung cancer risk at the OSHA PEL or other cumulative exposures in the range of interest. OSHA revised its preliminary quantitative risk assessment to fully address this issue in section VII.G.1.

The peer reviewers showed less enthusiasm for the highest reported average monthly Cr(VI) air concentration as an appropriate exposure metric or for an exposure threshold below which there exists no lung cancer risk. Dr. Hertz-Picciotto remarked that "the newly published Crump *et al.* (2003) uses the monthly maximum [Cr(VI) concentration], but fails to take duration into account, and the authors note considerable variability was present in duration at the highest monthly exposure" and "the inadequacy of the attempt to prove a threshold is excellently presented [by OSHA]" (Ex. 36–1–4–4). Dr. Gaylor stated "a threshold concentration or threshold cumulative exposure to Cr(VI) below which no excess lung cancer is expected cannot be established from the available information (Ex. 36–1–4–1)." Dr. Smith added "the [OSHA] reasons given for dismissing Exponent's threshold inference are valid. I would add [Exponent's] assessment ignores duration of exposure. For example, it is unlikely one could detect increased lung cancer risks in smokers whose 'peak exposure' was a quarter pack per day if they only smoked for three years. This would not mean that a quarter pack per day is a threshold (Ex. 36–1–4–2)."

The peer reviewers found the range of excess lifetime risks of lung cancer presented by OSHA to be sound and reasonable. These preferred risk estimates were those bounded by the maximum likelihood estimates determined from the featured Gibb and Luippold data sets. Dr. Gaylor wrote "the confidence limits are tighter for the Luippold study, somewhat over a factor of two for the range from the lower to the upper 95% confidence limit, compared to a range of about 3.5 for the confidence limits in the Gibb study. However, the Gibb cohort is larger than the Luippold cohort. It appears reasonable to consider the two studies jointly to provide estimates of lung cancer risk" (Ex. 36–1–4–1). Dr. Gaylor went on to point out that the range of maximum likelihood between the featured data sets understates the [statistical] uncertainty in the risk estimates. He recommended that the uncertainty be expressed as the lower 95% confidence limit from the Luippold data set and the 95% upper confidence limit for the Gibb data set. OSHA agrees and has revised section VII.F to make clear that while the maximum likelihood range represents the most likely estimates of lung cancer risk, the 95% confidence bounds are the better representation of statistical uncertainty.

Dr. Gaylor suggested that the OSHA assessment make clear that the 45-year working lifetime exposure should be regarded as a worst case scenario and that the typical worker would be exposed to Cr(VI) for a shorter period of time. Dr. Smith also questioned the need to estimate risk from a 45-year working lifetime. He suggested that OSHA could probably make more confident estimates of risk for shorter exposure durations (*e.g.*, ten years) within the range observed in the cohort studies. This would avoid the uncertainties of an upward extrapolation. OSHA does not disagree with these comments. However, the OSH Act is clear on the agency statutory obligation to consider the risk of material impairment from regular exposure to the hazardous agent for a full working life. The risk of lung cancer from Cr(VI) exposures for less than a full working lifetime are discussed in section VIII on Significance of Risk and section IX on Benefits Analysis.

Dr. Hertz-Picciotto felt that OSHA may have overstated the consistency in lung cancer risk between the two primary studies and the four weaker supporting studies. She pointed out that two of the supporting cohorts overlapped the featured cohorts and were not truly independent data sets. She indicated that the weaker supporting studies had serious bias that rendered the discussion of overlap in confidence intervals to be relatively meaningless and, thus, prevented a definitive evaluation of consistency. OSHA agrees that the magnitude and direction of potential bias introduced by lack of exposure data, inadequate follow-up, and other limitations in the

supporting studies prevents strong statements regarding consistency among risks estimates. However, OSHA believes the finding that its risk predictions based on the Gibb and Luippold data sets are within a statistical precision that is compatible with other exposure-response data sets enhances confidence in the estimates. OSHA notes that there was no overlap in the Mancuso and Luippold cohorts, even though they worked at the same plant, due to vastly different selection criteria and exposure estimation based on different industrial hygiene surveys. The Hayes and Gibb cohort have some overlap but the cohorts primarily worked at different facilities and exposure estimates were, again, based on different monitoring surveys. In the case of both cohort pairs, statistical comparisons show that the risk estimates from one data set would not be consistent with the other data set at the 95% confidence level. OSHA believes the risks from the different cohorts can be considered independent estimates. OSHA has revised sections VII.E and VII.F to clarify the positions discussed above.

Dr. Smith suggested that OSHA consider presenting risk estimates that can be readily calculated from the source data without use of a complex mathematical model. He contends that this would allow the reader to better understand how the risks relate to measures reported in the published studies. He provided some illustrations of simple and transparent risk estimations from the Gibb *et al.* study. OSHA agrees there is merit to comparing risk estimates easily calculated from the cohort mortality data with the more precise estimates determined from the linear relative risk model as a kind of "reality check". OSHA has included such calculations in sections VII.C.4 for the Gibb data set and section VII.D for the Luippold data set.

OSHA does not agree with assertions by Dr. Smith that "there is no valid basis to conclude that more complex calculations [from mathematical models], such as found in the source material and draft [OSHA] document, have any greater validity than this estimate [directly calculated from the published cohort data]" and "there is no gain in validity in doing a full life table analysis but there is certainly a loss in transparency (Ex. 36–1–4–2)." OSHA believes excess risk estimated from standard, well-supported mathematical model constructs that incorporate the entire mortality data set is considerably more accurate, more robust, more stable and more statistically rigorous than a simple calculation from a single relative risk result determined from a small subset of the cohort data as applied by Dr. Smith. The life table analysis adjusts for both the increasing probability of developing lung cancer with advancing age and the competing risk of death from other causes. These age-related factors are not accounted for in a simple relative risk calculation and may lead to a less accurate risk estimate.

While the peer reviewers felt that most uncertainties in the risk assessment were adequately characterized, they suggested certain topics receive more attention. Dr. Hertz-Picciotto suggested that sensitivity analyses on plausible alternate exposure assumptions for workers in the Gibb and Luippold cohorts during the periods when there was very limited air monitoring data "would add concrete information on the magnitude of uncertainty in the risk estimates (Ex. 36–1–4–4)." Environ, while under contract with OSHA, had access to annual exposure estimates on individual workers in the Gibb cohort. They explored the feasibility of generating plausible alterative exposures using a forward and reverse replacement scheme for the air concentrations imputed during periods in the Gibb *et al.* study when air monitoring was unavailable (Ex. 36–2). Unfortunately, lack of job title information and job-specific monitoring data combined with apparent high job transfer and turnover among workers made this approach impracticable for estimating plausible exposures that could lead to a meaningful analysis. OSHA did not have access to individual exposure data for the Luippold cohort.

Dr. Hertz-Picciotto recommended that OSHA address the potential impact on risk of the healthy worker survivor effect. The healthy worker survivor effect refers to a common observation that long-term workers have been found to have lower mortality than short-term workers. As a result, exposure-response analyses based on mortality of long-term healthy workers will tend to underestimate the risk to short-term workers and vice versa. This healthy worker effect may partially explain the higher risk estimates for the same cumulative exposures from the Gibb cohort, which included a higher proportion of workers with short exposure duration, relative to the Luippold cohort of longer-term workers. The healthy worker survivor effect may have also influenced risks estimated from the Mancuso cohort. OSHA agrees that the healthy worker survivor effect contributes to the uncertainty in the risk estimates and has included a discussion in section VII.G.3 on issues and uncertainties and in the section VII.E.1 on the Mancuso data set.

Dr. Smith thought that some important issues surrounding smoking needed to be better addressed in the preliminary risk assessment document. He agreed that OSHA adequately discussed the confounding due to smoking but suggested that it be made clear that the linear relative risk model, in the absence of any explicit interaction term between smoking and Cr(VI), implicitly assumes a synergy (i.e., lung cancer risk from smoking and Cr(VI) together is greater than the sum of the risks from either agent alone) between the two exposures. OSHA believes Dr. Smith has a valid point. Although the linear relative risk model makes no explicit assumptions with regard to an interaction between smoking and Cr(VI) exposure, the model does assume a multiplicative relationship between the background rate of lung cancer in the reference population and Cr(VI) exposure. Therefore, to the extent that smoking is a predominant influence on the background lung cancer risk, the linear relative risk model implicitly assumes a multiplicative (*e.g.*, greater than additive and synergistic, in most situations) relationship between cumulative Cr(VI) exposure and smoking. Since the background lung cancer rate reflects a mixture of smokers and non-smokers, the expectation is that the projected OSHA risks from Cr(VI) exposure are overestimated for a non-smoker to some unknown extent. By the same token, the model may underestimate the risk from Cr(VI) exposure to a heavy smoker. A discussion of this has been included in section VII.G.3.

Finally, the peer reviewers believed that OSHA adequately presented its position that workers in the Gibb and Luippold cohorts were primarily exposed to the less carcinogenic, highly water-soluble Cr(VI) compounds and that the lung cancer risks for workers exposed to equivalent levels of other Cr(VI) compounds will be of a similar magnitude and possibly greater in the case of certain less water-soluble Cr(VI). However, the peer reviewers stated that they lacked the expertise in toxicology and experimental carcinogenesis to critically evaluate its consistency with the existing scientific data. OSHA has made it clear in section VII.G.4 that the animal studies demonstrating higher carcinogenic potency for sparingly water-soluble Cr(VI), such as calcium chromate and strontium chromates, can not provide reliable quantitative estimates of human risk. This is because the studies employed an inadequate

number of dose levels or the studies employed routes of administration (*e.g.*, intratracheal instillation) less relevant to occupational exposure.

I. Preliminary Conclusions

OSHA believes that the best quantitative estimates of excess lifetime lung cancer risks are those derived from the data sets described by Gibb *et al.* and Luippold *et al.* Both data sets show a significant positive trend in lung cancer mortality with increasing cumulative Cr(VI) exposure. The exposure assessments for these two cohorts were reconstructed from air measurements and job histories over three or four decades and were superior to those of other worker cohorts. The linear relative risk model generally provided the best fit among a variety of different models applied to the Gibb *et al.* and Luippold *et al.* data sets. It also provided an adequate fit to four other supporting data sets. Thus, OSHA believes the linear relative risk model is the most appropriate model to estimate excess lifetime risk from occupational exposure to Cr(VI). Using the Gibb *et al.* and Luippold *et al.* data sets and a linear relative risk model, OSHA preliminarily concludes that the lifetime lung cancer risk is best expressed by the three-to five-fold range of risk projections bounded by the maximum likelihood estimates from the two featured data sets. This range of projected risks is within the 95 percent confidence intervals from all six data sets.

OSHA does not believe that it is appropriate to employ a threshold dose-response approach to estimate cancer risk from a genotoxic carcinogen, such as Cr(VI). Federal Agencies, including OSHA, assume an exposure threshold for cancer risk assessments to genotoxic agents only when there is convincing evidence that such a threshold exists. In addition, OSHA does not consider absence of a statistically significant effect in an epidemiologic or animal study that lacks power to detect such effects to be convincing evidence of a threshold. OSHA also does not consider theoretical reduction capacities determined in vitro with preparations that do not fully represent physiological conditions within the respiratory tract to be convincing evidence of a threshold. Finally, as previously discussed, linear (and some non-linear) no-threshold risk models adequately fit the existing exposure-response data.

The Gibb and Luippold cohorts were predominantly exposed to water-soluble chromates, particularly sodium dichromate. The scientific evidence indicates that the water-soluble Cr(VI) compounds are generally less potent carcinogens than slightly-water soluble and water-insoluble Cr(VI) compounds. These less water-soluble Cr(VI) compounds are retained in the lung for longer periods, are more likely to concentrate at the lung cell surface, and are a more persistent source of locally available Cr(VI) for uptake into target cells than the highly water-soluble Cr(VI) compounds. Risks estimated from chromate production workers primarily exposed to water-soluble chromates in the Gibb and Luippold cohorts should adequately represent risks to workers exposed to other water-soluble Cr(VI) compounds. OSHA believes that workers exposed to equivalent levels of the potentially more carcinogenic, less water-soluble Cr(VI) compounds may even be at greater risk of lung cancer than predicted from the Gibb and Luippold cohorts.

As with any risk assessment, there is some degree of uncertainty in the projected risks that result from the data, assumptions, and methodology used in the analysis. The exposure estimates in the Gibb *et al.* and Luippold *et al.* data sets relied, to some extent, on a paucity of air measurements using less desirable sampling techniques to reconstruct Cr(VI) exposures, particularly in the 1940s and 1950s. Additional uncertainty is introduced when extrapolating from the cohort exposures to higher Cr(VI) levels for shorter periods to an equivalent cumulative exposure of lower intensity and longer duration of interest to OSHA. The study cohorts were mostly smokers but detailed information on their smoking behavior was unavailable. While the risk assessments make some adjustments for the confounding effects of smoking, it is unknown whether the assessments fully account for any interactive effects that smoking and Cr(VI) exposure may have on the carcinogenic action. In any case, OSHA does not have reason to believe the above uncertainties would introduce errors that would result in serious overprediction or underprediction of risk.

OSHA s preliminary estimate of lung cancer risk from a 45 year occupational exposure to Cr(VI) at an 8-hour TWA at the current PEL of 52 $\mu g/m^3$ is 101 to 351 excess deaths per 1000 workers. This range, which is defined by maximum likelihood estimates based on the Gibb and Luippold epidemiological cohorts, is OSHA's best estimate of excess risk; it does not account for uncertainty due to the statistical nature of the analyses, or for other potential sources of uncertainty or bias. The wider range of 62 to 493 per 1000 represents the statistical uncertainty associated with OSHA's excess risk estimate at the current PEL, based on lowest and highest 95% confidence bounds on the maximum likelihood estimates for the two featured data sets. The excess lung cancer risks at alternative 8 hour TWA PELs that were under consideration by the Agency are shown in Table VI–8, together with the uncertainty bounds for the primary and supporting studies at these exposure concentrations. The excess lung cancer risks at alternate 8 hour TWA PELs under consideration by the Agency are shown in Table VI–8. For example, OSHA s best estimate of excess risk from 45 years' exposure at 1 $\mu g/m^3$ Cr(VI) is 2.1 to 4.6 per 1000; an interval of 1.2 − 16 per 1000 represents the statistical uncertainty of OSHA s estimate. The 45-year exposure estimates satisfy the Agency s statutory obligation to consider the risk of material impairment for an employee with regular exposure to the hazardous agent for the period of his working life (29 U.S.C. 651 *et seq.*). Occupational risks from Cr(VI) exposure to less than a full working lifetime are considered in Section VIII on the Significance of Risk and in Section IX. on the Benefits Analysis.

VIII. Significance of Risk

In promulgating health standards, OSHA uses the best available information to evaluate the risk associated with occupational exposures, to determine whether this risk is severe enough to warrant regulatory action, and to determine whether a new or revised rule will substantially reduce this risk. OSHA makes these findings, jointly referred to as the "significant risk determination", based on the requirements of the OSH Act and the Supreme Court's interpretation of the Act in the "benzene" decision of 1980 (*Industrial Union Department, AFL–CIO* v. *American Petroleum Institute,* 448 U.S. 607). The OSH Act directs the Secretary of Labor to

> set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard * * * for the period of his working life [6(b)(5)].

OSHA's authority to promulgate regulations for the cause of worker protection is limited by the requirement that standards be "reasonably necessary and appropriate to provide safe or healthful employment" [3(8)].

In the benzene decision, the Supreme Court's interpretation of Section 3(8)

further defined OSHA's regulatory authority. The Court stated:

> By empowering the Secretary to promulgate standards that are "reasonably necessary or appropriate to provide safe or healthful employment and places of employment," the Act implies that, before promulgating any standard, the Secretary must make a finding that the workplaces in question are not safe (IUD v. API 448 U.S. at 642).

"But 'safe' is not the equivalent of 'risk-free' ", the Court maintained. "[T]he Secretary is required to make a threshold finding that a place of employment is unsafe—in the sense that significant risks are present and can be eliminated or lessened by a change in practices" (*IUD* v. *API* 448 U.S. at 642). It has been Agency practice to establish this finding by estimating risk to workers using quantitative risk assessment, and determining the significance of this risk based on judicial guidance, the language of the OSH Act, and Agency policy considerations.

The Agency has considerable latitude in defining significant risk and in determining the significance of any particular risk. The Court did not stipulate a means to distinguish significant from insignificant risks, but rather instructed OSHA to develop a reasonable approach to the significant risk determination. The Court stated that "it is the Agency's responsibility to determine in the first instance what it considers to be a "significant" risk", and did not express "any opinion on the * * * difficult question of what factual determinations would warrant a conclusion that significant risks are present which make promulgation of a new standard reasonably necessary or appropriate" (448 U.S. at 659). The Court also stated that, while OSHA's significant risk determination should be supported by substantial evidence, the Agency "is not required to support the finding that a significant risk exists with anything approaching scientific certainty". Furthermore, "A reviewing court [is] to give OSHA some leeway where its findings must be made on the frontiers of scientific knowledge [and] * * * the Agency is free to use conservative assumptions in interpreting the data with respect to carcinogens, risking error on the side of overprotection rather than underprotection", so long as such assumptions are based in "a body of reputable scientific thought" (448 U.S. at 655, 656).

To make the significance of risk determination for a new or proposed standard, OSHA uses the best available scientific evidence to identify material health impairments associated with potentially hazardous occupational exposures, and, when possible, to provide a quantitative assessment of exposed workers' risk of these impairments. OSHA has reviewed extensive epidemiological and experimental research pertaining to adverse health effects of occupational Cr(VI) exposure, including lung cancer, and has established preliminary quantitative estimates of the excess lung cancer risk associated with currently allowable Cr(VI) exposure concentrations and the expected impact of the proposed PEL. OSHA has preliminarily determined that long-term exposure at the current PEL causes significant risk to workers' health, and that adoption of the proposed PEL will significantly reduce this risk.

A. Material Impairment of Health

As discussed in Section VI of this preamble, inhalation exposure to Cr(VI) causes a variety of adverse health effects, including lung cancer, nasal septum damage, and asthma. OSHA considers these conditions to be material impairments of health, as they are marked by significant discomfort and long-lasting adverse effects, can have adverse occupational and social consequences, and may in some cases have permanent or potentially life-threatening consequences. Based on this finding and on the scientific evidence linking Cr(VI) inhalation to each of these effects, OSHA concludes that exposure to Cr(VI) causes "material impairment of health or functional capacity" within the meaning of the OSH Act.

OSHA considers lung cancer, an irreversible and frequently fatal disease, to be a clear material impairment of health. OSHA's finding that inhaled Cr(VI) causes lung cancer is based on the best available epidemiological data, reflects substantial evidence from animal and mechanistic research, and is consistent with the conclusions of other government and public health organizations, including NIOSH, EPA, ACGIH, NTP, and IARC (Exs. 35–117; 35–52; 35–158; 17–9–D; 18–3, p. 213). The Agency's primary evidence comes from two epidemiological studies that show significantly increased incidence of lung cancer among workers in the chromate production industry (Exs. 25; 33–10). The high quality of the data collected in these studies and the analyses performed on them has been confirmed by OSHA and by independent peer review. Supporting evidence of Cr(VI) carcinogenicity comes from occupational cohort studies in chromate production, chromate pigment production, and chromium plating, and by cell culture research into the processes by which Cr(VI) disrupts normal gene expression and replication. Studies demonstrating uptake, metabolism, and genotoxicity of a variety of soluble and insoluble Cr(VI) compounds support the Agency's position that all Cr(VI) compounds should be regulated as occupational carcinogens (Exs. 35–148; 35–68; 35–67; 35–66; 12–5; 35–149; 35–134).

While OSHA has relied primarily on the association between Cr(VI) inhalation and lung cancer to demonstrate the necessity of the proposed standard, the Agency has also determined that several other material health impairments can result from exposure to airborne Cr(VI). As shown in several cross-sectional and cohort studies, inhalation of Cr(VI) can cause nasal passage atrophy, ulceration, and septum perforation (Exs. 35–1; 7–3; 9–126; 35–10; 9–18; 3–84; 7–50; 31–22–12). Septum ulcerations are often accompanied by swelling and bleeding, heal slowly, and in some cases may progress to a permanent perforation that can only be repaired surgically. Inhalation of Cr(VI) can also lead to occupational asthma, a potentially life-threatening condition in which workers become allergic to Cr(VI) compounds and experience symptoms such as coughing, wheezing, and difficulty in breathing upon exposure to small amounts of airborne Cr(VI). Several case reports have documented occupational asthma from Cr(VI) exposure, confirming Cr(VI) as the sensitizing agent by bronchial challenge (Exs. 35–7; 35–12; 35–16; 35–21).

B. Risk Assessment

When possible, epidemiological or experimental data and statistical methods are used to characterize the risk of disease that workers may experience under the current PEL, as well as the expected reduction of risk that would occur with implementation of the proposed PEL. The Agency finds that the available epidemiological data are sufficient to support quantitative risk assessment for lung cancer among Cr(VI)-exposed workers. Using the best available studies, OSHA has preliminarily identified a range of expected risk from regular occupational exposure at the current PEL (101–351 excess lung cancer deaths per 1000 workers) and at the proposed PEL of 1 $\mu g/m^3$ (2.1–9.1 per 1000 workers), assuming a working lifetime of 45 years' exposure in each case. These values represent the best estimates of multiple analysts working with data on two extensively studied worker populations,

and are highly consistent across analyses using a variety of modeling techniques and assumptions. While some attempts have been made to assess the relationship between Cr(VI) exposure level and noncancer adverse health effects, the Agency does not believe that a reliable quantitative risk assessment can be performed for noncancer effects at this time, and has therefore characterized noncancer risk qualitatively.

For preliminary estimates of lung cancer risk from Cr(VI) exposure, OSHA has relied upon data from two cohorts of chromate production workers. The Gibb cohort, which originates from a chromate production facility in Baltimore, Maryland, includes 2357 workers who began work between 1950 and 1974 and were followed up through 1992 (Ex. 25). The extensive exposure documentation available for this cohort, the high statistical power afforded by the large cohort size, and the availability of information on individual workers' race and smoking status provide a particularly strong basis for risk analysis. The Luippold cohort, from a facility in Painesville, Ohio, includes 482 workers who began work between 1940 and 1972, worked for at least one year at the plant, and were followed up through 1997 (Ex. 33–10). This cohort also provides a very strong basis for risk analysis, in that it has high-quality documentation of worker Cr(VI) exposure and mortality, a long period of followup, and a large proportion of relatively long-term employees (55% > 5 years).

Risk assessments were performed on the Gibb cohort data by Environ International Corporation (Ex. 33–12), under contract with OSHA; Park *et al.*, as part of an ongoing effort by NIOSH (Ex. 33–13); and Exponent on behalf of the Chrome Coalition (Ex. 31–18–15–1). A variety of statistical models were considered, allowing OSHA to identify the most appropriate models and assess the resulting risk estimates' sensitivity to alternate modeling approaches. Models were tried with additive and relative risk assumptions; various exposure groupings and lag times; linear and nonlinear exposure-response functions; external and internal standardization; reference lung cancer rates from city-, state-, and national-level data; inclusion and exclusion of short-term workers; and a variety of ways to control for the effects of smoking. OSHA's preferred approach, a relative risk model using Baltimore lung cancer reference rates, and NIOSH's preferred approach, a relative risk model using detailed smoking information and U.S. lung cancer reference rates, are among several models that use reasonable assumptions and provide good fits to the data. As discussed in section VII, the Environ, Park *et al.*, and linear Exponent models yield similar predictions of excess risk from exposure at the current and proposed PELs (see Tables VII–3 and VII–4). OSHA's preferred model predicts about 350 excess lung cancers per 1000 workers exposed for a working lifetime of 45 years at the current PEL (MLE 351, 95% CI 181–493) when person-years of exposure are spread evenly across exposure groups (see Table VII–3). Implementation of the proposed PEL is expected to reduce this risk to about 10 excess lung cancers per 1000 workers (MLE 9.1, 95% CI 4–16).

Environ and Crump *et al.* performed risk assessments on the Luippold cohort, exploring additive and relative risk models, linear and quadratic exposure-response functions, and several exposure groupings (Exs. 35–59; 35–58). Additive and relative risk models by both analyst groups fit the data adequately with linear exposure-response. The linear models by all of the analyst groups predicted similar excess risks, from which OSHA has selected preferred estimates based on the Crump *et al.* analysis of about 100 excess lung cancer deaths per 1000 workers exposed for 45 years at the current PEL (MLE 101, 95% CI 62–147), and two excess lung cancer deaths per 1000 workers exposed for 45 years at the proposed PEL (MLE 2.1, 95% CI 1.2–3.1).

The risk assessments performed on the Luippold cohort yield somewhat lower estimates of lung cancer risk than those performed on the Gibb cohort. This discrepancy is probably not due to statistical error in the risk estimates, as the confidence intervals for the estimates do not overlap. The risk estimates based on the Gibb and Luippold cohorts are nonetheless reasonably close. OSHA believes that both cohorts support reasonable estimates of lung cancer risk, and based on their results has selected a representative range of 101–351 per 1000 for 45 years' occupational exposure at the current PEL and 2.1–9.1 per 1000 for 45 years' occupational exposure at the proposed PEL for the significant risk determination. OSHA's confidence in these risk estimates is further strengthened by the results of the independent peer review to which the risk assessment and the primary supporting studies were submitted, which generally supported the Agency's approach and results.

Although nasal damage and asthma are well-established effects of occupational exposure to airborne Cr(VI), OSHA has preliminarily determined that there are no adequate studies to support a quantitative risk assessment for these effects. The Agency has nonetheless made careful use of the best available scientific information in its evaluation of noncancer health risks from occupational Cr(VI) exposure. In lieu of a quantitative analysis linking the risk of noncancer health effects with specific occupational exposure conditions, the Agency has considered information on the extent of these effects and occupational factors affecting risk, as discussed below.

Damage to the nasal mucosa and septum can occur from inhalation of airborne Cr(VI) or transfer of Cr(VI) on workers' hands to the interior of the nose. Epidemiological studies have found varying, but substantial, prevalence of nasal damage among workers exposed to high concentrations of airborne Cr(VI). In the cohort of 2357 chromate production workers studied by Gibb *et al.*, over 60% experienced nasal septum ulcerations at some point during their employment, with half of these workers' first ulcerations occurring within 22 days from the date they were hired (Ex. 31–22–12). The authors found a statistically significant relationship between nasal ulceration and workers' contemporaneous exposures, with about half of the workers who developed ulcerations first diagnosed with ulcerations while employed in a job with average exposure concentrations greater than 20 $\mu g/m^3$. Nasal septum perforations were reported among 17% of the Gibb cohort workers, and appeared to develop over relatively long periods of exposure (median time 172 days from hire date to diagnosis).

Another important study, Lindberg and Hedenstierna's 1983 examination of nasal effects among Swedish chrome platers, characterizes the prevalence of nasal irritation, atrophy, ulceration, and perforation among workers exposed to various concentrations of Cr(VI) (Ex. 9–126). Workers' daily average exposure concentrations were measured as 8-hour averages using personal air samplers, and estimates of workers' peak exposures were derived from 6-hour average concentrations collected with stationary equipment near the chrome electroplating baths. Among 43 workers exposed almost exclusively to Cr(VI), septum ulceration and perforation were not observed among those exposed to peak exposures less than 20 $\mu g/m^3$ or those exposed to 8-hour average concentrations less than 2 $\mu g/m^3$, a result used by the EPA to identify a lowest-observed adverse effect level (LOAEL) for their inhalation reference

concentration (Ex. 35–156). Nasal septum atrophy, a condition that can progress to ulceration and perforation, was observed less frequently among workers with 8-hour mean exposure concentrations less than 2 μg/m³ and those with peak exposures less than 20 μg/m³ than among workers exposed to higher concentrations. It is not clear whether workers who had nasal septum atrophy at these exposure levels eventually developed ulcerations or perforations. Although Lindberg and Hedenstierna's results suggest increasing risk of nasal septum damage with increasing exposure concentrations, there are considerable uncertainties associated with the cross-sectional study design and the possible contribution of hand-to-nose transfer of Cr(VI) to the observed nasal effects.

C. Significance of Risk and Risk Reduction

The Supreme Court's benzene decision of 1980 states that "before he can promulgate any permanent health or safety standard, the Secretary [of Labor] is required to make a threshold finding that a place of employment is unsafe—in the sense that significant risks are present and can be eliminated or lessened by a change in practices" (*IUD* v. *API*, 448 U.S. at 642). The Court broadly describes the range of risks OSHA might determine to be significant:

> It is the Agency's responsibility to determine in the first instance what it considers to be a "significant" risk. Some risks are plainly acceptable and others are plainly unacceptable. If, for example, the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2 percent benzene will be fatal, a reasonable person might well consider the risk significant and take the appropriate steps to decrease or eliminate it. (*IUD* v. *API*,448 U.S. at 655).

The Court further stated, "The requirement that a 'significant' risk be identified is not a mathematical straitjacket * * *. Although the Agency has no duty to calculate the exact probability of harm, it does have an obligation to find that a significant risk is present before it can characterize a place of employment as 'unsafe' and proceed to promulgate a regulation." (*IUD* v. *API*,448 U.S. at 655).

Table VIII–1 presents the estimated excess risk of lung cancer associated with various levels of Cr(VI) exposure allowed under the current rule, based on OSHA's risk assessment and assuming either 20 years' or 45 years' occupational exposure to Cr(VI) as indicated. The purpose of the OSH Act, as stated in Section 6(b), is to ensure "that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard * * * for the period of his working life." 29 U.S.C. 655(b)(5). Taking a 45-year working life from age 20 to age 65, as OSHA has done in significant risk determinations for previous standards, the Agency preliminarily finds an excess lung cancer risk of approximately 100 to 350 per 1000 workers exposed at the current PEL of 52 μg/m³ Cr(VI). This risk is clearly significant, falling well above the level of risk the Supreme Court indicated a reasonable person might consider acceptable. Even assuming only a 20-year working life, the excess risk of about 50 to 200 per 1000 workers is still clearly significant. The proposed PEL of 1 μg/m³ Cr(VI) is expected to reduce these risks substantially, to below 10 excess lung cancers per 1000 workers. However, even at the proposed PEL, the risk posed to workers with a lifetime of regular exposure is still clearly significant.

Table VIII–1.—Expected Excess Lung Cancer Deaths Per 1000 Workers

	Cr(VI) concentratin, μg/m³	*20-year exposure*	*45-year exposure*
Current PEL	52	43–198	101–351
	20	17–83	41–164
	10	9–43	21–86
	5.0	4.3–22	10–45
	2.5	2.1–11	5.3–23
Proposed PEL	1.0	0.85–4.4	2.1–9.1
	0.5	0.43–2.2	1.1–4.6
	0.25	0.21–1.1	0.53–2.3

Workers exposed to lower concentrations of Cr(VI) and for shorter periods of time may also have significant excess cancer risk. OSHA's estimates of risk are therefore proportional to concentration for any given exposure duration; for example, workers exposed for 20 years to 10 μg/m³ Cr(VI) have about ten times the risk of workers exposed for 20 years to 1 μg/m³ Cr(VI). The Agency's risk estimates are also roughly proportional to duration for any given exposure concentration, but not exactly proportional due to competing mortality effects. The estimated risk to workers exposed at any fixed concentration for 10 years is about one-half the risk to workers exposed for 20 years; the risk for five years' exposure is about one-fourth the risk for 20 years. For example, about 11 to 55 out of 1000 workers exposed at the current PEL for five years are expected to die from lung cancer as a result of their exposure. Those exposed to 5 μg/m³ Cr(VI) for 5 years have an estimated excess risk of 1–6 lung cancer deaths per 1000 workers. It is thus not only workers exposed for many years at high levels who have significant cancer risk under the current standard; even workers exposed for shorter periods at levels below the current PEL are at substantial risk, and will benefit from implementation of the proposed PEL.

To further demonstrate significant risk, OSHA compares the risk from currently permissible Cr(VI) exposures to risks found across a broad variety of occupations. The Agency has used similar occupational risk comparisons in the significant risk determination for substance-specific standards promulgated since the benzene decision. This approach is supported by evidence in the legislative record that Congress intended the Agency to regulate unacceptably severe occupational hazards, and not "to establish a utopia free from any hazards"(116 Cong. Rec. 37614 (1970), Leg. Hist 480), or to address risks comparable to those that exist in virtually any occupation or workplace. It is also consistent with Section 6(g) of the OSH Act, which states: "In

determining the priority for establishing standards under this section, the Secretary shall give due regard to the urgency of the need for mandatory safety and health standards for particular industries, trades, crafts, occupations, businesses, workplaces or work environments."

Fatal injury rates for most U.S. industries and occupations may be obtained from data collected by the Bureau of Labor Statistics. Table VIII–2 shows average annual fatality rates per 1000 employees for several industries between 1992 and 2001, as well as projected fatalities per 1000 employees for periods of 20 and 45 years based on these annual rates (Ex. 35–305). While it is difficult to compare aggregate fatality rates meaningfully to the risks estimated in the quantitative risk assessment for Cr(VI), which target one specific hazard (inhalation exposure to Cr(VI)) and health outcome (lung cancer), these rates provide a useful frame of reference for considering risk from Cr(VI) inhalation. For example, OSHA's best estimate of excess lung cancer deaths per 1000 workers from regular occupational exposure to Cr(VI) in the range of 2.5–5 μg/m³ is roughly comparable to the average number of fatal injuries in high-risk occupations such as mining, assuming the same duration of employment (*see* Table VIII–1). Regular exposures at higher levels, including the current PEL of 52 μg/m³ Cr(VI), are expected to cause substantially more deaths per 1000 workers from lung cancer than result from occupational injuries in most private industry. At the proposed PEL of 1 μg/m³ Cr(VI) the Agency's estimate of excess lung cancer mortality falls much closer to the private industry average fatal injury rate, given the same employment time, but still exceeds the rates found in lower-risk industries such as finance and health services.

Table VIII–2.—Fatal Inuries per 1000 Employees, by Industry

	Over 1 year	*Over 20 years*	*Over 45 years*
All Private Industry	0.06	1.1	2.5
Coal Mining	0.41	8.3	18.6
Mining (General)	0.27	5.5	12.3
Construction	0.19	3.9	8.7
Manufacturing	0.04	0.8	1.8
Wholesale Trade	0.04	0.8	1.7
Retail Trade	0.03	0.6	1.4
Finance, Insurance, and Real Estate	0.02	0.3	0.7
Health Services	0.01	0.2	0.4

Because there is little available information on the incidence of occupational cancer, risk from Cr(VI) exposure cannot be compared with overall risk from other workplace carcinogens. However, OSHA's previous risk assessments provide estimates of risk from exposure to certain carcinogens. These risk assessments, like the current assessment for Cr(VI), were based on animal or human data of reasonable or high quality and used the best information then available. Table VIII–3 shows the Agency's best estimates of cancer risk from 45 years' occupational exposure to several carcinogens, as published in the preambles to final rules promulgated since the benzene decision in 1980.

Table VIII–3.—Selected OSHA Risk Estimates (Excess Cancers per 1000 Workers)

Standard	*Risk at prior PEL*	*Risk at current PEL*	*Federal Register date*
Ethylene Oxide	63–109 per 1000	1.2–2.3 per 1000	June 22, 1984.
Asbestos	64 per 1000	6.7 per 1000	June 20, 1986.
Benzene	95 per 1000	10 per 1000	September 11, 1987.
Formaldehyde	0.4–6.2 per 1000	.0056 per 1000	December 4, 1987.
Formaldehyde	*.0056 per 1000	*<.0056 per 1000	May 27, 1992.
Methylenedianiline	**6–30 per 1000	0.8 per 1000	August 10, 1992.
Cadmium	58–157 per 1000	3–15 per 1000	September 14, 1992.
1,3-Butadiene	11.2–59.4 per 1000	1.3–8.1 per 1000	November 4, 1996.
Methylene Chloride	126 per 1000	3.6 per 1000	January 10, 1997.
Chromium VI		106–351 per 1000	October 2004

*From information in December 4, 1987 **Federal Register.**
**No prior standard; reported risk is based on estimated exposures at the time of the rulemaking.

At 106–351 excess lung cancer deaths per 1000 workers, the estimated risk from lifetime occupational exposure to Cr(VI) at the current PEL is much higher than the estimated risk from permissible exposures to other workplace carcinogens for which OSHA has performed risk assessments (Table VIII–3, "Risk at Current PEL"). The Cr(VI) risk estimate is also higher than many risks the Agency has found to be significant in previous rules (Table VIII–3, "Risk at Prior PEL"). The estimated risk from lifetime occupational exposure to Cr(VI) at the proposed PEL is 2.2–9.1 excess lung cancer deaths per 1000 workers, a range comparable to the risks from other carcinogenic exposures remaining under recent rules (Table VIII–3, "Risk at Current PEL").

Based on the results of the quantitative risk assessment, the Supreme Court's guidance on acceptable risk, comparison with rates of occupational fatality in various industries, and comparison with cancer risk estimates developed in previous rules, OSHA preliminarily finds that the risk of lung cancer posed to workers under currently permissible levels of occupational Cr(VI) exposure is significant. The proposed PEL of 1 μg/m³ is expected to significantly reduce risks to workers in Cr(VI)-exposed occupations. OSHA additionally finds that nasal septum ulceration and

perforation can occur with significant frequency and seriousness in exposure conditions allowed by the current rule. The proposed reduction of the Cr(VI) PEL from 52 μg/m³ to 1 μg/m³ is expected to substantially reduce or eliminate workers' risk of these adverse health effects.

IX. Summary of the Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis

A. Introduction

OSHA's Preliminary Economic and Initial Regulatory Flexibility Analysis (PEA) addresses issues related to the costs, benefits, technological and economic feasibility, and the economic impacts (including small business impacts) of the Agency's Occupational Exposure to Hexavalent Chromium rule. The full Preliminary Economic and Regulatory Flexibility Analysis has been placed in the docket as Ex. 35–391. The analysis also evaluates regulatory alternatives to the proposed rule. This rule is an economically significant rule under 3(f)(1) of Executive Order 12866 and has been reviewed by the Office of Information and Regulatory Affairs in the Office of Management and Budget, as required by executive order.

The purpose of this Preliminary Economic and Regulatory Flexibility Analysis is to:

- Identify the establishments and industries potentially affected by the proposed rule;
- Estimate current exposures and the technologically feasible methods of controlling these exposures;
- Estimate the benefits of the rule in terms of the reduction in lung cancer and dermatoses employers will achieve by coming into compliance with the standard;
- Evaluate the costs and economic impacts that establishments in the regulated community will incur to achieve compliance with the proposed standard;
- Assess the economic feasibility of the rule for affected industries; and
- Evaluate the principal regulatory alternatives to the proposed rule that OSHA has considered.

The Full Preliminary Economic Analysis contains the following chapters:

Chapter I. Introduction
Chapter II. Industrial Profile
Chapter III.Technological Feasibility
Chapter IV. Costs of Compliance
Chapter V. Economic Impacts
Chapter VI. Benefits and Net Benefits
Chapter VII. Regulatory Flexibility Analysis
Chapter VIII. Environmental Impacts
Chapter IX. Non Regulatory Alternatives.

These chapters are summarized in sections B to G of this Preamble summary.

B. Introduction and Industrial Profile (Chapters I and II)

The proposed standard for occupational exposure to hexavalent chromium was developed by OSHA in response to evidence that occupational exposure to Cr(VI) poses a significant risk of lung cancer, nasal septum ulcerations and perforations and dermatoses. Exposure to Cr(VI) can also lead to asthma. To protect exposed workers from these effects, OSHA has set a Permissible Exposure Limit (PEL) of 1 μg/m³ measured as an 8-hour time weighted average. OSHA has also examined alternative PELs ranging from 20 μg/m³ to 0.25 μg/m³ measured as 8-hour time weighted averages.

OSHA's proposed standards for occupational exposure to Cr(VI) are similar in format and content to other OSHA health standards promulgated under Section 6(b)(5) of the Act. In addition to setting PELS, the proposal requires employers to:

- Monitor the exposure of employees (except in shipyards and construction);
- Establish regulated areas when exposures may reasonably be expected to exceed the PEL (except in shipyards and constructions);
- Implement engineering and work practice controls to reduce employee exposures to Cr(VI);
- Provide respiratory protection to supplement engineering and work practice controls where they are not feasible, where such controls are insufficient to meet the PELS, or in emergencies;
- Provide other protective clothing and equipment as necessary for dermal protection;
- Make industrial hygiene facilities (hand washing stations) available in some situations;
- Provide medical surveillance when employees are exposed above the PEL in general industry (In the shipyard and construction sectors, medical exposure is only required for signs or symptoms of Cr(VI) related disease);
- Train workers about the hazards of Cr(VI) (including elements already required by OSHA's Hazard Communication Standard); and
- Keep records related to the standard.

The contents of the standards, and the reasons for proposing the separate standards for general industry, construction and shipyard employment, are more fully discussed the Summary and Explanation Section of this Preamble.

Chapter II of the full PEA describes the uses of Cr(VI) and the industries in which such uses occur. Employee exposures are defined in terms of "application groups," i.e., groups of firms where employees are exposed to Cr(VI) when performing a particular function. This methodology is appropriate to exposure to Cr(VI) where a widely used chemical like chromium may lead to exposures in many kinds of firms in many industries, but the processes used, exposures generated, and controls needed to achieve compliance may be the same. For example, because a given type of welding produces Cr(VI) exposures that are essentially the same regardless of whether the welding occurs in a ship, on a construction site, as part of a manufacturing process, or as part of a repair process, it is appropriate to analyze such processes as a group. However, OSHA's analysis of costs and economic feasibility reflect the fact that baseline controls, ease of implementing ancillary provisions, and the economic situation of the employer may differ within different industries in an application group. One complication with the use of the application group concept is that some firms may have exposures in two or more different application groups. For example, a large transportation equipment company may engage in chromium electroplating, painting with paints that use chromium pigments, and welding of metal containing chromium.

The most common reasons to encounter occupational exposure to Cr(VI), in addition to the production and use of chromium metal and chromium metal alloys, are chromium electroplating; welding of metals containing chromium, such as stainless steel or other high chromium steels, or with chromium coatings; the production and use of Cr(VI) containing compounds, particularly Cr(VI) pigments, but also Cr(VI) catalysts, chromic acid, and the production of chromium-containing pesticides.

Some industries are seeing sharp declines in chromium use. However, many of the industries that are seeing a sharp decline have either a small number of employees or have low exposure levels (*e.g.*, Wood Working, Printing Ink Manufacturers, and Printing). In the case of lead chromate in Pigment Production, OSHA's sources indicate that there is no longer domestic output containing lead chromates. Therefore, this trend has been recognized in the PEA. Painting activities in General Industry primarily

involve the application of strontium chromate coatings to aerospace parts; these exposures are likely to continue into the foreseeable future. Similarly, removal of lead chromate in Construction and Maritime is likely to present occupational risks for many years.

In application groups where exposures are particularly significant, both in terms of workforce size and exposure levels—notably in electroplating and welding—OSHA anticipates very little decline in exposures to hexavalent chromium due to the low potential for substitution in the foreseeable future.

Table IX–1 shows the application groups analyzed in OSHA's PEA, as well as the principle industries in each application group, and for each provides the number of establishments affected, the number of employees working in those establishments, the number of entities (firms or governments) fitting SBA's small business criteria for the industry, and the number of employees in those firms. (The table shows data for both establishments, and entities–defined as firms or governments. An entity may own more than one establishment.) The table also shows the revenues of affected establishment and entities. (This table provides the latest available data at the time this analysis was produced. However, since the analysis was produced, there have been changes to some of the affected industries. OSHA will continue to incorporate more recent data as it becomes available.) As shown in the table, there are a total of 38,000 to 55,000 establishments, depending on the degree of overlap between application groups in some industries, affected by the proposed standard.

Table IX-1. Characteristics of Industries and Application Groups Affected by OSHA's Proposed Standard for Hexavalent Chromium

	Industry or Application Group	NAICS	Category	SBA Small Business Classification (Limit for revenues or employment)[A]		Affected Entities[B]		Affected Establishments[B]			
						Small Business or Government Entities	Total	< 20 Employees	≥ 20 Employees	Small Businesses	Total
1	Electroplating - General Industry	All General Industry		500 employees	[B]	2,781	3,015	1,477	2,021	2,969	3,498
		331		500 employees	[C]	98	106	56	59	90	115
		332812	Metal Coating, Engraving (Except Jewelry and Silverware), and Allied Services to Manufacturers	500 employees		722	792	119	807	838	928
		332813	Electroplating, Plating, Polishing, Anodizing, and Coloring	500 employees		1,153	1,172	770	457	1,203	1,227
		332 (Other)	Fabricated Metal Product Manufacturing	500 employees	[D]	268	328	275	252	279	527
		333	Machinery Manufacturing	500 employees	[E]	138	144	94	65	140	159
		338 (except 33661)	Transportation Equipment Manufacturing	1,000 employees	[F]	213	263	72	232	223	304
		339	Miscellaneous Manufacturing	500 employees		108	109	18	100	117	118
		Other General Industry			[G]	81	101	73	49	70	122
	Total Electroplating					2,781	3,015	1,477	2,021	2,960	3,498
2A	Welding - General Industry	31-33	Manufacturing		[H]	14,566	15,018	9,112	8,132	15,274	17,244
2B	Welding - Maritime Industry	336611	Ship Building and Repairing	1,000 employees	[I]	261	279	111	196	278	307
2C	Welding - Construction Industry	233[Z], 234[AA],235[BB]	Building, Developing, and General Contracting; Heavy Construction; Special Trade Contractors	$28.5 million	[J]	2,394	2,419	2,220	277	2,410	2,497
2D	Welding - Government	999200	State	50,000 population		0	26	0	26	0	26
		999300	Local	50,000 population		231	815	0	815	231	815
	Total Welding					17,452	18,555	11,443	9,448	18,191	20,889
3A	Painting - General Industry	31-33	Manufacturing								
		332812	Metal Coating, Engraving (Except Jewelry and Silverware), and Allied Services to Manufacturers	500 employees		82	82	43	73	118	118
		336411, 336414, 336415, 336419, 336992	Transportation Equipment Manufacturing	1,000 employees	[K]	68	73	42	72	78	114
3B	Painting - Maritime Industry	33661	Ship and Boat Building	1,000 employees	[L]	781	791	555	321	808	878
3C	Painting - Construction Industry	234[AA],235[BB]	Heavy Construction, Special Trade Contractors	$28.5 million		8,343	8,440	5,524	1,055	6,482	8,579
		234[AA]	Heavy Construction	$28.5 million						944	
		235[BB]	Special Trade Contractors	$12.0 million						5,538	
3D	Painting - Government	999200	State	50,000 population		0	26	0	26	0	26
		999300	Local	50,000 population		628	1,439	0	1,439	828	1,439
	Total Painting					7,902	8,851	8,164	2,988	14,594	9,150

Table IX-1. Characteristics of Industries and Application Groups Affected by OSHA's Proposed Standard for Hexavalent Chromium

				Affected Employees[II]		Revenues ($)[JJ]			Revenues per Entity ($)		
	Industry or Application Group	NAICS	Category	Small Business or Government Entities	Total	Small Business or Government Entities	Establishments with < 20 Employees	Total	Small Business or Government Entities	Establishments with < 20 Employees	Total
1	Electroplating - General Industry	All General Industry		25,479	33,592	$21,324,663,027	$2,458,040,049	$26,502,032,675	$7,723,529	$1,662,857	$8,790,081
		331		977	1,543	$1,937,012,146	$89,629,709	$3,043,112,348	$19,765,430	$1,600,531	$28,708,607
		332812	Metal Coating, Engraving (Except Jewelry and Silverware), and Allied Services to Manufacturers	7,759	8,817	$4,471,294,171	$74,666,885	$4,991,006,612	$8,192,926	$827,453	$8,301,778
		332813	Electroplating, Plating, Polishing, Anodizing, and Coloring	10,594	11,684	$1,710,129,336	$300,217,773	$1,770,100,469	$1,483,200	$389,893	$1,510,325
		332 (Other)	Fabricated Metal Product Manufacturing	1,859	5,433	$1,340,621,777	$297,490,267	$3,762,522,743	$5,002,320	$1,081,783	$11,471,106
		333	Machinery Manufacturing	698	1,155	$1,452,685,721	$140,996,999	$1,627,894,399	$10,528,157	$1,499,968	$12,893,711
		336 (except 33661)	Transportation Equipment Manufacturing	2,135	3,215	$26,521,611,237	$232,407,315	$39,851,510,652	$124,514,607	$3,227,679	$151,526,856
		339	Miscellaneous Manufacturing	917	1,037	$2,314,796,502	$21,214,996	$2,585,030,049	$21,433,301	$1,176,611	$23,715,672
		Other General Industry		340	708	$233,265,779	$127,461,076	$485,072,072	$3,624,029	$1,746,042	$4,802,894
	Total Electroplating			25,479	33,592	$39,981,616,668	$1,284,065,021	$58,316,249,364	$14,460,848	$869,387	$19,342,040
2A	Welding - General Industry	31-33	Manufacturing	40,779	45,326	$108,500,153,472	$8,351,326,981	$120,718,959,291	$7,448,864	$916,520	$8,039,222
2B	Welding - Maritime Industry	336611	Ship Building and Repairing	4,082	4,720	$6,599,192,787	$135,596,427	$10,071,786,544	$32,947,099	$1,221,589	$36,099,593
2C	Welding - Construction Industry	233[Z], 234[AA],235[BB]	Building, Developing, and General Contracting; Heavy Construction; Special Trade Contractors	53,837	60,450	$5,692,029,178	$2,187,657,249	$8,354,044,489	$2,377,623	$985,431	$2,826,724
2D	Welding - Government	999200	State	0	126	$0	N/A	$336,658,634,000	N/A	N/A	$12,956,109,000
		999300	Local	231	615	$847,770,000	N/A	$64,736,832,720	$3,670,000	N/A	$79,431,697
	Total Welding			98,909	111,439	$123,639,145,437	$10,874,582,657	$538,738,457,044	$7,084,526	$932,846	$29,034,678
3A	Painting - General Industry	31-33	Manufacturing								
		332812	Metal Coating, Engraving (Except Jewelry and Silverware), and Allied Services to Manufacturers	6,817	8,617	$464,316,049	$32,039,306	$464,316,049	$5,662,391	$745,100	$5,662,391
		336411, 336414, 336415, 336419, 336992	Transportation Equipment Manufacturing	670	1,297	$15,348,456,496	$264,105,530	$29,829,873,691	$225,712,596	$6,288,227	$405,885,941
3B	Painting - Maritime Industry	33661	Ship and Boat Building	2,506	3,155	$14,344,823,950	$677,982,136	$18,951,028,194	$16,367,252	$1,221,589	$21,429,671
3C	Painting - Construction Industry	234[AA],235[BB]	Heavy Construction, Special Trade Contractors	29,956	32,608	$11,616,107,029	$2,874,735,626	$12,501,994,459	$1,831,327	$484,203	$1,941,303
		234[AA]	Heavy Construction			$9,027,356,999		$9,425,998,657			
		235[BB]	Special Trade Contractors			$2,063,201,175		$2,269,442,385			
									N/A	N/A	$12,958,109,000
3D	Painting - Government	999200	State	0	1,535	$0	N/A	$338,858,834,000	$3,670,000	N/A	$83,257,411
		999300	Local	1,678	6,813	$2,304,760,000	N/A	$91,027,413,680	$6,981,653	$591,963	$58,392,351
	Total Painting			41,827	52,025	$55,169,021,699	$3,848,662,798	$499,128,701,514			

Table IX-1. Characteristics of Industries and Application Groups Affected by OSHA's Proposed Standard for Hexavalent Chromium

	Industry or Application Group	NAICS	Category	SBA Small Business Classification (Limit for revenues or employment)[A]	Affected Entities[B]		Affected Establishments[B]			
					Small Business or Government Entities	Total	< 20 Employees	≥ 20 Employees	Small Businesses	Total
4	Chromate (Chromite Ore Production)	325188	All Other Basic Inorganic Chemical Mfg.	1,000 employees	0	1	0	2	0	2
5	Chromate Pigment Producers	325131	Inorganic Dye and Pigment Mfg.	1,000 employees	2	3	1	2	2	3
6	Chromated Copper Arsenate Producers	325320	Pesticide and Other Agricultural Chemical Mfg.	500 employees	3	3	0	3	3	3
7	Chromium Catalyst Producers	325188	All Other Basic Inorganic Chemical Mfg.	1,000 employees	3	3	0	5	5	5
8	Paint and Coatings Producers	325510	Paint and Coating Mfg.	500 employees	165	174	132	84	180	216
9	Printing Ink Producers	325910	Printing Ink Mfg.	500 employees	6	9	10	3	9	13
10	Plastic Colorant Producers and Users	325211	Plastics Material and Resin Mfg.	500 employees	96	104	45	92	100	137
		325991	Custom Compounding of Purchased Resin	500 employees						
		3261	Plastic Product Mfg.	500 employees [M]						
11	Plating Mixture Producers	325998	All Other Miscellaneous Chemical Product and Preparation Mfg.	500 employees	10	10	4	8	10	10
12	Wood Preserving	321114	Wood Preservation	500 employees	N/A	N/A	N/A	N/A	N/A	N/A
13	Chromium Metal Producers	331112	Electrometallurgical Ferroalloy Product Mfg.	750 employees	0	1	0	1	0	1
14	Steel Mills	331111	Iron and Steel Mills	1,000 employees	48	54	17	53	49	70
15	Iron and Steel foundries	3315	Iron foundries	500 employees	278	306	144	198	289	342
		331512	Steel investment foundries	500 employees						
		331513	Steel foundries (except investment)	500 employees						
16	Chromium Dioxide Producers	325188	All Other Inorganic Chemicals, n.e.c.	1,000 employees	N/A	N/A	N/A	N/A	N/A	N/A
17	Chromium Dye Producers	3251317	Chrome Colors and Other Inorganic Pigments	1,000 employees	3	3	1	3	4	4
18	Chromium Sulfate Producers	325188	All Other Inorganic Chemicals, n.e.c.	1,000 employees	2	3	5	0	2	5

Table IX-1. Characteristics of Industries and Application Groups Affected by OSHA's Proposed Standard for Hexavalent Chromium

				Affected Employees[a]		Revenues ($)[b]			Revenues per Entity ($)		
	Industry or Application Group	NAICS	Category	Small Business or Government Entities	Total	Small Business or Government Entities	Establishments with < 20 Employees	Total	Small Business or Government Entities	Establishments with < 20 Employees	Total
4	Chromate (Chromite Ore Production)	325188	All Other Basic Inorganic Chemical Mfg.	0	150	$0	$0	$114,000,000	N/A	N/A	$114,000,000
5	Chromate Pigment Producers	325131	Inorganic Dye and Pigment Mfg.	50	52	$155,766,777	$2,197,133	$157,963,909	$77,883,388	$2,197,133	$52,654,636
6	Chromated Copper Arsenate Producers	325320	Pesticide and Other Agricultural Chemical Mfg.	27	27	$76,632,194	$0	$76,632,194	$26,210,731	N/A	$26,210,731
7	Chromium Catalyst Producers	325188	All Other Basic Inorganic Chemical Mfg.	313	313	$280,072,617	$0	$280,072,617	$93,357,606	N/A	$93,357,606
8	Paint and Coatings Producers	325510	Paint and Coating Mfg.	1,779	2,569	$2,795,429,904	$440,533,212	$3,899,407,813	$16,941,999	$3,337,373	$22,410,389
9	Printing Ink Producers	325910	Printing Ink Mfg.	77	112	$95,077,283	$51,943,618	$140,018,733	$15,846,214	$5,194,382	$15,557,637
10	Plastic Colorant Producers and Users	325211 325991 3261	Plastics Material and Resin Mfg. Custom Compounding of Purchased Resin Plastic Product Mfg.	303	492	$849,604,409	$46,926,948	$1,346,164,556	$6,852,129	$1,042,666	$12,943,890
11	Plating Mixture Producers	325998	All Other Miscellaneous Chemical Product and Preparation Mfg.	49	118	$312,210,037	$17,540,363	$744,813,779	$31,221,004	$4,385,091	$74,481,376
12	Wood Preserving	321114	Wood Preservation	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
13	Chromium Metal Producers	331112	Electrometallurgical Ferroalloy Product Mfg.	0	63	$0	$0	$72,676,523	N/A	N/A	$72,676,523
14	Steel Mills	331111	Iron and Steel Mills	3,182	5,205	$6,184,955,092	$35,620,837	$13,532,955,897	$170,519,898	$2,095,343	$250,610,291
15	Iron and Steel foundries	3315 331512 331513	Iron foundries Steel Investment foundries Steel foundries (except investment)	23,461	30,222	$3,751,280,407	$104,926,176	$4,922,922,329	$13,493,814	$728,668	$16,087,981
16	Chromium Dioxide Producers	325188	All Other Inorganic Chemicals, n.e.c.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
17	Chromium Dye Producers	3251317	Chrome Colors and Other Inorganic Pigments	104	104	$235,671,033	$2,185,058	$235,671,033	$78,623,678	$2,185,058	$76,623,678
18	Chromium Sulfate Producers	325188	All Other Inorganic Chemicals, n.e.c	4	11	$5,798,347	$14,495,866	$14,495,866	$2,899,173	$2,899,173	$4,831,955

Table IX-1. Characteristics of Industries and Application Groups Affected by OSHA's Proposed Standard for Hexavalent Chromium

	Industry or Application Group	NAICS	Category	SBA Small Business Classification (Limit for revenues or employment)[A]	Affected Entities[B]		Affected Establishments[B]			
					Small Business or Government Entities	Total	< 20 Employees	≥ 20 Employees	Small Businesses	Total
19	Chemical Distributors	42269[CC]	Other Chemical and Allied Products	100 employees	1,228	1,258	1,577	209	1,568	1,786
20	Textile Dyeing	313	Textile Mills	500 employees [N]	992	1,026	759	374	1,030	1,133
		314	Textile Product Mills	500 employees [O]						
21	Colored Glass Producers	3272123	Other Pressed and Blown Glass and Glassware Mfg.	750 employees	22	23	19	6	22	25
		3272129	Other Pressed and Blown Glass and Glassware Mfg.	750 employees						
22	Printing	32311	Printing Ink Mfg.	500 employees	490	495	400	100	493	500
		323113	Commercial Screen Printing\	500 employees						
23	Leather Tanning	3161	Leather and Hide Tanning and Finishing	500 employees [P]	N/A	N/A	N/A	N/A	N/A	N/A
24	Chromium Catalyst Users	325110	Petrochemical Mfg., Including Styrene	1,000 employees	33	71	0	183	44	183
		325120	Industrial Gas Mfg., Including Hydrogen and Ammonia Gas	1,000 employees						
		325211	Plastics Materials, Synthetic Resins, and Nonvulcanizable Elastomers, Including Polyethylene	750 employees						
		325199	Industrial Inorganic Chemicals, Not Otherwise Classified, Including Butadiene and Methanol	1000 employees						
24A	Chromium Catalyst Users - Service Companies	561790	Other Services to Buildings and Dwellings, Including Catalyst handling	$6 million	5	11	4	21	6	25
	Total Chromium Catalyst Users				38	82	4	184	50	186
25	Refractory Brick Producers	327125	Nonclay Refractory Mfg.	750 employees	1	8	0	8	1	8
26A	Wood Working -General Industry	321	General Industry	500 employees	203	219	100	167	238	267
26B	Wood Working - Maritime Industry	336611	Ship Building and Repairing	1,000 employees [Q]	48	64	37	42	52	79
26C	Wood Working - Construction Industry	2332[DD], 2333[EE], 2349[FF], 23551[GG]	Construction	$26.5 million [R]	7,217	7,285	5,960	1,489	7,304	7,449
26D	Wood Working - Government	999200	State	50,000 population	0	26	0	26	0	26
		999300	Local	50,000 population	27	94	0	94	27	94
	Total Wood Working				7,495	7,688	8,097	1,838	7,619	7,935

Table IX-1. Characteristics of Industries and Application Groups Affected by OSHA's Proposed Standard for Hexavalent Chromium

				Affected Employees[a]		Revenues ($)[b]			Revenues per Entity ($)		
	Industry or Application Group	NAICS	Category	Small Business or Government Entities	Total	Small Business or Government Entities	Establishments with < 20 Employees	Total	Small Business or Government Entities	Establishments with < 20 Employees	Total
19	Chemical Distributors	42269[cc]	Other Chemical and Allied Products	2,917	3,572	$4,806,227,832	$2,194,757,331	$5,670,907,660	$3,913,866	$1,391,729	$4,666,658
20	Textile Dyeing	313 314	Textile Mills Textile Product Mills	19,798	25,341	$5,005,894,765	$423,916,784	$8,386,454,435	$5,046,265	$558,520	$8,224,614
21	Colored Glass Producers	3272123	Other Pressed and Blown Glass and Glasssware Mfg.	154	295	$190,209,506	$17,256,484	$383,162,528	$8,645,667	$906,236	$15,769,675
		3272129	Other Pressed and Blown Glass and Glasssware Mfg.								
22	Printing	32311	Printing Ink Mfg.	6,269	6,600	$384,050,231	$98,720,864	$402,525,299	$783,778	$246,802	$813,182
		323113	Commercial Screen Printing\								
23	Leather Tanning	3161	Leather and Hide Tanning and Finishing	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
24	Chromium Catalyst Users	325110	Petrochemical Mfg., Including Styrene	65	243	$4,267,606,002	N/A	$15,809,540,416	$129,321,394	N/A	$222,669,583
		325120	Industrial Gas Mfg., Including Hydrogen and Ammonia Gas								
		325211	Plastics Materials, Synthetic Resins, and Nonvulcanizable Elastomers, Including Polyethylene								
		325199	Industrial Inorganic Chemicals, Not Otherwise Classified, Including Butadiene and Methanol								
24A	Chromium Catalyst Users - Service Companies	561790	Other Services to Buildings and Dwellings, Including Catalyst handling	121	707	$7,307,698	$3,825,078	$42,292,582	$1,481,540	$906,270	$3,844,780
	Total Chromium Catalyst Users			186	950	$4,274,913,700	$3,825,078	$15,851,833,000	$112,497,729	$906,270	$193,315,037
25	Refractory Brick Producers	327125	Nonclay Refractory Mfg.	15	90	$49,494,145	N/A	$296,964,870	$49,494,145	N/A	$49,494,145
26A	Wood Working -General Industry	321	General Industry	320	388	$1,389,573,470	$113,191,992	$1,717,809,321	$6,746,667	$1,131,920	$7,843,678
26B	Wood Working - Maritime Industry	336611	Ship Building and Repairing	261	319	$1,844,559,942	$45,198,809	$2,174,382,406	$38,426,332	$1,221,589	$33,974,725
26C	Wood Working - Construction Industry	2332[DD], 2333[EE], 2349[FF], 23551[GG]	Construction	12,947	13,952	$52,803,055,536	$10,242,955,458	$58,935,013,853	$7,318,483	$1,718,617	$7,615,378
26D	Wood Working - Government	999200	State	0	27	$0	N/A	$338,858,834,000	N/A	N/A	$12,958,109,000
		999300	Local	27	94	$99,060,000	N/A	$7,428,628 360	$3,670,000	N/A	$79,030,089
	Total Wood Working			13,555	14,780	$56,116,278,949	$10,401,346,259	$405,114,667,940	$7,487,182	N/A	$52,694,442

Table IX-1. Characteristics of Industries and Application Groups Affected by OSHA's Proposed Standard for Hexavalent Chromium

Industry or Application Group		NAICS	Category	SBA Small Business Classification (Limit for revenues or employment)[A]	Affected Entities[B]		Affected Establishments[B]			
					Small Business or Government Entities	Total	< 20 Employees	≥ 20 Employees	Small Businesses	Total
27	Solid Waste Incineration	562213	Solid Waste Combustors and Incinerators	$10.5 million	87	97	66	55	70	121
27A	Solid Waste Incineration - govt	999300	Local	50,000 population	0	33	0	33	0	33
	Total Incineration				87	130	66	88	70	154
28	Oil and Gas Well Drilling	213111	Drilling Oil and Gas Wells	500 employees	N/A	N/A	N/A	N/A	N/A	N/A
29	Portland Cement Producers	327310	Cement Mfg.	750 employees	141	178	130	138	156	268
30	Superalloy Producers	331492	Secondary Smelting, Refining and Alloying of Nonferrous Metal	750 employees	1	11	0	18	1	18
		331528	Other Nonferrous Foundries	500 employees						
31B	Construction - Refractory Brick Restoration and Maintenance	235[BB]	Special Trade Contractors	$12.0 million	180	182	166	18	182	184
31C	Construction - Hazardous Waste Site Work	2333[EE]	Nonresidential Building Construction	$28.5 million	201	203	181	49	204	210
31CG	Hazardous Waste Site Work - Government	999200	State	50,000 population	0	1	0	1	0	1
		999300	Local	50,000 population	64	228	0	228	84	228
31D	Construction - Industrial Rehabilitation and Maintenance	23493[HH]	Industrial Nonbuilding Structure Construction	$28.5 million	231	235	221	62	240	283
31DG	Industrial Rehabilitation and Maintenance - Government	999200	State	50,000 population	0	18	0	18	0	18
		999300	Local	50,000 population	24	83	0	83	24	83
	Total Construction				700	948	548	457	714	1,005
32	Precast Concrete Products Producers	327331, 327332, 327390	Concrete Pipe, Brick, and Block Mfg	500 employees	2,813	2,929	2,303	1,400	3,286	3,703
	Total – All Affected Entities				32,783	34,552	23,487	14,904	34,297	38,391

Note: Total affected entities, establishments, employees, and revenues were estimated by adding entities (establishments, etc.) from each industry segment calculated by the following method:

General Industry = general industry welding entities + 1/2 (remaining general industry entities)
Maritime = maritime painting entities + 1/2 (remaining maritime entities)
Construction = construction woodworking entities + 1/2 (remaining construction entities)
Government = government painting entities

Table IX-1. Characteristics of Industries and Application Groups Affected by OSHA's Proposed Standard for Hexavalent Chromium

	Industry or Application Group	NAICS	Category	Affected Employees[a]		Revenues ($)[b]			Revenues per Entity ($)		
				Small Business or Government Entities	Total	Small Business or Government Entities	Establishments with < 20 Employees	Total	Small Business or Government Entities	Establishments with < 20 Employees	Total
27	Solid Waste Incineration	562213	Solid Waste Combustors and Incinerators	682	2,285	$256,063,699	$112,006,353	$1,283,887,789	$3,821,848	$1,697,066	$13,235,956
27A	Solid Waste Incineration - govt	999300	Local	0	106	$0	N/A	$3,610,169,640	N/A	N/A	$109,399,080
	Total Incineration			682	2,391	$256,063,699	$112,006,353	$4,894,057,409	$3,821,848		$37,648,595
28	Oil and Gas Well Drilling	213111	Drilling Oil and Gas Wells	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
29	Portland Cement Producers	327310	Cement Mfg.	4,844	12,836	$2,346,722,985	$339,217,713	$5,953,218,570	$18,857,810	$2,609,367	$33,445,048
30	Superalloy Producers	331492	Secondary Smelting, Refining and Alloying of Nonferrous Metal	121	2,164	$26,787,791	N/A	$482,180,241	$26,787,791	N/A	$43,834,567
		331528	Other Nonferrous Foundries								
31B	Construction - Refractory Brick Restoration and Maintenance	235[BB]	Special Trade Contractors	387	392	$175,281,510	$79,407,856	$187,265,718	$973,786	$478,361	$1,040,365
31C	Construction - Hazardous Waste Site Work	2333[EE]	Nonresidential Building Construction	1,111	1,213	$928,919,198	$196,411,140	$1,013,517,325	$4,621,489	$1,219,945	$5,042,375
31CG	Hazardous Waste Site Work - Government	999200	State	0	2	$0	N/A	$12,956,109,000	N/A	N/A	$12,956,109,000
		999300	Local	192	877	$234,880,000	N/A	$17,957,530,980	$3,870,000	N/A	$79,458,102
31D	Construction - Industrial Rehabilitation and Maintenance	23493[HH]	Industrial Nonbuilding Structure Construction	1,139	1,684	$763,222,962	$135,692,924	$1,128,350,024	$ 303,996	$813,995	$4,884,632
31DG	Industrial Rehabilitation and Maintenance - Government	999200	State	0	18	$0	N/A	$233,209,962,000	N/A	N/A	$12,956,109,000
		999300	Local	24	83	$88,080,000	N/A	$8,542,625,720	$3,670,000	N/A	$78,826,618
	Total Construction			2,833	4,066	$2,190,383,669	$411,511,922	$272,995,360,745	$3,129,120	$750,934	$290,420,597
32	Precast Concrete Products Producers	327331, 327332, 327390	Concrete Pipe, Brick, and Block Mfg	59,825	71,220	$8,431,493,928	$20,794,317,954	$9,995,322,907	$2,997,332	$885,373	$3,412,538
	Total – All Affected Entities			306,763	380,599	$242,603,809,053	$35,196,413,601	$720,482,070,078	$7,400,406	$1,498,581	$20,854,523

Note: Total affected entities, establishments, employees, and revenues were estimated by adding entities (establishments, etc.) from each industry segment calculated by the following method:
General Industry = general industry welding entities + 1/2 (remaining general industry entities)
Maritime = maritime painting entities + 1/2 (remaining maritime entities)
Construction = construction woodworking entities + 1/2 (remaining construction entities)
Government = government painting entities

Footnotes

[A] SBA size standards taken from 13 CFR Ch.1 § 121.201. January 1, 2003

[B] Includes industries in NAICS 31-33, NAICS 42, NAICS 51.

[C] Except 311221 "Wet Corn Milling", 311312 "Cane Sugar Refining", 311313 "Beet Sugar Manufacturing", and 311821 Cookie and Cracker Manufacturing, which have an SBA size standard of 750 employees, and also 311223 "Other Oilseed Processing", 311225 "Fats and Oils Refining and Blending", 311230 "Breakfast Cereal Manufacturing", 311422 "Special Canning", which have an SBA size standard of 1,000 employees.

[D] Except 332811 "Metal Heat Treating," 332991 "Ball and Roller Bearing Manufacturing," and 332998 "Enameled Iron and Metal Sanitary Ware Manufacturing," all of which have an SBA size standard of 750 employees; 332431 "Metal Can Manufacturing," 332992 "Small Arms Ammunition Manufacturing," and 332994 "Small Arms Manufacturing," all of which have an SBA size standard of 1,000 employees; and 332993 "Ammunition (except Small Arms) Manufacturing," the SBA size standard for which is 1,500 employees.

[E] Except 333120 "Construction Machinery Manufacturing," 333415 "Air-Conditioning and Warm Air Heating Equipment," and 333924 Industrial Truck, Tractor, Trailer," all of which have an SBA size standard of 750 employees; and except 333313 Office Machinery Manufacturing," 333611 "Turbine and Turbine Generator Set Unit Manufacturing," and 333618 "Other Engine Equipment Manufacturing," all of which have an SBA size standard of 1,000 employees.

[F] Except for 336212 "Truck Trailer Manufacturing," 336214 "Travel Trailer and Camper Manufacturing," 336311 "Carburetor, Piston, Piston Ring and Valve Manufacturing," 336321 "Vehicular Lighting Equipment Manufacturing," 336360 "Motor Vehicle Seating and Interior Trim Manufacturing," 336370 "Motor Vehicle Metal Stamping," 336991 Motorcycle, Bicycle and Parts Manufacturing," and 336999 "All Other Transportation Equipment Manufacturing," all of which have an SBA size standard of 500 employees; 336312 "Gasoline Engine and Engine Parts Manufacturing," 336322 "Other Motor Vehicle Electrical and Electronic Equipment Manufacturing," 336330 "Motor Vehicle Steering and Suspension Components Manufacturing (except Spring)," 336340 "Motor Vehicle Brake System Manufacturing," 336350 "Motor Vehicle Transmission and Power Train Parts Manufacturing," 336391 Motor Vehicle Air-Conditioning Manufacturing," 336399 "All Other Motor Vehicle Parts Manufacturing, all of which have an SBA size standard of 750 employees; and 336411 "Aircraft Manufacturing," which has an SBA size standard of 1,500 employees.

[G] Includes industries in NAICS 31-33, NAICS 42, NAICS 44-45, NAICS 51, NAICS 53, NAICS 54, NAICS 56, NAICS 61, NAICS 71, and NAICS 81.

[H] Includes industries in NAICS 11, NAICS 22, NAICS 31-33, NAICS 42, NAICS 44-45, NAICS 48-49, NAICS 51, NAICS 52, NAICS 53, NAICS 54, NAICS 56, NAICS 61, NAICS 62, NAICS 71, NAICS 72, and NAICS 81.

[I] Except 336612 "Boat Building," which has an SBA size standard of 500 employees.

[J] Except 2331 "Land Subdivision and Land Development," which has an SBA size standard of $6.0 million.

[K] Except 336411 "Aircraft Manufacturing"

[L] Except 336612 "Boat Building," which has an SBA size standard of 500 employees.

[M] All of NAICS CODE 3261 have an SBA size standard of 500 employees except 326192 "Resilient Floor Covering Mfg.", the size standard for which is 750 employees.

[N] All of NAICS CODE 313 have an SBA size standard of 500 employees except 313210 "Broad Woven Fabric Mills", 313320 "Broad Woven Finishing Mills", and 313320 "Fabric Coating Mills" all of which have a size standard of 1,000 employees.

[O] All of NAICS CODE 314 have an SBA size standard of 500 employees except 314992 "Tire Cord and Tire Fabric Mill", the size standard for which is 1,000 employees.

[P] All of NAICS CODE 3161 have an SBA size standard of 500 employees except 316211 "Rubber and Plastics Footwear Mfg.", the size standard for which is 1,000 employees.

[Q] Except 336612 "Boat Building," which has an SBA size standard of 500 employees.

[R] Except 23551 which has an SBA size standard of $12 million.

[Z] 1997 NAICS Code is 233, Building, Developing, and General Contracting. 2002 NAICS Code is 236, Construction of Buildings.

[AA] 1997 NAICS Code is 234, Heavy Construction. 2002 NAICS Code is 236, Heavy and Civil Engineering Construction.

[BB] 1997 NAICS Code is 235, Special Trades Contractors. 2002 NAICS Code is 236, Special Trades Contractors.

[CC] 1997 NAICS Code is 42269, Other Chemical and Allied Products. 2002 NAICS Code is 424690, Other Chemical and Allied Products Merchant Wholesalers.

[DD] 1997 NAICS Code is 2332, Residential Building Construction. 2002 NAICS Code is 23611, Residential Building Construction.

[EE] 1997 NAICS Code is 2333, Nonresidential Building Construction. 2002 NAICS Code is 2362, Nonresidential Building Construction.

[FF] 1997 NAICS Code is 2349, Other Heavy Construction. 2002 NAICS Code is 237, Heavy and Civil Engineering Construction.

[GG] 1997 NAICS Code is 23551, Carpentry. 2002 NAICS Codes are 23835, Finish Carpentry Contractors, and 23813, Framing Contractors.

[HH] 1997 NAICS Code is 23493, Industrial Non-Building Structure Construction. 2002 NAICS Code is 23621, Industrial Building Construction.

[II] "Entities" refer to business firms or governmental bodies; "establishments" refer to industrial plants. Data on affected entities, establishments, and employees are from multiple sources; see the industrial profiles in Chapter II in the PEA (Ex. 35-391) for the complete list of references.

[JJ] Industry revenues were estimated from data reported in I.R.S., ***Corporation Source Book of Statistics of Income, 2000.*** Data on revenues for State and Local Governments were taken from U.S. Census Bureau, ***Government Finances: 1999-2000***, January 2003.

Source: U.S. Dept. of Labor, OSHA, Office of Regulatory Analysis, based on IT, 2004.

Various types of welding applications account for the greatest number of establishments and number of employees affected by the proposed standard.

Table IX–2 shows the current exposures to Cr(VI) by application group. The exposure data relied on by OSHA in developing the exposure profile and evaluating technological feasibility was compiled in a database of exposures taken from OSHA compliance officers, Site visits by OSHA contractors and the National Institute for Occupational Safety and Health (NIOSH), the U.S. Navy, published literature, and interested parties.

In all sectors OSHA has used the best available information to determine baseline exposures and technological feasibility. In a few sectors this information has been difficult to obtain and OSHA has had to rely on limited data in the industry or used analogous operations from similar processes. In these cases OSHA (or its contractor) discussed issues with industry experts and used their professional judgment to determine technological feasibility. The sectors that fall into the above categories are steel mills, welding in construction, woodworking and catalyst users.

Data obtained for steel mills included several sources such as NIOSH HHEs, IMIS exposure data and a site visit from IT Corporation, an OSHA contractor. OSHA's contractor could only obtain permission to conduct a site visit at a steel mill that used the teeming and primary rolling method versus continuous casting which is now used in approximately 95% of the steel mills. OSHA acknowledges this and uses exposures from analogous operations with additional information from industry experts. OSHA requests worker exposure information from steel mills using the continuous casting process. Exposure information was also limited for welding at construction sites. OSHA could use analogous operations from welding in maritime in open spaces. This could give a more detailed distribution for the baseline exposure profile. OSHA requests comments on the use of the Maritime data as an analogous operation for welding at construction sites.

In several sectors, such as woodworking and catalyst use, OSHA anticipates that airborne exposures will be low. In these cases exposure monitoring has been performed infrequently. OSHA then used professional judgment or has calculated exposure using total dust exposure to estimate employees' exposures to Cr(VI).

OSHA's analysis of technological feasibility analyzes employee exposures at the operation or task level to the extent that such data are available. There are a total of 380,000 workers exposed to Cr(VI), of which 84,000 are exposed above the proposed PEL of 1 microgram per cubic meter.

Table IX-2. Exposure Profile by Application Group for Cr(VI)

Application Group	Total	Number of Exposed Workers (ug/m^3)							
		Below LOD	LOD to 0.25	0.25 to 0.5	0.5 to 1.0	1.0 to 5.0	5.0 to 10.0	10.0 to 20.0	> 20.0
Electroplating	33,590	20,688	675	465	1,502	3,943	3,150	1,673	1,494
		61.6%	2.0%	1.4%	4.5%	11.7%	9.4%	5.0%	4.4%
Welding General Industry	45,326	20,271	449	0	4,541	6,107	2,683	7,572	3,703
		44.7%	1.0%	0.0%	10.0%	13.5%	5.9%	16.7%	8.2%
Welding (maritime)	4,666	2,140	566	571	556	442	99	102	190
		45.9%	12.1%	12.2%	11.9%	9.5%	2.1%	2.2%	4.1%
Welding (construction)	60,450	20,855	1,360	1,360	10,881	12,846	1,514	6,348	5,286
		34.5%	2.2%	2.2%	18.0%	21.3%	2.5%	10.5%	8.7%
Welding (government)	942	325	21	21	170	199	23	100	83
		34.5%	2.2%	2.2%	18.0%	21.1%	2.4%	10.6%	8.8%
Painting General Industry	8,143	2,421	1,266	843	1,069	1,174	430	471	469
		29.7%	15.5%	10.4%	13.1%	14.4%	5.3%	5.8%	5.8%
Painting Maritime	3,154	538	353	302	312	985	271	117	276
		17.1%	11.2%	9.6%	9.9%	31.2%	8.6%	3.7%	8.8%
painting (construction)	32,282	6,522	7,989	1,141	9,130	5,217	1,141	326	815
		20.2%	24.7%	3.5%	28.3%	16.2%	3.5%	1.0%	2.5%
Painting Government	8,063	1,630	1,996	285	2,281	1,304	285	111	171
		20.2%	24.8%	3.5%	28.3%	16.2%	3.5%	1.4%	2.1%
Chromate Production	150	1	89	24	24	12	0	0	0
		0.7%	59.3%	16.0%	16.0%	8.0%	0.0%	0.0%	0.0%
Chromate pigmen Producers	52	0	0	0	1	16	5	6	24
		0.0%	0.0%	0.0%	1.9%	30.8%	9.6%	11.5%	46.2%
Chromated Copper Arsenate (CCA) Producers	27	0	12	0	5	5	5	0	0
		0.0%	44.4%	0.0%	18.5%	18.5%	18.5%	0.0%	0.0%
Chromium Catalyst Producers	313	0	127	25	31	71	11	29	19
		0.0%	40.6%	8.0%	9.9%	22.7%	3.5%	9.3%	6.1%
Paint and Coatings Producers	2,569	400	1,443	38	38	150	0	21	479
		15.6%	56.2%	1.5%	1.5%	5.8%	0.0%	0.8%	18.6%
Printing Ink Producers	113	27	4	3	17	62	0	0	0
		23.9%	3.5%	2.7%	15.0%	54.9%	0.0%	0.0%	0.0%
Plastic Colorant Producers and users	492	37	15	15	0	250	36	64	75
		7.5%	3.0%	3.0%	0.0%	50.8%	7.3%	13.0%	15.2%
Plating Mixture Producers	118	0	16	80	0	22	0	0	0
		0.0%	13.6%	67.8%	0.0%	18.6%	0.0%	0.0%	0.0%
Chromium Material Producers	47	16	8	1	13	4	5	0	0
		34.0%	17.0%	2.1%	27.7%	8.5%	10.6%	0.0%	0.0%
Steel Mills	5,205	1,634	567	1,689	289	1,026	0	0	0
		31.4%	10.9%	32.4%	5.6%	19.7%	0.0%	0.0%	0.0%
Iron and Steel Foundries	30,252	4,214	11,875	3,481	4,578	4,495	643	322	644
		13.9%	39.3%	11.5%	15.1%	14.9%	2.1%	1.1%	2.1%
Chromium Dye Producers	104	0	0	0	0	40	6	10	48

Application Group	Total	Number of Exposed Workers (ug/m^3)							
		Below LOD	LOD to 0.25	0.25 to 0.5	0.5 to 1.0	1.0 to 5.0	5.0 to 10.0	10.0 to 20.0	> 20.0
		0.0%	0.0%	0.0%	0.0%	38.5%	5.8%	9.6%	46.2%
Chromium Sulfate Producers	11	0	8	0	0	3	0	0	0
		0.0%	72.7%	0.0%	0.0%	27.3%	0.0%	0.0%	0.0%
Chemical Distributors	3,572	3,572	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Textile Dyeing	25,341	17,992	3,386	3,963	0	0	0	0	0
		71.0%	13.4%	15.6%	0.0%	0.0%	0.0%	0.0%	0.0%
Colored Glass Producers	295	291	2	0	0	2	0	0	0
		98.6%	0.7%	0.0%	0.0%	0.7%	0.0%	0.0%	0.0%
Printing	6,600	6,600	0	0	0	0	0	0	0
		100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Chromium Catalyst Users	949	20	141	294	172	161	161	0	0
		2.1%	14.9%	31.0%	18.1%	17.0%	17.0%	0.0%	0.0%
Refractory Brick Producer	90	21	54	3	12	0	0	0	0
		23.3%	60.0%	3.3%	13.3%	0.0%	0.0%	0.0%	0.0%
Woodworking Construction	13,952	4,651	0	4,651	0	3,100	0	1,550	0
		33.3%	0.0%	33.3%	0.0%	22.2%	0.0%	11.1%	0.0%
Woodworking Maritime	319	239	80	0	0	0	0	0	0
		74.9%	25.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Woodworking General Industry	388	334	0	0	0	0	0	54	0
		86.1%	0.0%	0.0%	0.0%	0.0%	0.0%	13.9%	0.0%
Woodworking Government	121	40	0	40	0	27	0	14	0
		33.1%	0.0%	33.1%	0.0%	22.3%	0.0%	11.6%	0.0%
Solid Waste Incineration	1,544	1,069	0	289	186	0	0	0	0
		69.2%	0.0%	18.7%	12.0%	0.0%	0.0%	0.0%	0.0%
Solid Waste Incineration Government	51	29	0	13	9	0	0	0	0
		56.9%	0.0%	25.5%	17.6%	0.0%	0.0%	0.0%	0.0%
Portland Cement Producers	12,636	1,314	10,690	632	0	0	0	0	0
		10.4%	84.6%	5.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Superalloy Production	2,164	1,466	588	100	0	0	0	10	0
		67.7%	27.2%	4.6%	0.0%	0.0%	0.0%	0.5%	0.0%
Construction Other—not including welding, painting and woodworking	3,289	2,594	622	73	0	0	0	0	0
		78.9%	18.9%	2.2%	0.0%	0.0%	0.0%	0.0%	0.0%
Construction Other (government)	780	610	129	41	0	0	0	0	0
		78.2%	16.5%	5.3%	0.0%	0.0%	0.0%	0.0%	0.0%
Precast Concrete Products Producers	71,220	18,448	50,920	1,852	0	0	0	0	0
		25.9%	71.5%	2.6%	0.0%	0.0%	0.0%	0.0%	0.0%
Total	380,192	141,339	95,451	22,458	36,132	41,667	10,468	18,900	13,776
		37.2%	25.1%	5.9%	9.5%	11.0%	2.8%	5.0%	3.6%

C. Technological Feasibility

In Chapter II of OSHA's PEA, OSHA also assesses the technological feasibility of the proposed standard across a range of potential PELs in all affected industry sectors.

Many employers, and some entire application groups already have nearly all exposures below the proposed PEL. However, OSHA recognizes that some employers in some application groups may not be able to achieve the proposed PEL with engineering controls and work practices for all job categories and may need to use respirators.

In general, OSHA considered the following kinds of possible controls that could reduce employee exposures to Cr(VI): Local exhaust ventilation (LEV) which could include the maintenance or upgrade of the current LEV or installation of additional LEV; process enclosures that would isolate the worker

from the exposure; process modifications that would reduce the generation of Cr(VI) dust or fume in the work place; improved housekeeping; improved work practices; and the supplemental use of respiratory protection if engineering controls are not sufficient to meet the proposed PEL. The technologies used in this analysis are commonly known, readily available and are currently used to some extent in the affected industries and processes. OSHA's assessment of feasible controls and what PELs they can achieve is based on information collected by Shaw Environmental, Inc., consultant to OSHA, on current exposure levels and associated existing controls, on the availability of additional controls needed to reduce employee exposures and on other evidence presented in the docket.

OSHA has determined that the primary controls most likely to be effective in reducing employee exposure to Cr(VI) are LEV, process enclosure and process modification, or substitution. In some cases, firms need not improve their local exhaust systems, but instead must spend more effort insuring that the exhaust system is working according to design specification throughout the process. In other cases, employers will need to upgrade or install new LEV. This includes installing duct work, a type of hood and/or a collection system. Examples of processes that would need to improve, maintain, or install LEV include hard chrome plating and welding processes that generate large volumes of fume such as shielded metal arc welding (SMAW) and gas metal arc welding (GMAW). (LEV is defined to include portable LEV systems such as fume extraction guns (FEG).) Other sectors where new or better maintained LEV may be needed are: painting and abrasive blasting, chromate production, the production of pigments, catalyst, dyes and plastic colorants.

OSHA estimates that process enclosures will be needed for difficult to control operations such as dusty operations. These enclosures would isolate the employees from high exposure processes and reduce the need for respirators. For example, the packaging of chromic acid in small bags is totally enclosed and therefore, employees only need to enter the room during product upset or planned changes. This technology could also be applied to other packaging operations involving similar sized bags in other industries such as pigment manufacturing, catalyst production and plastic colorants. Process modifications can also be effective in reducing exposures in some industries. For example, employers can significantly reduce employee exposure through the use of automation in catalyst production, the use of fume suppressants in electroplating and significant reduction of welding fume emission, by up to 80 percent, is attainable using the pulsed arc GMAW welding process as compared to the conventional short arc GMAW process.

OSHA recognizes that there are certain instances where the supplemental use of respirators may be needed because engineering and work practices are not sufficient to reduce airborne exposures below the proposed PEL. For example, this is the case for hard chrome electroplating in some circumstances. There are many factors that are involved in the generation of Cr(VI) including the size of the part and the thickness of the coating needed. In some worst case conditions, respirators will be needed to supplement engineering controls. Welding also includes many factors that contribute to Cr(VI) exposures; these include type of welding, the base metal, the consumable, as well as the environment in which the welding is being conducted. As a result, engineering controls and work practices may not be sufficient in the most severe conditions and therefore the supplemental use of respirators will be needed. Table IX–3 shows OSHA's estimate of respirator use by industry for each of the proposed PELs.

Table IX–3 identifies sectors where respirators will be needed for some workers. Even at a PEL of 1 $\mu g/m^3$, a majority of exposed workers in the chromium catalyst user application group will need respirators, but this use is largely intermittent. As a result, workers will not need to wear respirators on a daily basis.

PELs lower than 1 $\mu g/m^3$ could not be achieved by means of engineering controls and work practices alone for some types of welding (particularly GMAW and SMAW) and in hard chromium plating. Based on this finding, OSHA has preliminarily determined that a PEL of 1 $\mu g/m^3$ is the lowest technologically feasible level.

For a complete analysis of technical feasibility please see the Preliminary Economic Analysis, Chapter III, where feasibility is reviewed for each industry/process by job category.

TABLE IX-3. Respiratory Use by Industry at Various Potential PELs after Engineering and Work Practice Controls Have Been Applied

Industry	# Employees	0.25 µg/m³	0.50 µg/m³	1 µg/m³	5 µg/m³	10 µg/m³	20 µg/m³
		Number and Percentage of Employees Using Respirators					
Electroplating	33,591	7,229	3,934	710	0	0	0
		21.5%	11.7%	2.1%	0.0%	0.0%	0.0%
Welding SS General Industry	45,326	14,921	10,471	1,688	808	148	118
Welding SS Maritime	4,666	948	298	41	0	0	0
Welding SS Construction	60,450	9,199	8,912	5,930	5,563	875	788
Welding SS Government	942	143	139	92	87	14	12
Welding SS Grand Total	111,384	25,211	19,820	7,751	6,458	1,037	918
		22.6%	17.8%	7.0%	5.8%	0.9%	0.8%
Painting General Industry	8,143	1,369	157	157	0	0	0
Painting Construction	32,282	7,875	6,369	3,324	1,012	506	253
Painting Maritime	3,154	732	558	520	199	117	69
Painting Government	8,063	1,967	1,591	830	253	126	63
Grand Total Painting	51,642	11,943	8,675	4,832	1,463	749	386
		23.1%	16.8%	9.4%	2.8%	1.5%	0.7%
Producers of Chromates	150	75	21	21	0	0	0
		50.0%	14.0%	14.0%	0.0%	0.0%	0.0%
Chromate pigment producers	52	39	12	12	0	0	0
		75.0%	23.1%	23.1%	0.0%	0.0%	0.0%
CCA Producers	27	6	0	0	0	0	0
		22.2%	0.0%	0.0%	0.0%	0.0%	0.0%
Chromium Catalyst producers	313	125	91	82	0	0	0
		39.9%	29.1%	26.2%	0.0%	0.0%	0.0%
Paint and Coatings producers	2,569	0	0	0	0	0	0
		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Printing Ink Producers	113	3	0	0	0	0	0
		2.7%	0.0%	0.0%	0.0%	0.0%	0.0%
Plastic Colorant	492	0	0	0	0	0	0
		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Plating Mixtures	118	0	0	0	0	0	0
		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Ferrochromium	47	5	0	0	0	0	0
		10.6%	0.0%	0.0%	0.0%	0.0%	0.0%
Steel mills	5,205	0	0	0	0	0	0
		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Iron and Steel Foundries	30,252	2,574	0	0	0	0	0
		8.5%	0.0%	0.0%	0.0%	0.0%	0.0%
Chromium Dye Producers	104	**10**	**10**	**10**	0	0	0
		9.6%	**9.6%**	**9.6%**	0.0%	0.0%	0.0%
Chromium sulfate producers	11	0	0	0	0	0	0
		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Chemical Distributors	3,572	0	0	0	0	0	0
		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Textile Dyeing	25,341	0	0	0	0	0	0
		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Producers of Colored Glass	295	0	0	0	0	0	0
		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Printing	6,600	0	0	0	0	0	0
		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Chromium Catalyst Users	949	**705**	**705**	**705**	0	0	0
		74.3%	74.3%	74.3%	0.0%	0.0%	0.0%
Producers of refractory bricks	90	0	0	0	0	0	0
		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Wood Working	14,780	0	0	0	0	0	0
		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Solid Waste Incinerations	1,595	0	0	0	0	0	0
		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Portland cement producers	12,636	0	0	0	0	0	0
		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Non-ferrous metallurgical uses of chromium	2,164	39	39	0	0	0	0
		1.8%	1.8%	0.0%	0.0%	0.0%	0.0%
Construction Other	4,069	90	0	0	0	0	0
		2.2%	0.0%	0.0%	0.0%	0.0%	0.0%
Precast Cast Concrete	71,220	0	0	0	0	0	0
		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
All Industries	380,192	48,058	33,309	14,125	7,921	1,786	1,304
		12.7%	8.8%	3.7%	2.1%	0.5%	0.3%

Bold numbers indicate intermittent use

Construction other - Welding, painting and woodworking not included

D. Costs

The costs employers are expected to incur to comply with the proposed standard are $223 million per year. In addition, OSHA estimates that employers will incur $67 million per year to comply with the personal protective equipment and hygiene requirements already present in existing generic standards. The proposed requirements to provide protective clothing and equipment and hygiene

areas are closely aligned with the requirements of OSHA's current generic PPE and Sanitation standards (*e.g.* 1910.132 and 1926.95 for PPE and 1910.142 and 1926.51 for the hygiene requirements). Therefore, OSHA estimates that the marginal cost of complying with the new PPE and sanitation requirements of the Cr(VI) standard were lower for firms currently subject to and in compliance with existing generic standards. OSHA's research on these current standards, however, uncovered some noncompliance. The baseline chosen for the Cr(VI) regulatory impact analysis reflects this non-compliance with current requirements. Although OSHA estimates that employers would need to spend an additional $67 million per year to bring themselves into compliance with the personal protective equipment and hygiene requirements already prescribed in existing generic standards, this additional expenditure is not attributable to the Cr(VI) rulemaking. However, by incurring the obligation and expense of providing PPE to their employees, employers are essentially transferring a benefit to employees $24 million per year.

All costs are measured in 2003 dollars. Any one-time costs are annualized over a ten year period, and all costs are annualized at a discount rate of 7 percent. (A sensitivity analysis using a discount rate of 3 percent is presented in the discussion of net benefits.) The derivation of these costs is presented in Chapter III of the full PEA. Table IX–4 provides the annualized costs by provision and by industry. Engineering control costs represent 45 percent of the costs of the new provisions of the proposed standard, and respiratory protection costs represent 19 percent of the costs of the new provisions of the proposed standard.

Table IX-4. Annualized Costs for All Establishments Affected by OSHA's Proposed Standard for Hexavalent Chromium (by Application Group and Regulatory Requirement for a PEL of 1 ug/m^3)

	Application Group	Engineering Controls	Initial Exposure Monitoring	Periodic Exposure Monitoring	Respiratory Protection
1	Electroplating	$38,179,276	$536,969	$3,238,675	$2,189,604
2A	Welding (general industry)	$31,230,424	$3,729,347	$19,082,460	$16,277,836
2B	Welding (maritime industry)	$1,294,354	$41,001	$0	$392,984
2C	Welding (construction industry)	$16,408,707	$107,472	$0	$9,897,057
2D	Welding (government)	$253,727	$35,616	$0	$157,812
3A	Painting (general industry)	$827,520	$100,567	$406,599	$2,184,738
3B	Painting (maritime industry)	$339,058	$33,949	$0	$6,992,874
3C	Painting (construction industry)	$0	$30,351	$0	$0
3D	Painting (government)	$0	$6,480	$0	$0
4	Chromate (chromite ore) production	$309,000	$2,585	$3,087	$13,937
5	Chromate Pigment Producers	$47,400	$4,288	$17,495	$39,774
6	Chromated Copper Arsenate (CCA) Producers	$0	$3,502	$14,065	$2,680
7	Chromium Catalyst Producers	$2,272,600	$13,232	$71,440	$587,133
8	Paint and Coatings Producers	$4,224,524	$99,510	$128,901	$32,797
9	Printing Ink Producers	$0	$10,909	$7,890	$198,295
10	Plastic Colorant Producers and Users	$0	$230,301	$1,143,725	$327,473
11	Plating Mixture Producers	$144,780	$7,905	$28,902	$0
12	Wood Preserving	$0	$0	$0	$0
13	Chromium Material Producers	$23,500	$5,470	$9,177	$10,197
14	Steel Mills	$455,071	$48,299	$35,763	$165,268
15	Iron and Steel Foundries	$1,984,734	$432,919	$863,111	$2,270,528
16	Chromium Dioxide Producers	$0	$0	$0	$0
17	Chromium Dye Producers	$0	$30,966	$153,686	$63,217
18	Chromium Sulfate Producers	$0	$5,297	$18,525	$0
19	Chemical Distributors	$0	$502,670	$0	$0
20	Textile Dyeing	$0	$439,585	$0	$0
21	Colored Glass Producers	$1,337	$18,619	$0	$0
22	Printing	$0	$157,113	$0	$0
23	Leather Tanning	$0	$0	$0	$0
24	Chromium Catalyst Users	$0	$88,754	$178,042	$566
24A	Chromium Catalyst Users (Service)	$0	$28,584	$136,534	$0
25	Refractory Brick Producers	$0	$17,189	$16,295	$5,529
26A	Woodworking (general industry)	$43,050	$75,375	$0	$0
26B	Woodworking (maritime industry)	$0	$9,742	$0	$0
26C	Woodworking (construction industry)	$2,703,987	$918,618	$0	$0
26D	Woodworking (government)	$43,560	$14,799	$0	$0
27	Solid Waste Incineration	$0	$258,213	$532,755	$246,691
27A	Incinerators (government)	$0	$16,337	$37,392	$11,005
28	Oil and Gas Well Drilling	$0	$0	$0	$0
29	Portland Cement Producers	$0	$95,191	$0	$0
30	Superalloy Producers	$12,000	$13,770	$9,177	$15,490
31B	Construction (Refractory Repair)	$0	$0	$0	$0
31C	Construction (Hazardous Waste Work)	$0	$23,606	$0	$0
31CG	Haz. Waste (government)	$0	$25,517	$0	$0
31D	Construction (Industrial Rehabilitation)	$0	$0	$0	$0
31DG	Industrial Rehab. (government)	$490	$16,617	$0	$0
32	Precast Concrete Products Producers	$0	$3,706,667	$0	$0
	General Industry (including Government)	$80,052,993	$10,779,163	$26,133,697	$24,800,570
	Construction	$19,112,694	$1,080,047	$0	$9,897,057
	Maritime	$1,633,412	$84,692	$0	$7,385,858
	Total	$100,799,100	$11,943,903	$26,133,697	$42,083,485

Table IX-4. Annualized Costs for All Establishments Affected by OSHA's Proposed Standard for Hexavalent Chromium (by Application Group and Regulatory Requirement for a PEL of 1 ug/m^3)

	Application Group	Housekeeping	Medical Surveillance	Information and Training	Recordkeeping
1	Electroplating	$9,189,100	$459,403	$500,074	$132,200
2A	Welding (general industry)	$0	$1,175,453	$1,845,145	$96,600
2B	Welding (maritime industry)	$0	$814	$75,239	$9,900
2C	Welding (construction industry)	$0	$11,633	$1,622,152	$157,600
2D	Welding (government)	$0	$197	$80,631	$10,800
3A	Painting (general industry)	$664,000	$111,462	$416,016	$40,100
3B	Painting (maritime industry)	$0	$269	$215,172	$13,400
3C	Painting (construction industry)	$0	$3,812	$2,047,572	$154,500
3D	Painting (government)	$0	$996	$824,967	$43,100
4	Chromate (chromite ore) production	$6,400	$418	$2,734	$900
5	Chromate Pigment Producers	$3,150	$2,584	$989	$300
6	Chromated Copper Arsenate (CCA) Producers	$0	$319	$460	$130
7	Chromium Catalyst Producers	$16,000	$17,866	$5,842	$1,820
8	Paint and Coatings Producers	$231,160	$20,105	$39,535	$11,120
9	Printing Ink Producers	$16,430	$0	$1,448	$1,070
10	Plastic Colorant Producers and Users	$21,320	$0	$13,958	$2,860
11	Plating Mixture Producers	$54,570	$686	$1,829	$510
12	Wood Preserving	$0	$0	$0	$0
13	Chromium Material Producers	$4,190	$452	$827	$270
14	Steel Mills	$224,500	$36,204	$63,150	$20,700
15	Iron and Steel Foundries	$720,800	$186,849	$421,191	$186,700
16	Chromium Dioxide Producers	$0	$0	$0	$0
17	Chromium Dye Producers	$5,290	$0	$2,056	$580
18	Chromium Sulfate Producers	$10,100	$457	$291	$100
19	Chemical Distributors	$4,859,700	$4	$34,858	$0
20	Textile Dyeing	$712,800	$81	$276,803	$76,300
21	Colored Glass Producers	$18,500	$91	$1,099	$200
22	Printing	$52,600	$0	$70,307	$18,700
23	Leather Tanning	$0	$0	$0	$0
24	Chromium Catalyst Users	$466,300	$2,652	$6,593	$1,080
24A	Chromium Catalyst Users (Service)	$71,510	$47,942	$10,593	$3,350
25	Refractory Brick Producers	$40,620	$12	$937	$300
26A	Woodworking (general industry)	$814,900	$1,580	$6,315	$500
26B	Woodworking (maritime industry)	$0	$95	$2,292	$400
26C	Woodworking (construction industry)	$0	$3,745	$320,994	$44,900
26D	Woodworking (government)	$0	$32	$3,736	$400
27	Solid Waste Incineration	$0	$145	$22,923	$4,820
27A	Incinerators (government)	$0	$10	$1,150	$140
28	Oil and Gas Well Drilling	$0	$0	$0	$0
29	Portland Cement Producers	$504,400	$650	$130,586	$40,300
30	Superalloy Producers	$16,580	$453	$9,325	$2,940
31B	Construction (Refractory Repair)	$0	$42	$14,028	$1,890
31C	Construction (Hazardous Waste Work)	$0	$131	$34,747	$5,620
31CG	Haz. Waste (government)	$0	$74	$22,405	$3,270
31D	Construction (Industrial Rehabilitation)	$0	$182	$50,939	$8,220
31DG	Industrial Rehab. (government)	$0	$11	$4,740	$490
32	Precast Concrete Products Producers	$9,593,400	$3,877	$870,527	$268,600
	General Industry (including Government)	$28,318,320	$2,071,066	$5,694,042	$971,250
	Construction	$0	$19,546	$4,090,431	$372,730
	Maritime	$0	$1,178	$292,704	$23,700
	Total	$28,318,320	$2,091,791	$10,077,177	$1,367,680

Table IX-4. Annualized Costs for All Establishments Affected by OSHA's Proposed Standard for Hexavalent Chromium (by Application Group and Regulatory Requirement for a PEL of 1 ug/m^3)

			Current Requirements for PPE and Hygiene Areas			
	Application Group	Total for Incremental Requirements	PPE (not supplied in baseline)	PPE (supplied in baseline)	Hygiene Areas	Total for Incremental and Current Requirements
1	Electroplating	$54,425,302	$0	$12,163,429	$1,688,800	$68,277,530
2A	Welding (general industry)	$73,437,266	$0	$0	$0	$73,437,266
2B	Welding (maritime industry)	$1,814,292	$0	$0	$0	$1,814,292
2C	Welding (construction industry)	$28,204,622	$0	$0	$0	$28,204,622
2D	Welding (government)	$538,783	$0	$0	$0	$538,783
3A	Painting (general industry)	$4,751,003	$10,872,247	$2,338,343	$348,400	$18,309,992
3B	Painting (maritime industry)	$7,594,722	$5,661,140	$921,241	$407,800	$14,584,903
3C	Painting (construction industry)	$2,236,235	$0	$944,546	$0	$3,180,780
3D	Painting (government)	$875,543	$0	$263,107	$0	$1,138,650
4	Chromate (chromite ore) production	$339,062	$0	$17,909	$4,400	$361,371
5	Chromate Pigment Producers	$115,980	$0	$6,089	$3,000	$125,069
6	Chromated Copper Arsenate (CCA) Producers	$21,156	$12,587	$2,086	$1,200	$37,028
7	Chromium Catalyst Producers	$2,985,933	$110,290	$26,303	$12,700	$3,135,226
8	Paint and Coatings Producers	$4,787,651	$3,777,438	$602,900	$142,300	$9,310,290
9	Printing Ink Producers	$236,043	$6,435	$851	$6,200	$249,529
10	Plastic Colorant Producers and Users	$1,739,637	$31,030	$5,180	$33,600	$1,809,448
11	Plating Mixture Producers	$239,182	$0	$100,396	$9,400	$348,978
12	Wood Preserving	$0	$0	$0	$0	$0
13	Chromium Material Producers	$54,083	$0	$0	$0	$54,083
14	Steel Mills	$1,048,954	$0	$0	$0	$1,048,954
15	Iron and Steel Foundries	$7,066,833	$0	$0	$0	$7,066,833
16	Chromium Dioxide Producers	$0	$0	$0	$0	$0
17	Chromium Dye Producers	$255,794	$21,250	$4,643	$5,800	$287,488
18	Chromium Sulfate Producers	$34,770	$18,113	$965	$2,800	$56,647
19	Chemical Distributors	$5,397,232	$0	$0	$0	$5,397,232
20	Textile Dyeing	$1,505,570	$1,236,379	$226,048	$1,383,800	$4,351,797
21	Colored Glass Producers	$39,846	$0	$0	$0	$39,846
22	Printing	$298,720	$373,708	$60,835	$171,700	$904,962
23	Leather Tanning	$0	$0	$0	$0	$0
24	Chromium Catalyst Users	$743,988	$143,158	$27,090	$39,200	$953,436
24A	Chromium Catalyst Users (Service)	$298,513	$0	$82,380	$33,900	$414,793
25	Refractory Brick Producers	$80,882	$29,900	$5,262	$5,300	$121,343
26A	Woodworking (general industry)	$941,720	$0	$0	$0	$941,720
26B	Woodworking (maritime industry)	$12,530	$0	$0	$0	$12,530
26C	Woodworking (construction industry)	$3,992,244	$4,848,041	$578,853	$2,858,900	$12,278,038
26D	Woodworking (government)	$62,527	$48,096	$20,338	$27,600	$158,561
27	Solid Waste Incineration	$1,065,547	$0	$613,804	$80,200	$1,759,552
27A	Incinerators (government)	$66,035	$0	$46,816	$19,700	$132,550
28	Oil and Gas Well Drilling	$0	$0	$0	$0	$0
29	Portland Cement Producers	$771,127	$1,051,893	$202,073	$213,800	$2,238,893
30	Superalloy Producers	$79,735	$0	$0	$0	$79,735
31B	Construction (Refractory Repair)	$15,961	$0	$0	$0	$15,961
31C	Construction (Hazardous Waste Work)	$64,105	$90,563	$262,183	$107,500	$524,350
31CG	Haz. Waste (government)	$51,266	$0	$165,417	$60,900	$277,582
31D	Construction (Industrial Rehabilitation)	$59,341	$0	$0	$0	$59,341
31DG	Industrial Rehab. (government)	$22,348	$0	$0	$0	$22,348
32	Precast Concrete Products Producers	$14,443,071	$25,688,840	$4,450,356	$4,859,400	$49,441,666
	General Industry (including Government)	$178,821,101	$43,421,364	$21,432,619	$9,154,100	$252,829,184
	Construction	$34,572,507	$4,938,603	$1,785,581	$2,966,400	$44,263,091
	Maritime	$9,421,545	$5,661,140	$921,241	$407,800	$16,411,725
	Total	$222,815,153	$54,021,107	$24,139,441	$12,528,300	$313,504,001

Source: U.S. Dept. of Labor, OSHA, Office of Regulatory Analysis, based on IT, 2004.

Costs for the new provisions for General Industry are $179 million per year, costs for constructions $35 million per year, and costs for the shipyard sector and $9 million per year. (In developing the costs for construction, OSHA assumed that all work by construction firms would be covered by the construction standard. However, in practice some work by construction firms takes the form of maintenance operations that would be covered by the

general industry standard. OSHA seeks comment on the extent to which welding, painting, and wood working done by construction firms might be covered by the general industry standard.) Table IX–4 also shows the costs by application group. The various types of welding represent the most expensive application group, accounting for 47 percent of the total costs.

OSHA also presents the distribution of compliance costs according at the time they are imposed in Table IX–5. Because firms will have the choice of whether to finance expenditures in order to spread out, for example, startup costs over several years, OSHA considers it unlikely that a firm would be impacted in an amount equal to the entire startup cost in the year that the initial requirements are imposed. On the other hand, capital markets are not perfectly liquid and particular firms may face additional lending constraints, therefore OSHA believes that identifying startup costs and the time distribution of imposed costs, in addition to the annualized costs, is relevant when exploring the question of economic feasibility and the overall impact of this rulemaking.

E. Economic Impacts

To determine whether the proposed rule's projected costs of compliance would raise issues of economic feasibility for employers in affected industries, i.e., would adversely alter the competitive structure of the industry,

Table IX-5. Estimated Total First-Year Compliance Costs Associated with the Proposed Standard for Hexavalent Chromium

Cost Category	General Industry	Government	Construction	Maritime	Total
Engineering Controls	$242,133,012	$1,559,708	$100,270,508	$10,157,887	$354,121,115
Initial Exposure Assessment	$149,391,244	$575,213	$7,585,801	$571,473	$158,123,732
Respiratory Protection	$28,642,044	$71,534	$11,104,439	$7,673,020	$47,491,038
Housekeeping	$44,183,186	$0	$0	$0	$44,183,186
Medical Surveillance	$8,871,106	$1,315	$21,199	$1,466	$8,895,086
Training and Familiarization	$15,372,902	$1,607,142	$8,555,306	$650,203	$26,185,553
Recordkeeping	$1,319,313	$56,382	$405,565	$28,194	$1,809,454
Total for Incremental Requirements	**$489,912,807**	**$3,871,296**	**$127,942,818**	**$19,082,242**	**$640,809,163**
PPE (supplied in baseline)	$24,698,382	$495,677	$1,785,581	$921,241	$27,900,881
PPE (not supplied in baseline)	$58,754,760	$48,096	$4,938,603	$5,661,140	$69,402,600
Hygiene Areas	$35,227,714	$335,882	$7,223,809	$1,432,863	$44,220,268
Total for Incremental and Current Requirements	**$608,593,662**	**$4,750,951**	**$141,890,812**	**$27,097,487**	**$782,332,912**

Source: U.S. Dept. of Labor, OSHA, Office of Regulatory Analysis, based on IT, 2004.

OSHA developed quantitative estimates of the economic impact of the proposed rule on the affected establishments. In this analysis, compliance costs are compared with industry revenues and profits.

To assess the potential economic impacts of the proposed standard, OSHA compared the anticipated costs of achieving compliance against revenues and profits of entities affected by the rule. OSHA compared the baseline financial data (from Table IX–1) with total annualized costs of compliance by computing compliance costs as a percentage of revenues. This impact assessment is presented in Table IX–6. This table is considered a screening analysis because it measures costs as a percentage of pre-tax profits and revenues but does not predict impacts on pre-tax profits and sales.

Table IX-6. Economic Impacts on All Entities Affected by OSHA's Proposed Standard for Hexavalent Chromium (by Application Group for a PEL of 1 ug/m^3)

	Application Group	NAICS	Category	Cost per Entity[L]			Impacts for Incremental-Requirement Costs	
				Incremental-Requirement Costs	Revenue per Entity[M]	Profit per Entity[M]	Cost/Revenue Impact	Cost/Profit Impact
1	Electroplating - General Industry	All General Industry		$19,040	$6,790,061	$337,538	0.22%	5.64%
		331		$16,825	$26,706,607	$854,339	0.06%	1.97%
		332812	Metal Coating, Engraving (Except Jewerly and Silverware), and Allied Services to Manufacturers	$24,276	$6,301,776	$399,369	0.39%	6.06%
		332613	Electroplating, Plating, Polishing, Anodizing, and Coloring	$14,058	$1,510,325	$95,715	0.93%	14.69%
		Other 332	Fabricated Metal Product Manufacturing	$24,095	$11,471,106	$698,751	0.21%	3.45%
		333	Machinery Manufacturing	$15,276	$12,693,711	$638,709	0.12%	2.39%
		336 (except 33661)	Transportation Equipment Manufacturing	$22,164	$151,526,656	$4,508,524	0.01%	0.49%
		339	Miscellaneous Manufacturing	$22,096	$23,715,672	$1,687,930	0.09%	1.31%
		Other General Industry[A]		$16,759	$4,802,694	$179,025	0.35%	9.36%
2A	Welding - General Industry	31-33[B]	Manufacturing	$4,891	$8,039,222	$368,301	0.06%	1.33%
2B	Welding - Maritime Industry	336611	Ship Building and Repairing	$6,503	$36,099,593	$1,676,090	0.02%	0.39%
2C	Welding - Construction Industry	233[C]	Building, Developing, and General Contracting; Heavy Construction; Special Trade Contractors	$11,660	$2,626,724	$109,075	0.44%	10.69%
2D	Welding - Government	999200	State	$2,537	$12,956,109,000	N/A	0.00%	N/A
		999300	Local	$580	$109,399,080	N/A	0.00%	N/A
3A	Painting - General Industry	31-33	Manufacturing					
		332812	Metal Coating, Engraving (Except Jewerly and Silverware), and Allied Services to Manufacturers	$29,165	$5,662,391	$358,848	0.52%	8.13%
		336411, 336414, 336415, 336419, 336992	Transportation Equipment Manufacturing	$32,299	$405,885,941	$13,192,511	0.01%	0.24%
3B	Painting - Maritime Industry	33661	Ship and Boat Building	$9,601	$21,429,871	$996,168	0.04%	0.96%
3C	Painting - Construction Industry	234[D], 235[E]	Heavy Construction, Special Trade Contractors	$347	$1,941,303	$47,804	0.02%	0.73%
		234[D], 235[E]	Heavy Construction	$711	$9,995,757	$355,849	0.01%	0.20%

Table IX-6. Economic Impacts on All Entities Affected by OSHA's Proposed Standard for Hexavalent Chromium (by Application Group for a PEL of 1 ug/m^3)

				Cost per Entity[L]			Impacts for Incremental-Requirement Costs	
	Application Group	NAICS	Category	Incremental-Requirement Costs	Revenue per Entity[M]	Profit per Entity[M]	Cost/Revenue Impact	Cost/Profit Impact
		235[E]	Special Trade Contractors	$265	$412,651	$17,933	0.07%	1.59%
3D	Painting - Government	999200	State	$3,995	$12,956,109,000	N/A	0.00%	N/A
		999300	Local	$536	$86,627,088	N/A	0.00%	N/A
4	Chromate (Chromite Ore Production)	325188	All Other Basic Inorganic Chemical Mfg.	$339,062	$114,000,000	$6,498,000	0.30%	5.22%
5	Chromate Pigment Producers	325131	Inorganic Dye and Pigment Mfg.	$36,660	$52,654,636	$2,121,962	0.07%	1.82%
6	Chromated Copper Arsenate Producers	325320	Pesticide and Other Agricultural Chemical Mfg.	$7,052	$26,210,731	$1,460,199	0.03%	0.46%
7	Chromium Catalyst Producers	325188	All Other Basic Inorganic Chemical Mfg.	$995,311	$93,357,606	$3,762,312	1.07%	26.45%
8	Paint and Coatings Producers	325510	Paint and Coating Mfg.	$27,515	$22,410,389	$1,063,776	0.12%	2.59%
9	Printing Ink Producers	325910	Printing Ink Mfg.	$26,227	$15,557,637	$786,018	0.17%	3.34%
10	Plastic Colorant Producers and Users	325211	Plastics Material and Resin Mfg.	$16,727	$12,943,690	$662,596	0.13%	2.52%
		325991	Custom Compounding of Purchased Resin					
		3261	Plastic Product Mfg.					
11	Plating mixture Producers	325998	All Other Miscellaneous Chemical Product and Preparation Mfg.	$23,918	$31,221,004	$1,577,379	0.08%	1.52%
12	Wood Preserving	321114	Wood Preservation	N/A	N/A	N/A	N/A	N/A
13	Chromium Metal Producers	331112	Electrometallurgical Ferroalloy Product Mfg.	$54,083	$72,676,523	$1,435,797	0.07%	3.77%
14	Steel Mills	331111	Iron and Steel Mills	$19,425	$250,610,291	$4,951,057	0.01%	0.39%
15	Iron and Steel foundries	3315	Iron foundries	$23,094	$16,087,981	$782,085	0.14%	2.95%
		331512	Steel Investment foundries					
		331513	Steel foundries (except investment)					
16	Chromium Dioxide Producers	325188	All Other Inorganic Chemicals, n.e.c.	N/A	N/A	N/A	N/A	N/A
17	Chromium Dye Producers	3251317	Chrome Colors and Other Inorganic Pigments	$85,265	$76,623,676	$3,166,534	0.11%	2.69%
18	Chromium Sulfate Producers	325188	All Other Inorganic Chemicals, n.e.c.	$11,590	$4,831,955	$194,726	0.24%	5.95%
19	Chemical Distributors	42269[F]	Other Chemical and Allied Products	$4,290	$4,666,658	$195,107	0.09%	2.20%
20	Textile Dyeing	313	Textile Mills	$1,467	$6,224,614	$195,272	0.02%	0.75%
		314	Textile Product Mills					
21	Colored Glass Producers	3272123	Other Pressed and Blown Glass and Glassware Mfg.	$1,732	$15,769,675	$497,154	0.01%	0.35%
		3272129	Other Pressed and Blown Glass and Glassware Mfg.					
22	Printing	32311	Printing	$603	$613,162	$34,683	0.07%	1.74%

Table IX-6. Economic Impacts on All Entities Affected by OSHA's Proposed Standard for Hexavalent Chromium (by Application Group for a PEL of 1 ug/m^3)

	Application Group	NAICS	Category	Cost per Entity[L]			Impacts for Incremental-Requirement Costs	
				Incremental-Requirement Costs	Revenue per Entity[M]	Profit per Entity[M]	Cost/Revenue Impact	Cost/Profit Impact
		323113	Commercial Screen Printing					
23	Leather Tanning	3161	Leather and Hide Tanning and Finishing	N/A	N/A	N/A	N/A	N/A
24	Chromium Catalyst Users	325110	Petrochemical Mfg., Including Styrene	$10,479	$222,869,583	$9,959,565	0.00%	0.11%
24A	Chromium Catalyst Users - Service Companies	561790	Other Services to Buildings and Dwellings, Including Catalyst handling	$27,138	$3,844,780	$147,632	0.71%	18.38%
25	Refractory Brick Producers	327125	Nonclay Refractory Mfg.	$13,480	$49,494,145	$2,092,266	0.03%	0.64%
26A	Wood Working -General Industry	321	General Industry	$4,300	$7,843,878	$243,160	0.05%	1.77%
26B	Wood Working - Maritime Industry	336611	Ship Building and Repairing	$196	$33,974,725	$1,579,825	0.00%	0.01%
26C	Wood Working - Construction Industry	2332[G], 2333[H], 2349[I], 23551[J]	Construction	$548	$7,815,378	$324,338	0.01%	0.17%
26D	Wood Working - Government	999200	State	$522	$12,956,109,000	N/A	0.00%	0.00%
		999300	Local	$521	$108,838,617	N/A	0.00%	0.00%
27	Solid Waste Incineration	562213	Solid Waste Combustors and Incinerators	$10,985	$13,235,956	$424,411	0.08%	2.59%
27A	Solid Waste Incineration - govt	999300	Local Governments	$2,001	$151,220,000	N/A	0.00%	0.00%
28	Oil and Gas Well Drilling	213111	Drilling Oil and Gas Wells	N/A	N/A	N/A	N/A	N/A
29	Portland Cement Producers	327310	Cement Mfg.	$4,332	$33,445,048	$2,431,957	0.01%	0.18%
30	Superalloy Producers	331492	Secondary Smelting, Refining and Alloying of Nonferrous Metal	$7,249	$43,834,567	$1,304,473	0.02%	0.56%
		331528	Other Nonferrous Foundries					
31B	Construction - Refractory Brick Restoration and Maintenance	235[E]	Special Trade Contractors	$87	$1,040,365	$45,190	0.01%	0.19%
31C	Construction - Hazardous Waste Site Work	2333[H] ,	Nonresidential Building Construction	$319	$5,042,375	$212,284	0.01%	0.15%
31CG	Hazardous Waste Site Work - Government	999200	State	$196	$12,956,109,000	N/A	0.00%	0.00%
		999300	Local	$228	$109,435,929	N/A	0.00%	0.00%
31D	Construction - Industrial Rehabilitation and Maintenance	23493[K]	Industrial Nonbuilding Structure Construction	$210	$4,884,832	$202,024	0.00%	0.10%
31DG	Industrial Rehabilitation and Maintenance - Government	999200	State	$217	$12,956,109,000	N/A	0.00%	0.00%
		999300	Local	$216	$108,554,940	N/A	0.00%	0.00%
32	Precast Concrete Products Producers	327331, 327332, 327390	Concrete Pipe, Brick, and Block Mfg	$4,931	$3,412,538	$248,143	0.14%	1.99%

Footnotes

[A] Includes industries in NAICS 31-33, NAICS 42, NAICS 44-45, NAICS 51, NAICS 53, NAICS 54, NAICS 56, NAICS 61, NAICS 71, and NAICS 81.

[B] Includes industries in NAICS 11, NAICS 22, NAICS 31-33, NAICS 42, NAICS 44-45, NAICS 48-49, NAICS 51, NAICS 52, NAICS 53, NAICS 54, NAICS 56, NAICS 61, NAICS 62, NAICS 71, NAICS 72, and NAICS 81.

[C] 1997 NAICS Code Is 233, Building, Developing, and General Contracting. 2002 NAICS Code Is 236, Construction of Buildings.

[D] 1997 NAICS Code Is 234, Heavy Construction. 2002 NAICS Code is 236, Heavy and Civil Engineering Construction.

[E] 1997 NAICS Code Is 235, Special Trades Contractors. 2002 NAICS Code Is 236, Special Trades Contractors.

[F] 1997 NAICS Code Is 42269, Other Chemical and Allied Products. 2002 NAICS Code is 424690, Other Chemical and Allied Products Merchant Wholesalers.

[G] 1997 NAICS Code is 2332, Residential Building Construction. 2002 NAICS Code is 23611, Residential Building Construction.

[H] 1997 NAICS Code is 2333, Nonresidential Building Construction. 2002 NAICS Code Is 2362, Nonresidential Building Construction.

[I] 1997 NAICS Code Is 2349, Other Heavy Construction. 2002 NAICS Code Is 237, Heavy and Civil Engineering Construction.

[J] 1997 NAICS Code Is 23551, Carpentry. 2002 NAICS Codes are 23835, Finish Carpentry Contractors, and 23813, Framing Contractors.

[K] 1997 NAICS Code Is 23493, Industrial Non-Building Structure Construction. 2002 NAICS Code is 23621, Industrial Building Construction.

[L] "Entities" refer to business firms or governmental bodies; "establishments" refer to industrial plants. Data on affected entities, establishments, and employees are from multiple sources; see the industrial profiles in Chapter II in the PEA (Ex. 35-391) for the complete list of references.

[M] Industry revenues and profits were estimated from data reported in I.R.S., ***Corporation Source Book of Statistics of Income, 2000.*** Data on revenues for State and Local Governments were taken from U.S. Census Bureau, ***Government Finances: 1999-2000***, January 2003.

Source: U.S. Dept. of Labor, OSHA, Office of Regulatory Analysis, based on IT, 2004.

This screening analysis is used to determine whether the compliance costs potentially associated with the standard would lead to significant impacts on establishments in the affected industries. The actual impact of the standard on the viability of establishments in a given industry will depend on the price elasticity of demand for the services sold by establishments in that industry.

Price elasticity refers to the relationship between the price charged for a service and the demand for that service; that is, the more elastic the relationship, the less able an establishment is to pass the costs of compliance through to its customers in the form of a price increase and the more it will have to absorb the costs of compliance from its profits. When demand is inelastic, establishments can recover most of the costs of compliance simply by raising the prices they charge for that service; under this scenario, profit rates are largely unchanged and the industry remains viable. On the other hand, when demand is elastic, establishments cannot recover all the costs simply by passing the cost increase through in the form of a price increase; instead, they must absorb some of the increase from their profits. Commonly, this will mean both reductions in the quantity of goods and services produced and in profits. In general, "when an industry is subject to a higher cost, it does not simply swallow it, it raises its price and reduces its output, and in this way shifts a part of the cost to its consumers and a part to its suppliers," in the words of the court in *American Dental Association* v. *Secretary of Labor* (984 F.2d 823, 829 (Seventh Cir. 1993)).

Specifically if demand is completely inelastic (i.e., price elasticity is 0), then the impact of compliance costs that amount to 1 percent of revenues would be a 1 percent increase in the price of the product or service, with no decline in demand or in profits. Such a situation is rare but might be approximately correct in situations in which there are few, if any, substitutes for the product or service offered by the affected sector or if the products or services of the affected sector account for only a small portion of the income of its consumers. If the demand is perfectly elastic (i.e., the price elasticity is infinitely large), then no increase in price is possible, and before-tax profits would be reduced by an amount equal to the costs of compliance (minus any savings resulting from improved worker health) if the industry attempted to keep producing the same amount of goods and services as previously. Under this scenario, if the costs of compliance represent a large percentage of the sector's profits, some establishments might be forced to close. This scenario is highly unlikely to occur, however, because it can only arise when there are other goods and services that are, in the eye of the consumer, perfect substitutes for the goods and services the affected establishments produce or provide.

A common intermediate case would be a price elasticity of one. In this situation, if the costs of compliance amount to 1 percent of revenues, then production would decline by 1 percent and prices would rise by 1 percent. In this case, the industry revenues would stay the same, with somewhat lower production but similar profit rates. Consumers would, however, get less of the product or the service for their expenditures, and producers would collect lower total profits; this, as the court described in *ADA* v. *Secretary of Labor*, is the more typical case.

Table IX–6 provides costs as percentage of revenues and profits for all affected establishments. OSHA believes that this is the best way to examine its statutory responsibility to determine whether the standard affects the viability of an industry as a whole. There is only one industry where costs exceed one percent of revenues (chromium catalyst production), and none in which costs exceed 1.5 percent of revenues. In only four industries (electroplating, construction welding, chromium catalyst production and chromium catalyst service) do compliance costs exceed 10 percent of profits.

In the case of construction, such cost changes are unlikely to significantly alter the demand for construction welding services which are essential for many projects and not subject to foreign competition. Independent electroplating shops have also been subject to annual changes larger in magnitude than the

costs of hexavalent chromium. The required price increase to fully restore profits of 0.93 percent is significantly less than the average annual increase in price of electroplating services. While such an additional price change might cause some small drop in the demand for services, the historical data clearly show that such price changes can be incurred without affecting the viability of the industry. Chromium catalyst production and service companies are also unlikely to be affected by costs of the relative magnitude found here. While there may be a small long term shift from the use of chromium catalysts as a result of the regulation, most companies are locked into the use of specific catalyst without major new investments. As a result, while there may be some long term shift away from the use of chromium catalysts, a price change of one percent are unlikely to immediately prompt such a change. This also means that the market for the services of chrome catalyst services is likely to be maintained. Further, faced with a new regulation, companies are more rather than less likely to turn to a service company to handle chromium products. Based on these considerations, OSHA preliminarily determines that the proposed standard is economically feasible.

Table IX–7 shows costs as percentage of profits and revenues for firms classified as small by the Small Business Administration and Table IX–8 shows costs as a percentage of revenues and profits for establishments with less than 20 employees. These Tables show greater potential impacts, especially for small electroplating establishments. Based on these results, OSHA has prepared an Initial Regulatory Flexibility Analysis to examine the impacts on small businesses and how they can be alleviated.

Table IX-7. Economic Impacts on Small Business Entities Affected by OSHA's Proposed Standard for Hexavalent Chromium (by Application Group for a PEL of 1 ug/m^3)

	Application Group	NAICS	Category	Cost per Entity[L]			Impacts for Incremental-Requirement Costs	
				Incremental-Requirement Costs	Revenue per Entity[M]	Profit per Entity[M]	Cost/Revenue Impact	Cost/Profit Impact
1	Electroplating - General Industry	All General Industry		$17,073	$7,723,529	$296,584	0.22%	5.76%
		331		$12,869	$19,765,430	$588,199	0.07%	2.19%
		332812	Metal Coating, Engraving (Except Jewerly and Silverware), and Allied Services to Manufacturers	$23,931	$8,192,928	$392,471	0.39%	8.10%
		332813	Electroplating, Plating, Polishing, Anodizing, and Coloring	$13,902	$1,483,200	$93,996	0.94%	14.79%
		Other 332	Fabricated Metal Product Manufacturing	$12,799	$5,002,320	$304,711	0.26%	4.20%
		333	Machinery Manufacturing	$13,414	$10,528,157	$529,745	0.13%	2.53%
		336 (except 33661)	Transportation Equipment Manufacturing	$18,961	$124,514,607	$3,704,808	0.02%	0.51%
		339	Miscellaneous Manufacturing	$20,734	$21,433,301	$1,525,472	0.10%	1.36%
		Other General Industry[A]		$13,971	$3,824,029	$142,545	0.37%	9.80%
2A	Welding - General Industry	31-33[B]	Manufacturing	$4,502	$7,448,864	$341,255	0.06%	1.32%
2B	Welding - Maritime Industry	336611	Ship Building and Repairing	$8,035	$32,947,099	$1,531,548	0.02%	0.39%
2C	Welding - Construction Industry	233[C]	Building, Developing, and General Contracting; Heavy Construction; Special Trade Contractors	$10,715	$2,377,623	$98,731	0.45%	10.85%
2D	Welding - Government	999200	State	N/A	N/A	N/A	N/A	N/A
		999300	Local	$580	$3,670,000	N/A	0.02%	0.02%
3A	Painting - General Industry	31-33	Manufacturing					
		332812	Metal Coating, Engraving (Except Jewerly and Silverware), and Allied Services to Manufacturers	$29,185	$5,862,391	$358,848	0.52%	8.13%
		336411, 336414, 336415, 336419, 336992	Transportation Equipment Manufacturing	$19,580	$225,712,596	$7,336,338	0.01%	0.27%
3B	Painting - Maritime Industry	33661	Ship and Boat Building	$8,505	$18,367,252	$853,802	0.05%	1.00%
3C	Painting - Construction Industry	234[D], 235[E]	Heavy Construction, Special Trade Contractors	$340	$1,831,327	$44,949	0.02%	0.76%
		234[D], 235[E]	Heavy Construction	$708	$9,931,086	$353,547	0.01%	0.20%
		235[E]	Special Trade Contractors	$279	$379,684	$18,492	0.07%	1.69%

Table IX-7. Economic Impacts on Small Business Entities Affected by OSHA's Proposed Standard for Hexavalent Chromium (by Application Group for a PEL of 1 ug/m^3)

	Application Group	NAICS	Category	Cost per Entity[L]			Impacts for Incremental-Requirement Costs	
				Incremental-Requirement Costs	Revenue per Entity[M]	Profit per Entity[M]	Cost/Revenue Impact	Cost/Profit Impact
3D	Painting - Government	999200	State	N/A	N/A	N/A	N/A	N/A
		999300	Local	$536	$3,670,000	N/A	0.01%	0.02%
4	Chromate (Chromite Ore Production)	325188	All Other Basic Inorganic Chemical Mfg.	N/A	N/A	N/A	N/A	N/A
5	Chromate Pigment Producers	325131	Inorganic Dye and Pigment Mfg.	$54,112	$77,883,388	$3,138,701	0.07%	1.72%
6	Chromated Copper Arsenate Producers	325320	Pesticide and Other Agricultural Chemical Mfg.	$7,052	$26,210,731	$1,480,199	0.03%	0.48%
7	Chromium Catalyst Producers	325188	All Other Basic Inorganic Chemical Mfg.	$995,311	$93,357,606	$3,762,312	1.07%	26.45%
8	Paint and Coatings Producers	325510	Paint and Coating Mfg.	$24,564	$16,941,999	$804,203	0.14%	3.05%
9	Printing Ink Producers	325910	Printing Ink Mfg.	$26,872	$15,846,214	$800,596	0.17%	3.36%
10	Plastic Colorant Producers and Users	325211	Plastics Material and Resin Mfg.	$12,563	$8,852,129	$453,140	0.14%	2.77%
		325991	Custom Compounding of Purchased Resin					
		3261	Plastic Product Mfg.					
11	Plating mixture Producers	325998	All Other Miscellaneous Chemical Product and Preparation Mfg.	$23,918	$31,221,004	$4,675,601	0.08%	0.51%
12	Wood Preserving	321114	Wood Preservation	N/A	N/A	N/A	N/A	N/A
13	Chromium Metal Producers	331112	Electrometallurgical Ferroalloy Product Mfg.	N/A	N/A	N/A	N/A	N/A
14	Steel Mills	331111	Iron and Steel Mills	$14,413	$170,519,898	$3,366,791	0.01%	0.43%
15	Iron and Steel foundries	3315	Iron foundries	$20,120	$13,493,814	$655,975	0.15%	3.07%
		331512	Steel Investment foundries					
		331513	Steel foundries (except investment)					
16	Chromium Dioxide Producers	325188	All Other Inorganic Chemicals, n.e.c.	N/A	N/A	N/A	N/A	N/A
17	Chromium Dye Producers	3251317	Chrome Colors and Other Inorganic Pigments	$85,265	$78,623,678	$3,168,534	0.11%	2.69%
18	Chromium Sulfate Producers	325188	All Other Inorganic Chemicals, n.e.c.	$6,954	$2,899,173	$116,637	0.24%	5.95%
19	Chemical Distributors	42269[F]	Other Chemical and Allied Products	$3,659	$3,913,866	$163,627	0.10%	2.36%
20	Textile Dyeing	313	Textile Mills	$1,325	$5,046,265	$158,306	0.03%	0.84%
		314	Textile Product Mills					
21	Colored Glass Producers	3272123	Other Pressed and Blown Glass and Glassware Mfg.	$1,392	$8,645,887	$272,224	0.02%	0.51%
		3272129	Other Pressed and Blown Glass and Glassware Mfg.					
22	Printing	32311	Printing	$593	$783,776	$33,429	0.08%	1.77%
		323113	Commercial Screen Printing					

Table IX-7. Economic Impacts on Small Business Entities Affected by OSHA's Proposed Standard for Hexavalent Chromium (by Application Group for a PEL of 1 ug/m^3)

				Cost per Entity[L]			Impacts for Incremental-Requirement Costs	
	Application Group	NAICS	Category	Incremental-Requirement Costs	Revenue per Entity[M]	Profit per Entity[M]	Cost/Revenue Impact	Cost/Profit Impact
23	Leather Tanning	3161	Leather and Hide Tanning and Finishing	N/A	N/A	N/A	N/A	N/A
24	Chromium Catalyst Users	325110	Petrochemical Mfg., Including Styrene	$6,086	$129,321,394	$5,784,287	0.00%	0.11%
24A	Chromium Catalyst Users - Service Companies	561790	Other Services to Buildings and Dwellings, Including Catalyst handling	$11,349	$1,461,540	$56,120	0.78%	20.22%
25	Refractory Brick Producers	327125	Nonclay Refractory Mfg.	$13,480	$49,494,145	$2,092,266	0.03%	0.64%
26A	Wood Working -General Industry	321	General Industry	$3,815	$6,746,667	$209,147	0.06%	1.82%
26B	Wood Working - Maritime Industry	336611	Ship Building and Repairing	$175	$38,428,332	$1,786,917	0.00%	0.01%
26C	Wood Working - Construction Industry	2332[G], 2333[H], 2349[I], 23551[J]	Construction	$542	$7,316,483	$303,634	0.01%	0.16%
26D	Wood Working - Government	999200	State	N/A	N/A	N/A	N/A	N/A
		999300	Local	$521	$3,670,000	N/A	0.01%	0.04%
27	Solid Waste Incineration	562213	Solid Waste Combustors and Incinerators	$3,671	$3,821,846	$122,548	0.10%	3.00%
27A	Solid Waste Incineration - govt	999300	Local Governments	N/A	$3,670,000	N/A	N/A	0.11%
28	Oil and Gas Well Drilling	213111	Drilling Oil and Gas Wells	N/A	N/A	N/A	N/A	N/A
29	Portland Cement Producers	327310	Cement Mfg.	$2,940	$16,657,610	$1,211,258	0.02%	0.24%
30	Superalloy Producers	331492	Secondary Smelting, Refining and Alloying of Nonferrous Metal	$4,430	$26,787,791	$797,178	0.02%	0.56%
		331528	Other Nonferrous Foundries					
31B	Construction - Refractory Brick Restoration and Maintenance	235[E]	Special Trade Contractors	$84	$973,786	$42,298	0.01%	0.20%
31C	Construction - Hazardous Waste Site Work	2333[H]	Nonresidential Building Construction	$304	$4,621,489	$194,565	0.01%	0.16%
31CG	Hazardous Waste Site Work - Government	999200	State	N/A	N/A	N/A	N/A	N/A
		999300	Local	$226	$3,670,000	N/A	0.01%	0.03%
31D	Construction - Industrial Rehabilitation and Maintenance	23493[K]	Industrial Nonbuilding Structure Construction	$179	$3,303,996	$136,650	0.01%	0.13%
31DG	Industrial Rehabilitation and Maintenance - Government	999200	State	N/A	N/A	N/A	N/A	N/A
		999300	Local	$216	$3,670,000	N/A	0.01%	0.01%
32	Precast Concrete Products Producers	327331, 327332, 327390	Concrete Pipe, Brick, and Block Mfg.	$4,513	$2,997,332	$217,951	0.15%	2.07%

Footnotes

[A] Includes industries in NAICS 31-33, NAICS 42, NAICS 44-45, NAICS 51, NAICS 53, NAICS 54, NAICS 56, NAICS 61, NAICS 71, and NAICS 81.

[B] Includes industries in NAICS 11, NAICS 22, NAICS 31-33, NAICS 42, NAICS 44-45, NAICS 48-49, NAICS 51, NAICS 52, NAICS 53, NAICS 54, NAICS 56, NAICS 61, NAICS 62, NAICS 71, NAICS 72, and NAICS 81.

[C] 1997 NAICS Code is 233, Building, Developing, and General Contracting. 2002 NAICS Code is 236, Construction of Buildings.

[D] 1997 NAICS Code is 234, Heavy Construction. 2002 NAICS Code is 236, Heavy and Civil Engineering Construction.

[E] 1997 NAICS Code is 235, Special Trades Contractors. 2002 NAICS Code is 236, Special Trades Contractors.

[F] 1997 NAICS Code is 42269, Other Chemical and Allied Products. 2002 NAICS Code is 424690, Other Chemical and Allied Products Merchant Wholesalers.

[G] 1997 NAICS Code is 2332, Residential Building Construction. 2002 NAICS Code is 23611, Residential Building Construction.

[H] 1997 NAICS Code is 2333, Nonresidential Building Construction. 2002 NAICS Code is 2362, Nonresidential Building Construction.

[I] 1997 NAICS Code is 2349, Other Heavy Construction. 2002 NAICS Code is 237, Heavy and Civil Engineering Construction.

[J] 1997 NAICS Code is 23551, Carpentry. 2002 NAICS Codes are 23835, Finish Carpentry Contractors, and 23813, Framing Contractors.

[K] 1997 NAICS Code is 23493, Industrial Non-Building Structure Construction. 2002 NAICS Code is 23621, Industrial Building Construction.

[L] "Entities" refer to business firms or governmental bodies; "establishments" refer to industrial plants. Data on affected entities, establishments, and employees are from multiple sources; see the Industrial profiles in Chapter II in the PEA (Ex. 35-391) for the complete list of references.

[M] Industry revenues and profits were estimated from data reported in I.R.S., ***Corporation Source Book of Statistics of Income, 2000.*** Data on revenues for State and Local Governments were taken from U.S. Census Bureau, ***Government Finances: 1999-2000***, January 2003.

Source: U.S. Dept. of Labor, OSHA, Office of Regulatory Analysis, based on IT, 2004.

Table IX-8. Economic Impacts on Small (<20 Employees) Establishments Affected by OSHA's Proposed Standard for Hexavalent Chromium (by Application Group for a PEL of 1 ug/m^3)

	Application Group	NAICS	Category	Cost per Establishment[L] Incremental-Requirement Costs	Revenue per Establishment[M]	Profit per Establishment[M]	Impacts for Incremental-Requirement Costs: Cost/Revenue Impact	Impacts for Incremental-Requirement Costs: Cost/Profit Impact
1	Electroplating - General Industry	All General Industry		$7,985	$1,862,857	$63,854	0.48%	12.51%
		331		$7,985	$1,600,531	$47,630	0.50%	16.77%
		332812	Metal Coating, Engraving (Except Jewerly and Silverware), and Allied Services to Manufacturers	$7,985	$827,453	$39,764	1.27%	20.08%
		332813	Electroplating, Plating, Polishing, Anodizing, and Coloring	$7,985	$389,893	$24,709	2.05%	32.32%
		Other 332	Fabricated Metal Product Manufacturing	$7,985	$1,081,783	$85,896	0.74%	12.12%
		333	Machinery Manufacturing	$7,985	$1,499,968	$75,474	0.53%	10.58%
		336 (except 33661)	Transportation Equipment Manufacturing	$7,985	$3,227,879	$96,042	0.25%	8.31%
		339	Miscellaneous Manufacturing	$7,985	$1,178,811	$83,885	0.68%	9.52%
		Other General Industry[A]		$7,985	$1,748,042	$85,085	0.46%	12.27%
2A	Welding - General Industry	31-33[B]	Manufacturing	$2,203	$918,520	$41,989	0.24%	5.25%
2B	Welding - Maritime Industry	336611	Ship Building and Repairing	$2,028	$1,221,589	$56,786	0.17%	3.57%
2C	Welding - Construction Industry	233[C]	Building, Developing, and General Contracting; Heavy Construction; Special Trade Contractors	$5,742	$985,431	$40,920	0.58%	14.03%
2D	Welding - Government	999200	State	N/A	N/A	N/A	N/A	N/A
		999300	Local	N/A	N/A	N/A	N/A	N/A
3A	Painting - General Industry	31-33	Manufacturing					
		332812	Metal Coating, Engraving (Except Jewerly and Silverware), and Allied Services to Manufacturers	$6,187	$745,100	$47,220	0.83%	13.06%
		336411, 336414, 336415, 336419, 336992	Transportation Equipment Manufacturing	$6,187	$8,288,227	$204,386	0.10%	3.02%
3B	Painting - Maritime Industry	33661	Ship and Boat Building	$3,577	$1,221,589	$56,786	0.29%	8.30%
3C	Painting - Construction Industry	234[D], 235[E]	Heavy Construction, Special Trade Contractors	$251	$484,203	$10,042	0.05%	2.50%
		234[D], 235[E]	Heavy Construction	$251	$673,405	$23,973	0.04%	1.05%

Table IX-8. Economic Impacts on Small (<20 Employees) Establishments Affected by OSHA's Proposed Standard for Hexavalent Chromium (by Application Group for a PEL of 1 ug/m^3)

	Application Group	NAICS	Category	Cost per Establishment[L] Incremental-Requirement Costs	Revenue per Establishment[M]	Profit per Establishment[M]	Impacts for Incremental-Requirement Costs: Cost/Revenue Impact	Impacts for Incremental-Requirement Costs: Cost/Profit Impact
		235[E]	Special Trade Contractors	$251	$248,785	$10,806	0.10%	2.33%
3D	Painting - Government	999200	State	N/A	N/A	N/A	N/A	N/A
		999300	Local	N/A	N/A	N/A	N/A	N/A
4	Chromate (Chromite Ore Production)	325188	All Other Basic Inorganic Chemical Mfg.	N/A	N/A	N/A	N/A	N/A
5	Chromate Pigment Producers	325131	Inorganic Dye and Pigment Mfg.	$7,759	$2,197,133	$88,544	0.35%	8.76%
6	Chromated Copper Arsenate Producers	325320	Pesticide and Other Agricultural Chemical Mfg.	N/A	N/A	N/A	N/A	N/A
7	Chromium Catalyst Producers	325188	All Other Basic Inorganic Chemical Mfg.	N/A	N/A	N/A	N/A	N/A
8	Paint and Coatings Producers	325510	Paint and Coating Mfg.	$24,217	$3,337,373	$158,418	0.73%	15.29%
9	Printing Ink Producers	325910	Printing Ink Mfg.	$11,818	$5,194,382	$262,436	0.22%	4.43%
10	Plastic Colorant Producers and Users	325211	Plastics Material and Resin Mfg.	$8,480	$1,042,866	$53,384	0.81%	15.89%
		325991	Custom Compounding of Purchased Resin					
		3261	Plastic Product Mfg.					
11	Plating mixture Producers	325998	All Other Miscellaneous Chemical Product and Preparation Mfg.	$22,864	$4,385,091	$221,548	0.52%	10.23%
12	Wood Preserving	321114	Wood Preservation	N/A	N/A	N/A	N/A	N/A
13	Chromium Metal Producers	331112	Electrometallurgical Ferroalloy Product Mfg.	N/A	N/A	N/A	N/A	N/A
14	Steel Mills	331111	Iron and Steel Mills	$8,687	$2,095,343	$41,396	0.41%	20.99%
15	Iron and Steel foundries	3315	Iron foundries	$8,010	$728,888	$35,423	1.10%	22.81%
		331512	Steel Investment foundries					
		331513	Steel foundries (except investment)					
16	Chromium Dioxide Producers	325188	All Other Inorganic Chemicals, n.e.c.	N/A	N/A	N/A	N/A	N/A
17	Chromium Dye Producers	3251317	Chrome Colors and Other Inorganic Pigments	$20,803	$2,185,058	$87,252	0.96%	23.84%
18	Chromium Sulfate Producers	325188	All Other Inorganic Chemicals, n.e.c.	$6,954	$2,899,173	$118,837	0.24%	5.95%
19	Chemical Distributors	42269[F]	Other Chemical and Allied Products	$3,022	$1,391,729	$58,184	0.22%	5.19%
20	Textile Dyeing	313	Textile Mills	$982	$558,520	$17,521	0.18%	5.81%
		314	Textile Product Mills					
21	Colored Glass Producers	3272123	Other Pressed and Blown Glass and Glassware Mfg.	$1,127	$908,236	$28,597	0.12%	3.94%
		3272129	Other Pressed and Blown Glass and Glassware Mfg.					
22	Printing	32311	Printing	$428	$246,802	$10,526	0.17%	4.06%

Table IX-8. Economic Impacts on Small (<20 Employees) Establishments Affected by OSHA's Proposed Standard for Hexavalent Chromium (by Application Group for a PEL of 1 ug/m^3)

	Application Group	NAICS	Category	Cost per Establishment[L] Incremental-Requirement Costs	Revenue per Establishment[M]	Profit per Establishment[M]	Impacts for Incremental-Requirement Costs: Cost/Revenue Impact	Impacts for Incremental-Requirement Costs: Cost/Profit Impact
		323113	Commercial Screen Printing					
23	Leather Tanning	3161	Leather and Hide Tanning and Finishing	N/A	N/A	N/A	N/A	N/A
24	Chromium Catalyst Users	325110	Petrochemical Mfg., Including Styrene	N/A	N/A	N/A	N/A	N/A
24A	Chromium Catalyst Users - Service Companies	561790	Other Services to Buildings and Dwellings, Including Catalyst handling	$7,824	$906,270	$34,799	0.86%	22.48%
25	Refractory Brick Producers	327125	Nonclay Refractory Mfg.	$0	NA	NA	0.00%	0.00%
26A	Wood Working -General Industry	321	General Industry	$3,282	$1,131,920	$35,090	0.29%	9.35%
26B	Wood Working - Maritime Industry	336611	Ship Building and Repairing	$148	$1,221,589	$56,804	0.01%	0.26%
26C	Wood Working - Construction Industry	2332[Q], 2333[H], 2349[I], 23551[J]	Construction	$524	$1,718,617	$71,323	0.03%	0.73%
26D	Wood Working - Government	999200	State	N/A	N/A	N/A	N/A	N/A
		999300	Local	N/A	N/A	N/A	N/A	N/A
27	Solid Waste Incineration	562213	Solid Waste Combustors and Incinerators	$2,021	$1,697,066	$54,416	0.12%	3.71%
27A	Solid Waste Incineration - govt	999300	Local Governments	N/A	N/A	N/A	N/A	N/A
28	Oil and Gas Well Drilling	213111	Drilling Oil and Gas Wells	N/A	N/A	N/A	N/A	N/A
29	Portland Cement Producers	327310	Cement Mfg.	$2,275	$2,609,367	$189,740	0.09%	1.20%
30	Superalloy Producers	331492	Secondary Smelting, Refining and Alloying of Nonferrous Metal	N/A	N/A	N/A	N/A	N/A
		331528	Other Nonferrous Foundries					
31B	Construction - Refractory Brick Restoration and Maintenance	235[E]	Special Trade Contractors	$52	$478,361	$20,779	0.01%	0.25%
31C	Construction - Hazardous Waste Site Work	2333[H]	Nonresidential Building Construction	$226	$1,219,945	$51,360	0.02%	0.44%
31CG	Hazardous Waste Site Work - Government	999200	State	N/A	N/A	N/A	N/A	N/A
		999300	Local	N/A	N/A	N/A	N/A	N/A
31D	Construction - Industrial Rehabilitation and Maintenance	23493[K]	Industrial Nonbuilding Structure Construction	$52	$613,995	$25,394	0.01%	0.20%
31DG	Industrial Rehabilitation and Maintenance - Government	999200	State	N/A	N/A	N/A	N/A	N/A
		999300	Local	N/A	N/A	N/A	N/A	N/A
32	Precast Concrete Products Producers	327331, 327332, 327390	Concrete Pipe, Brick, and Block Mfg.	$3,395	$685,373	$64,380	0.38%	5.27%

Footnotes

[A] Includes industries in NAICS 31-33, NAICS 42, NAICS 44-45, NAICS 51, NAICS 53, NAICS 54, NAICS 56, NAICS 61, NAICS 71, and NAICS 81.

[B] Includes industries in NAICS 11, NAICS 22, NAICS 31-33, NAICS 42, NAICS 44-45, NAICS 48-49, NAICS 51, NAICS 52, NAICS 53, NAICS 54, NAICS 56, NAICS 61, NAICS 62, NAICS 71, NAICS 72, and NAICS 81.

[C] 1997 NAICS Code is 233, Building, Developing, and General Contracting. 2002 NAICS Code is 236, Construction of Buildings.

[D] 1997 NAICS Code is 234, Heavy Construction. 2002 NAICS Code is 236, Heavy and Civil Engineering Construction.

[E] 1997 NAICS Code is 235, Special Trades Contractors. 2002 NAICS Code is 236, Special Trades Contractors.

[F] 1997 NAICS Code is 42269, Other Chemical and Allied Products. 2002 NAICS Code is 424690, Other Chemical and Allied Products Merchant Wholesalers.

[G] 1997 NAICS Code is 2332, Residential Building Construction. 2002 NAICS Code is 23611, Residential Building Construction.

[H] 1997 NAICS Code is 2333, Nonresidential Building Construction. 2002 NAICS Code is 2362, Nonresidential Building Construction.

[I] 1997 NAICS Code is 2349, Other Heavy Construction. 2002 NAICS Code is 237, Heavy and Civil Engineering Construction.

[J] 1997 NAICS Code is 23551, Carpentry. 2002 NAICS Codes are 23835, Finish Carpentry Contractors, and 23813, Framing Contractors.

[K] 1997 NAICS Code is 23493, Industrial Non-Building Structure Construction. 2002 NAICS Code is 23621, Industrial Building Construction.

[L] "Entities" refer to business firms or governmental bodies; "establishments" refer to industrial plants. Data on affected entities, establishments, and employees are from multiple sources; see the industrial profiles in Chapter II in the PEA (Ex. 35-391) for the complete list of references.

[M] Industry revenues and profits were estimated from data reported in I.R.S., ***Corporation Source Book of Statistics of Income, 2000.*** Data on revenues for State and Local Governments were taken from U.S. Census Bureau, ***Government Finances: 1999-2000***, January 2003.

Source: U.S. Dept. of Labor, OSHA, Office of Regulatory Analysis, based on IT, 2004.

F. Benefits and Net Benefits

OSHA estimated the benefits associated with alternative PELs for Cr(VI) by applying the dose-response relationship developed in the risk assessment to current exposure levels. OSHA determined current exposure levels by first developing an exposure profile for industries with Cr(VI) exposures using OSHA inspection and site visit data, and then applying this profile to the current worker population. The industry by industry exposure profile was given in Table IX–2 above.

By applying the dose-response relationship to estimates of current exposure levels across industries, it is possible to project the number of lung cancers expected to occur in the worker population given current exposures (the "baseline"), and the number of these cases that would be avoided under alternative, lower PELs. OSHA assumed that exposures below the limit of detection (LOD) are equivalent to no exposure to Cr(VI), thus assigning no baseline or avoided lung cancers (and hence, no benefits) to these exposures. For exposures above the current PEL and for purposes of determining the benefit of reducing the PEL, OSHA assumed exposure at exactly the PEL. Consequently, the benefits computed below are attributable only to a change in the PEL. No benefits are assigned to the effect of a new standard increasing compliance with the current PEL. OSHA estimates that between 2,247 and 8,708 lung cancers attributable to Cr(VI) exposure will occur during the working lifetime of the current worker population. Table IX–9 shows the number of avoided lung cancers by PEL. At the proposed PEL of 1 $\mu g/m^3$, and estimated 1,970 to 7,500 lung cancers would be prevented over the working lifetime of the current worker population.

TABLE IX–9.—AVOIDED LUNG CANCERS ESTIMATES BY PEL

PEL ($\mu g/^3m$)	0.25	0.5	1	5	10	20
Avoided Cancers (Total)	2,147–8,270	2,078–7,968	1,970–7,500	1,440–5,233	1,052–3,649	585–1,864
Avoided Cancers (Annual)	48–184	46–177	44–167	32–116	23–81	13–41

Note that the Agency based these estimates on a worker that is employed in a Cr(VI) exposed occupation for his entire working life, from age 20 to 65. The calculation also does not allow workers to enter or exit Cr(VI) jobs, or switch to other exposure groups during their working lives. While the assumptions of 45 years of exposure and no mobility among exposure groups may seem restrictive, these assumptions actually are likely to yield somewhat conservative estimates of the number of avoided cancers, given the nature of the risk assessment model. For example, consider the case of job covered by five workers, each working nine years rather than one worker for 45 years. The former situation will likely yield a slightly higher rate of lung cancers, since more workers are exposed to the carcinogen (albeit for a shorter period of time) and that the average age of the workers exposed is likely to decrease. This is due to: (1) The linearity of the estimated dose-response relationship, and (2) once an individual accumulates a dose, the increase in relative risk persists for the remainder of his lifetime. For example, a worker exposed from age 20 to 30 will have a constant increased relative risk for about 50 or so years (from age 30 on, assuming no lag between exposure and increased risk and death at age 80), whereas a person exposed from age 40 to 50 will have only about 30 years of increased risk (again assuming no lag and death at age 80). The persistence of the increased relative risk for a lifetime follows directly from the risk assessment, and is typical of life table analysis. OSHA intends to investigate the implications of alternative exposure scenarios in the

course of further developing its economic benefits assessment.

For informational purposes only, OSHA has estimated the monetary value of the benefits associated with the draft proposed rule. These estimates are informational because OSHA cannot use benefit-cost analysis as a basis for determining the PEL for a health standard. In order to estimate monetary values for the benefits associated with the proposed rule, OSHA reviewed the approaches taken by other regulatory agencies for similar regulatory actions. OSHA found that occupational illnesses are analogous to the types of illnesses targeted by EPA regulations and has thus used them in this analysis.

OSHA is adopting EPA's approach, applying a value of $6.8 million to each premature fatality avoided. The $6.8 million value represents individuals' willingness-to-pay (WTP) to reduce the risk of premature death.

Nonfatal cases of lung cancer can be valued using a cost of illness (COI) approach, using data on associated medical costs. The EPA Cost of Illness Handbook (Ex.35–333) reports that the medical costs for a nonfatal case of lung cancer are, on average, $136,460. Updating the EPA figure to 2003 dollars yields the value of $160,030 Including values for lost productivity, the total COI which is applied to the OSHA estimate of nonfatal cases of lung cancer is $188,502.

An important limitation of the COI approach is that it does not measure individuals' WTP to avoid the risk of contracting nonfatal cancers or illnesses. As an alternative approach, nonfatal cancer benefits may be estimated by adjusting the value of lives saved estimates. In its Stage 2 Disinfection and Disinfection Byproducts water rule, EPA used studies on the WTP to avoid nonfatal lymphoma and chronic bronchitis as a basis for valuing nonfatal cancers. In sum, EPA valued nonfatal cancers at 58.3% of the value of a fatal cancer. Using WTP information would yield a higher estimate of the benefits associated with the reduction in nonfatal lung cancers, as the nonfatal cancers would be valued at $4 million rather than $188,502 per case. These values represent the upper bound values for nonfatal cases of lung cancer avoided.

Using these assumptions, and latency periods of 10, 20 and 35 years and possible increases in the value of life over time, OSHA estimated the total annual benefits of the standard at various PELS in Table IX–10, considering both the benefits from preventing fatal and non-fatal cases of lung cancer.

TABLE IX–10.—TOTAL ANNUAL LUNG CANCER BENEFITS

[Millions of 2003 Dollars]

PEL (μg/m³)	0.25	0.5	1	5	10	20
Undiscounted	$287–1,189	$278–1,145	$263–1,078	$192–753	$141–525	$78–269
Discount Rate = 3%	102–1,131	99–1,090	94–1,026	69–716	50–500	28–256
Discount Rate = 7%	27–773	26–745	25–701	18–490	14–342	8–175

Occupational exposure to Cr(VI) has also been linked to a multitude of other health effects, including irritated and perforated nasal septum, skin ulceration, asthma, and dermatitis. Current data on Cr(VI) exposure and health effects are insufficient to quantify the precise extent to which many of these ailments occur. However, it is possible to provide an upperbound estimate of the number of cases of dermatitis that occur annually and an upper estimate of the number that will be prevented by a standard. This estimate is an upperbound because it uses data on incidence of dermatitis among cement workers, where dermatitis is more common than it would be for other exposures to Cr(VI). It is important to note that if OSHA were able to quantify all Cr(VI)-related health effects, the quantified benefits would be somewhat higher than the benefits presented in this analysis.

Using National Institute for Occupational Safety and Health (NIOSH) data, Ruttenberg and Associates (Ex. XXXX) estimate that the incidence of dermatitis among concrete workers is between 0.2 and 1 percent. Applying the 0.2 percent–1 percent incidence rate indicates that there are presently 418–2,089 cases of dermatitis occurring annually. This approach represents an overestimate for cases of dermatitis in other application groups, since some dermatitis among cement workers is caused by other known factors, such as the high alkalinity of cement. If the measures in this draft proposed standard are 50 percent effective in preventing dermatitis, then there would be an estimated 209–1,045 cases of Cr(VI) dermatitis avoided annually.

To assign values to the cases of avoided dermatitis OSHA applied the COI approach. Ruttenberg and Associates computed that, on average, the medical costs associated with a case of dermatitis are $119 (in 2003 dollars) and the indirect and lost productivity costs are $1,239. These estimates were based on an analysis of BLS data on lost time associated with cases of dermatitis, updated to current dollars. Based on the Ruttenberg values, OSHA estimates that a Cr(VI) standard will yield $0.3 million to $1.4 million in annual benefits due to reduced incidence of dermatitis. (These benefits associated with dermatitis are not included in the net benefits analysis, as these benefits largely result from full compliance with existing requirements for PPE and hygiene areas.)

Occupational exposure to Cr(VI) can lead to nasal septum ulcerations and nasal septum perforations. As for cases of dermatitis, the data were insufficient to conduct a formal quantitative risk assessment to relate exposures and incidence. However, previous studies provide a basis for developing an approximate estimate of the number of nasal perforations expected under the current PEL as well as PELs of 0.25 μg/m³, 0.5 μg/m³, 1.0 μg/m³, 5.0 μg/m³, 10.0 μg/m³ and 20.0 μg/m³. Cases of nasal perforations were computed only for workers in electroplating and chrome production. The percentage of workers with nasal tissue damage is expected to be over 50 percent for those regularly exposed above approximately 20 μg/m³. Less than 25 percent of workers could reasonably be expected to experience nasal tissue damage if Cr(VI) exposure was kept below an 8-hour TWA of 5 μg/m³ and regular short-term exposures *e.g.* an hour or so) were below 10 μg/m³. Less than 10 percent of workers could reasonably be expected to experience nasal tissue damage at a TWA Cr(VI) below 2 μg/m³ [and short-term exposures below 10 μg/m³]. It appears likely that nasal damage might be avoided completely if all Cr(VI) [short-term and full shift] exposures were kept below 1 μg/m³.

OSHA estimates that 5,387 nasal perforations/ulcerations occur annually

under the current PEL. All of these are expected to be prevented under the proposed PEL of 1 μg/m³. Due to insufficient data, it was not possible to monetize the benefits. Thus, the benefits associated with a reduction in nasal perforations/ulcerations are excluded from the net benefits analysis presented below.

Finally, for informational purposes, OSHA examined the net benefits of the standard, based on the benefits and costs presented above, and the costs per case of cancer avoided as shown in Table IX–11.

TABLE IX–11.—ANNUAL NET BENEFITS AND COST PER CANCER AVOIDED BY PEL

[Millions of 2003 Dollars]

PEL (μg/m³)	0.25	0.5	1	5	10	20
Discount Rate = 3% Costs (Millions of 2003 Dollars)						
Total Annual	$524	$381	$212	$119	$91	$81
Net Benefits (Millions of 2003 Dollars)						
Minimum	−422	−282	−119	−51	−41	−53
Maximum	606	708	813	596	408	174
Midpoint	92	213	347	273	183	60
Cost Per Cancer Avoided (Millions of 2003 Dollars)						
Minimum	2.9	2,2	1.3	1.0	1.1	2.0
Maximum	11.0	8.3	4.8	3.7	3.9	6.2
Midpoint	6.9	5.2	3.1	2.4	2.5	4.1
Discount Rate = 7% Costs (Millions of 2003 Dollars)						
Total Annual	548	402	223	125	95	84
Net Benefits (Millions of 2003 Dollars)						
Minimum	−521	−376	−198	−107	−82	−77
Maximum	224	342	477	363	246	90
Midpoint	−149	−17	139	128	82	7
Cost Per Cancer Avoided (Millions of 2003 Dollars)						
Minimum	3.0	2.3	1.3	1.1	1.2	2.0
Maximum	11.5	8.7	5.1	3.9	4.1	6.5
Midpoint	7.2	5.5	3.2	2.5	2.6	4.2

In addition to examining alternative PELs, OSHA also examined alternatives to other provisions of the standard. These alternatives are discussed in the Initial Regulatory Flexibility Analysis in the next section.

As noted above, the OSH Act requires OSHA to set standards based on eliminating risk to the extent feasible. Eliminating risk to the extent feasible does not necessarily have anything to do with the results of a benefit cost analysis. Thus, these analyses of net benefits cannot be used as the basis for a decision concerning the choice of a PEL for a Cr(VI) standard.

Incremental costs and benefits are those that are associated with increasing stringency of the standard. Comparison of incremental benefits and costs provides and indication of the relative efficiency of the various PELs. OSHA cannot use this information in selecting a PEL, but it has conducted these calculations for informational purposes. Incremental costs, benefits, net benefits and cost per cancer avoided are presented in Table IX–12. Note that dermal benefits are excluded since they do not vary with the PEL and hence, do not affect the calculations.

TABLE IX–12.—INCREMENTAL BENEFITS, COSTS, NET BENEFITS AND COST PER CANCER AVOIDED

	20→10	10→5	5→1	1→0.5	0.5→0.25
Discount Rate = 3%					
Benefits	$133.0	$117.4	$167.4	$34.5	$22.3
Costs	−10.0	−28.0	−93.0	−169.0	−143.0
Net Benefits	123.0	89.4	74.4	134.5	120.7
Cost Per Cancer Avoided	1.6	0.1	−0.7	−2.3	−1.7
Discount Rate = 7%					
Benefits	86.2	76.4	109.1	22.5	14.5
Costs	−11.0	−30.0	−98.0	179.0	−146.0

TABLE IX–12.—INCREMENTAL BENEFITS, COSTS, NET BENEFITS AND COST PER CANCER AVOIDED—Continued

	20→10	10→5	5→1	1→0.5	0.5→0.25
Net Benefits	75.2	46.4	11.1	156.5	131.5
Cost Per Cancer Avoided	1.6	0.1	−0.7	−2.3	−1.7

G. Initial Regulatory Flexibility Analysis

Reasons Why Action by the Agency Is Being Considered

Several well-conducted scientific investigations have found increased lung cancer mortality among workers breathing Cr(VI) dusts and mists in the workplace. The high rate of lung cancer mortality has been documented in workers from several countries across multiple industries that use a broad spectrum of Cr(VI) compounds. Many of the studies found that the rate of lung cancer was greatest among workers in jobs where Cr(VI) exposure was highest and in workers employed in those jobs for the longest periods of time. These exposure-related trends implicate Cr(VI) as a likely causative agent and suggest that other known lung carcinogens to which the workers may be exposed, such as cigarette smoke, are unlikely to account for the increased lung cancers observed in the studies. The International Agency for Research on Cancer, the U.S. Environmental Protection Agency, and the American Conference of Governmental Industrial Hygienists have evaluated the human, animal, and other experimental evidence and concluded that Cr(VI) compounds are "known" or "confirmed" human carcinogens.

Two independent epidemiologic studies of workers from chromate production plants in Baltimore, Maryland (Gibb *et al.*, Ex. 31–22–11) and Painesville, Ohio (Luippold *et al.*, Ex. 33–10) were considered to present the strongest data sets for quantitative risk assessment. OSHA's analysis found that a linear, relative risk model provided the best fit to the data (Ex. 33–15; Ex. 33–12). The Agency preliminarily estimates that the excess lifetime lung cancer risk for workers exposed at the current Permissible Exposure Limit (PEL) of 52 μg/m³ Cr(VI), as an eight-hour time-weighted average for a 45-year working lifetime, ranges from 106 to 351 excess lung cancers per thousand workers exposed. OSHA applied the linear relative risk model to preliminarily estimate excess lifetime lung cancer risks from 45-year exposure at alternative PELs ranging from 0.25 μg/m³ to 20 μg/m³ (the range considered for the draft proposed standard). The projected risks at these alternate PELs are between four- and 200-fold lower than risks estimated at the current PEL. NIOSH and the Exponent group have reported similar lung cancer risks based on the Gibb (Ex. 33–13; Ex. 31–18–15–1) and the Luippold (Ex. 31–18–3) data sets and a relative risk model. The risk estimates at the very lowest Cr(VI) exposure levels under consideration (*e.g.*, 0.25 to 2.5 μg/m³) are considered to be somewhat more uncertain than those projected at the higher Cr(VI) levels because they involve risk model extrapolations below the range of exposures experienced by the Gibb and Luippold worker cohorts.

Exposure to airborne Cr(VI) can cause other adverse effects to the respiratory tract and the skin. Occupational surveys and medical examinations have found nasal septum ulcerations and perforations (i.e. "chrome holes") among chromium production workers and chrome electroplaters exposed repeatedly to relatively high levels of Cr(VI) (*e.g.*, 20 μg/m³ to 50 μg/m³). (Exs. 31–22–11; 9–126). Several case reports have also documented occupational asthma triggered by breathing Cr(VI) compounds in the workplace. Workers can also develop an allergic reaction of the skin known as allergic contact dermatitis as a result of repeated direct dermal contact with Cr(VI) solutions or other Cr(VI)-containing materials. Allergic contact dermatitis is most common on the hands and arms of workers who mix and use wet Cr(VI)-containing cement. Dermal contact with Cr(VI) can also cause an irritant dermatitis and ulceration of the skin called "chrome ulcers". This type of dermatitis is not an allergic condition and requires contact with a fairly concentrated form of Cr(VI). It has been reported primarily in chromate production plants and chrome electroplating facilities with poor industrial hygiene (work) practices.

A full discussion of the health effects and risk assessment that support the reasons why this action is being considered are given in Section VI of the Preamble, Health Effects, and Section VII, Quantitative Risk Assessment.

Objective of and Legal Basis for the Proposed Rule

The objective of the proposed rule is to reduce the numbers of fatalities and illnesses occurring among employees exposed to Cr(VI) in general industry, construction, and shipyard sectors. This objective will be achieved by requiring employers to install engineering controls where appropriate and to provide employees with the equipment, respirators, training, medical surveillance, and other protective measures to perform their jobs safely.

The legal basis for the rule is the responsibility given the U.S. Department of Labor through the Occupational Safety and Health Act of 1970 (OSH Act). The OSH Act authorizes the Secretary of Labor to promulgate occupational safety and health standards as necessary "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources." 29 U.S.C. 651(b). The legal authority can also be cited as 29 U.S.C. 655(b).

In addition to the statutory basis for a possible standard, the legal basis for the action also involves litigation on the need for and timetable for a Cr(VI) standard. See the Preamble Section III, for a fuller discussion.

Description and Estimate of Affected Small Entities

Table IX–1 above provides an overview of the number of small entities affected by the standard, by sector. Additional detail is provided in the Full Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis (Ex. 35–391).

Summary of Reporting, Recordkeeping, and Other Compliance Requirements

Table IX–13 shows the costs of the proposed standard for entities classified as small businesses by the SBA.

IX-13. Annualized Costs for Small Businesses Affected by OSHA's Proposed Standard for Hexavalent Chromium (by Application Group and Regulatory Requirement for a PEL of 1 ug/m^3)

	Application Group	Engineering Controls	Initial Exposure Monitoring	Periodic Exposure Monitoring	Respiratory Protection
1	Electroplating	$31,965,164	$646,859	$3,701,220	$1,812,409
2A	Welding (general industry)	$27,886,699	$3,321,234	$16,999,831	$14,595,338
2B	Welding (maritime industry)	$1,108,624	$36,905	$0	$355,039
2C	Welding (construction industry)	$14,898,873	$103,541	$0	$8,986,310
2D	Welding (government)	$62,301	$9,790	$0	$37,223
3A	Painting (general industry)	$1,252,774	$152,248	$615,545	$3,307,451
3B	Painting (maritime industry)	$307,929	$31,651	$0	$6,096,148
3C	Painting (construction industry)	$0	$29,734	$0	$0
3D	Painting (government)	$0	$2,682	$0	$0
4	Chromate (chromite ore) production	$0	$0	$0	$0
5	Chromate Pigment Producers	$47,400	$3,570	$13,808	$39,774
6	Chromated Copper Arsenate (CCA) Producers	$0	$3,502	$14,065	$2,680
7	Chromium Catalyst Producers	$2,272,600	$13,232	$71,440	$587,133
8	Paint and Coatings Producers	$3,594,464	$82,689	$104,921	$22,646
9	Printing Ink Producers	$0	$7,502	$5,452	$135,180
10	Plastic Colorant Producers and Users	$0	$160,679	$807,622	$209,210
11	Plating Mixture Producers	$144,780	$7,905	$28,902	$0
12	Wood Preserving	$0	$0	$0	$0
13	Chromium Material Producers	$0	$0	$0	$0
14	Steel Mills	$303,642	$31,621	$23,564	$102,318
15	Iron and Steel Foundries	$1,565,262	$341,451	$685,829	$1,770,253
16	Chromium Dioxide Producers	$0	$0	$0	$0
17	Chromium Dye Producers	$0	$30,966	$153,686	$63,217
18	Chromium Sulfate Producers	$0	$2,119	$7,410	$0
19	Chemical Distributors	$0	$441,314	$0	$0
20	Textile Dyeing	$0	$381,011	$0	$0
21	Colored Glass Producers	$669	$12,558	$0	$0
22	Printing	$0	$153,903	$0	$0
23	Leather Tanning	$0	$0	$0	$0
24	Chromium Catalyst Users	$0	$23,958	$48,061	$153
24A	Chromium Catalyst Users (Service)	$0	$3,663	$27,979	$0
25	Refractory Brick Producers	$0	$2,865	$2,716	$922
26A	Woodworking (general industry)	$35,400	$61,981	$0	$0
26B	Woodworking (maritime industry)	$0	$6,413	$0	$0
26C	Woodworking (construction industry)	$2,651,352	$900,736	$0	$0
26D	Woodworking (government)	$9,801	$3,330	$0	$0
27	Solid Waste Incineration	$0	$59,882	$129,602	$49,605
27A	Incinerators (government)	$0	$0	$0	$0
28	Oil and Gas Well Drilling	$0	$0	$0	$0
29	Portland Cement Producers	$0	$52,552	$0	$0
30	Superalloy Producers	$667	$765	$510	$861
31B	Construction (Refractory Repair)	$0	$0	$0	$0
31C	Construction (Hazardous Waste Work)	$0	$22,932	$0	$0
31CG	Haz. Waste (government)	$0	$7,194	$0	$0
31D	Construction (Industrial Rehabilitation)	$0	$0	$0	$0
31DG	Industrial Rehab. (government)	$0	$3,949	$0	$0
32	Precast Concrete Products Producers	$0	$3,217,948	$0	$0
	General Industry (including Government)	$69,141,622	$9,244,919	$23,442,160	$22,736,371
	Construction	$17,550,225	$1,056,943	$0	$8,986,310
	Maritime	$1,416,553	$74,969	$0	$6,451,187
	Total	$88,108,401	$10,376,832	$23,442,160	$38,173,867

IX-13. Annualized Costs for Small Businesses Affected by OSHA's Proposed Standard for Hexavalent Chromium (by Application Group and Regulatory Requirement for a PEL of 1 ug/m^3)

	Application Group	Housekeeping	Medical Surveillance	Information and Training	Recordkeeping
1	Electroplating	$8,108,190	$375,787	$418,922	$110,504
2A	Welding (general industry)	$0	$1,051,260	$1,638,701	$86,403
2B	Welding (maritime industry)	$0	$694	$65,381	$8,461
2C	Welding (construction industry)	$0	$10,629	$1,510,241	$143,018
2D	Welding (government)	$0	$49	$21,677	$2,976
3A	Painting (general industry)	$1,005,222	$168,741	$629,802	$60,707
3B	Painting (maritime industry)	$0	$230	$194,731	$11,976
3C	Painting (construction industry)	$0	$3,659	$1,978,139	$147,915
3D	Painting (government)	$0	$353	$318,230	$15,493
4	Chromate (chromite ore) production	$0	$0	$0	$0
5	Chromate Pigment Producers	$0	$2,483	$909	$280
6	Chromated Copper Arsenate (CCA) Producers	$0	$319	$460	$130
7	Chromium Catalyst Producers	$16,000	$17,866	$5,842	$1,820
8	Paint and Coatings Producers	$192,529	$15,810	$31,214	$8,746
9	Printing Ink Producers	$11,375	$0	$985	$741
10	Plastic Colorant Producers and Users	$17,150	$0	$9,533	$1,846
11	Plating Mixture Producers	$54,570	$686	$1,829	$510
12	Wood Preserving	$0	$0	$0	$0
13	Chromium Material Producers	$0	$0	$0	$0
14	Steel Mills	$157,142	$22,140	$38,762	$12,657
15	Iron and Steel Foundries	$608,890	$142,534	$321,261	$157,765
16	Chromium Dioxide Producers	$0	$0	$0	$0
17	Chromium Dye Producers	$5,290	$0	$2,056	$580
18	Chromium Sulfate Producers	$4,040	$183	$116	$40
19	Chemical Distributors	$4,266,556	$3	$30,603	$0
20	Textile Dyeing	$654,931	$80	$218,381	$59,710
21	Colored Glass Producers	$16,350	$63	$841	$150
22	Printing	$51,807	$0	$67,122	$17,797
23	Leather Tanning	$0	$0	$0	$0
24	Chromium Catalyst Users	$125,872	$716	$1,780	$292
24A	Chromium Catalyst Users (Service)	$17,161	$5,492	$1,870	$581
25	Refractory Brick Producers	$6,770	$2	$156	$50
26A	Woodworking (general industry)	$670,089	$1,288	$5,207	$413
26B	Woodworking (maritime industry)	$0	$74	$1,620	$300
26C	Woodworking (construction industry)	$0	$3,572	$309,717	$42,816
26D	Woodworking (government)	$0	$7	$835	$86
27	Solid Waste Incineration	$0	$35	$5,771	$1,060
27A	Incinerators (government)	$0	$0	$0	$0
28	Oil and Gas Well Drilling	$0	$0	$0	$0
29	Portland Cement Producers	$297,693	$257	$49,184	$14,893
30	Superalloy Producers	$921	$25	$518	$163
31B	Construction (Refractory Repair)	$0	$40	$13,335	$1,769
31C	Construction (Hazardous Waste Work)	$0	$123	$32,726	$5,269
31CG	Haz. Waste (government)	$0	$21	$6,325	$923
31D	Construction (Industrial Rehabilitation)	$0	$124	$35,559	$5,579
31DG	Industrial Rehab. (government)	$0	$3	$1,126	$116
32	Precast Concrete Products Producers	$8,513,073	$3,267	$734,285	$225,842
	General Industry (including Government)	$24,801,622	$1,809,470	$4,564,304	$783,274
	Construction	$0	$18,146	$3,879,717	$346,366
	Maritime	$0	$999	$261,732	$20,738
	Total	$24,801,622	$1,828,614	$8,705,752	$1,150,378

IX-13. Annualized Costs for Small Businesses Affected by OSHA's Proposed Standard for Hexavalent Chromium (by Application Group and Regulatory Requirement for a PEL of 1 ug/m^3)

			Current Requirements for PPE and Hygiene Areas			
	Application Group	Total for Incremental Requirements	PPE (not supplied in baseline)	PPE (supplied in baseline)	Hygiene Areas	Total for Incremental and Current Requirements
1	Electroplating	$47,139,054	$0	$10,004,481	$1,546,751	$58,690,286
2A	Welding (general industry)	$65,579,466	$0	$0	$0	$65,579,466
2B	Welding (maritime industry)	$1,575,105	$0	$0	$0	$1,575,105
2C	Welding (construction industry)	$25,652,611	$0	$0	$0	$25,652,611
2D	Welding (government)	$134,016	$0	$0	$0	$134,016
3A	Painting (general industry)	$7,192,490	$16,459,373	$3,539,991	$527,439	$27,719,293
3B	Painting (maritime industry)	$6,642,665	$5,162,686	$811,853	$382,830	$13,000,034
3C	Painting (construction industry)	$2,159,446	$0	$904,287	$0	$3,063,733
3D	Painting (government)	$336,758	$0	$94,645	$0	$431,403
4	Chromate (chromite ore) production	$0	$0	$0	$0	$0
5	Chromate Pigment Producers	$108,223	$0	$5,731	$2,300	$116,254
6	Chromated Copper Arsenate (CCA) Producers	$21,156	$12,587	$2,086	$1,200	$37,028
7	Chromium Catalyst Producers	$2,985,933	$110,290	$26,303	$12,700	$3,135,226
8	Paint and Coatings Producers	$4,053,019	$3,123,597	$464,353	$117,891	$7,758,861
9	Printing Ink Producers	$161,234	$4,385	$576	$4,243	$170,438
10	Plastic Colorant Producers and Users	$1,206,040	$20,784	$3,319	$28,377	$1,258,519
11	Plating Mixture Producers	$239,182	$0	$100,396	$9,400	$348,978
12	Wood Preserving	$0	$0	$0	$0	$0
13	Chromium Material Producers	$0	$0	$0	$0	$0
14	Steel Mills	$691,845	$0	$0	$0	$691,845
15	Iron and Steel Foundries	$5,593,244	$0	$0	$0	$5,593,244
16	Chromium Dioxide Producers	$0	$0	$0	$0	$0
17	Chromium Dye Producers	$255,794	$21,250	$4,643	$5,800	$287,488
18	Chromium Sulfate Producers	$13,908	$7,245	$386	$1,120	$22,659
19	Chemical Distributors	$4,738,477	$0	$0	$0	$4,738,477
20	Textile Dyeing	$1,314,112	$978,517	$176,040	$1,102,876	$3,571,544
21	Colored Glass Producers	$30,630	$0	$0	$0	$30,630
22	Printing	$290,629	$357,881	$57,692	$165,906	$872,109
23	Leather Tanning	$0	$0	$0	$0	$0
24	Chromium Catalyst Users	$200,831	$38,644	$7,313	$10,582	$257,369
24A	Chromium Catalyst Users (Service)	$56,746	$0	$14,327	$11,010	$82,082
25	Refractory Brick Producers	$13,480	$4,983	$877	$883	$20,224
26A	Woodworking (general industry)	$774,378	$0	$0	$0	$774,378
26B	Woodworking (maritime industry)	$8,408	$0	$0	$0	$8,408
26C	Woodworking (construction industry)	$3,908,193	$4,785,549	$555,884	$2,822,822	$12,072,449
26D	Woodworking (government)	$14,059	$10,822	$4,576	$6,204	$35,661
27	Solid Waste Incineration	$245,955	$0	$155,579	$42,719	$444,253
27A	Incinerators (government)	$0	$0	$0	$0	$0
28	Oil and Gas Well Drilling	$0	$0	$0	$0	$0
29	Portland Cement Producers	$414,579	$430,115	$77,799	$100,876	$1,023,369
30	Superalloy Producers	$4,430	$0	$0	$0	$4,430
31B	Construction (Refractory Repair)	$15,144	$0	$0	$0	$15,144
31C	Construction (Hazardous Waste Work)	$61,051	$90,000	$244,563	$104,120	$499,734
31CG	Haz. Waste (government)	$14,463	$0	$46,706	$17,161	$78,330
31D	Construction (Industrial Rehabilitation)	$41,261	$0	$0	$0	$41,261
31DG	Industrial Rehab. (government)	$5,193	$0	$0	$0	$5,193
32	Precast Concrete Products Producers	$12,694,415	$21,660,562	$3,698,534	$4,139,874	$42,193,386
	General Industry (including Government)	$156,523,742	$43,241,035	$18,486,352	$7,855,312	$226,106,441
	Construction	$31,837,707	$4,875,549	$1,704,734	$2,926,942	$41,344,932
	Maritime	$8,226,178	$5,162,686	$811,853	$382,830	$14,583,547
	Total	$196,587,626	$53,279,270	$21,002,939	$11,165,085	$282,034,920

Source: U.S. Dept. of Labor, OSHA, Office of Regulatory Analysis, based on IT, 2004.

Table IX–14 shows the unit costs these estimates are based on. (For a full discussion of the engineering control costs, and of the basis for the unit costs, see Chapter 3 of the Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis).

Table IX–14.—Unit Costs Applied in OSHA's Preliminary Analysis of the Proposed Standard

Cost description	Basis	Base cost	Escalation factor (October 2003 basis)	Index used for price escalation	Unit cost
Cost per hour for an outside industrial hygiene contractor.	Estimate by In-house CIH	$90.00	1	NONE	$90.00
Cost of a personal sampling pump	Gilian 3500; Sensidyne, 16333 Bayvista Drive, Clearwater, FL 33760.	680.00	1	NONE	680.00
Variable Cost per sample (*e.g.*, laboratory analysis).	Estimate by In-house CIH	60.00	1	NONE	60.00
Flat Fee For Training Course	Estimate by In-house CIH.	400.00	1	NONE	400.00
Cost of a calibration unit	GILIBRATOR–2; Sensidyne, 16333 Bayvista Drive, Clearwater, FL 33760.	1,075.00	1	NONE	1,075.00
Unit cost of OSHA-regulation warning signs with mounting materials.	July 1993 EMMED Co, Inc. Catalog	3.03	1.2702	CPI—All items	3.84
Cost of materials per qualitative fit-testing.	Banana Oil Fit Test Kit; Lab Safety Supply Catalog 2003, PO Box 1368, Janesville, WI 53547–1368.	0.07	1	NONE	0.07
Unit cost per worker for an air-supplied respirator.	Allegro One-Worker Full Face Kit; Lab Safety Supply Catalog 2003, PO Box 1368, Janesville, WI 53547–1368.	1,473.33	1	NONE	1,473.33
Unit cost per employee for a full-face respirator.	MSA Ultra Twin Full Face Respirator; Lab Safety Supply Catalog 2003, PO Box 1368, Janesville, WI 53547–1368.	243.00	1	NONE	243.00
Unit cost per employee for a half-mask respirator.	MSA Comfro Classic Half-Mask Respirator; Lab Safety Supply Catalog 2003, PO Box 1368, Janesville, WI 53547–1368.	35.30	1	NONE	35.30
Cost of replacement cartridges cartridges per mask).	MSA P100 Filter (2 Cartridge: Lab Safety Supply Catalog 2003, PO Box 1368, Janesville, WI 53547–1369.	13.74	1	NONE	13.74
Unit cost per employee for a blasting helmet air-supplied respirator.	Allegro Three Person Air Pump, Bullard 1/2″ Hose, 100′L, Bullard Helmet w/ constant air flow; Lab Safety Supply Catalog 2003, PO Box 1368, Janesville, WI 53547–1368.	1,164.00	1	NONE	1,164.00
Cost of materials to clean one respirator.	Respirator Cleaning/Storage Kit; Lab Safety Supply Catalog 2003, PO Box 1368, Janesville, WI 53547–1368.	1.86	1	NONE	1.86
Cost of PE coated Tyvek coveralls	KAPPLER Poly-Coat Coveralls; Lab Safety Supply Catalog 2003, PO Box 1368, Janesville, WI 53547– 1368.	6.60	1	NONE	6.60
Cost of Saranex coveralls	Tychem QC Coveralls; Lab Safety Supply Catalog 2003, PO Box 1368, Janesville, WI 53547–1368.	32.85	1	NONE	32.85
Cost of Tyvek coveralls	Tyvek Protective Wear Coveralls; Lab Safety Supply Catalog 2003, PO Box 1368, Janesville, WI 53547–1368.	4.50	1	NONE	4.50
Cost of bib aprons	Polypropylene Bib Apron; Lab Safety Supply Catalog 2003, PO Box 1368, Janesville, WI 53547–1368.	0.58	1	NONE	0.58
Cost of laundering uniforms for one employee per week.	Aramark Cincinnati Representative	5.50	1	NONE	5.50
Cost of laundering uniforms for one employee per week.	Aramark Cincinnati Representative	3.75	1	NONE	3.75
Cost of clear indirect vent goggles	Lab Supply Catalog 2003, PO Box 1368, Janesville, WI 53547–1368.	6.00	1	NONE	6.00
Cost of clear lens safety glasses	Lab Supply Catalog 2003, PO Box 1368, Janesville, WI 53547–1368.	5.00	1	NONE	5.00
Cost of grey lens safety glasses	Lab Supply Catalog 2003, PO Box 1368, Janesville, WI 53547–1368.	5.00	1	NONE	5.00
Cost of lined nitrile gloves	Ansell Sol-Vex Flock Lined Nitrile Gloves; Lab Safety Supply Catalog 2003, PO Box 1368, Janesville, WI 53547–1368.	2.50	1	NONE	2.50
Cost of powder surgical nitrile gloves	N-Dex 4-mil powdered disposable Nitrile Lab Gloves; Lab Safety Supply Catalog 2003, PO Box 1368, Janesville, WI 53547–1368.	0.24	1	NONE	0.24

Table IX–14.—Unit Costs Applied in OSHA's Preliminary Analysis of the Proposed Standard—Continued

Cost description	Basis	Base cost	Escalation factor (October 2003 basis)	Index used for price escalation	Unit cost
Cost of rough PVC gloves	BEST Super Flex PVC-gloves Coated Gloves; Lab Safety Supply Catalog 2003, PO Box 1368, Janesville, WI 53547–1368.	4.10	1	NONE	4.10
Unit cost of change rooms per employee.	Based upon Means Square Foot Costs, 1989.	856.00	1.4742	CPI—All items	1,261.92
Cost per shower head	Based upon Means Square Foot Costs, 1989.	3,590.00	1.4742	CPI—All items	5,292.39
Cost per hand washing facility	Glacier Bay 4 in Chrome Two Handle Bar Faucet, 40 in x 24In. White Double Bowl Utility Tub, 505 E. Kemper Rd., Cincinnati, OH 45246—Estimated Installation Cost.	500.00	1	NONE	500.00
Variable cost per shower (soap, clean towel, water, etc.).	Estimate	0.50	1	NONE	0.50
Variable cost per hand washing facility (roll paper towels, liquid soap, water).	Kimberly-Clark OnePak Dispenser, WINDSOFT Bleached White Paper Roll Towels; The Betty Mills Company, 60 East 3rd Ave, Ste 201, San Mateo, CA 94401 (2003).	0.06	1	NONE	0.06
Unit cost of HEPA vacuums	CONSAD (1993) base price is 1991	1,580.00	1.4742	CPI—All items	2,329.24
Unit cost of HEPA vacuum replacement filters.	CONSAD (1993) base price is 1991	212.00	1.4742	CPI—All items	312.53
Unit cost of garbage bags and disposal	Estimate—Including RCRA disposal	500.00	1	NONE	500.00
Full cost of a comprehensive medical exam.	1994 Quote from two hospitals. Bethesda Care, Cincinnati, OH and Abington Memorial Hospital, Willow Grove, PA.	282.00	1.4211	CPI—Medical Care Services.	400.76
Full cost of a limited medical exam	2003 cost of physical exams in Maryland (as directed by OSHA)..	125.00	1	NONE	125.00
Cost of additional medical testing after exam results are abnormal.	Estimated to be equal to cost of limited medical exam.	150.00	1.4211	CPI—Medical Care Services.	213.17
Cost of a partial comprehensive medical exam.	1994 Quote from two hospitals. Bethesda Care, Cincinnati, OH and Abington Memorial Hospital, Willow Grove, PA—Estimated half of comprehensive and/or limited exam cost.	141.00	1.4211	CPI—Medical Care Services.	200.38
Cost of a partial medical exam	1994 Quote from two hospitals. Bethesda Care, Cincinnati, OH and Abington Memorial Hospital, Willow Grove, PA—Estimated half of comprehensive and/or limited exam cost.	75.00	1.4211	CPI—Medical Care Services.	106.59
Cost per employee for training aids and materials.	Estimate	2.00	1	NONE	2.00
Cost per employee for computer file space.	Estimate	1.00	1	NONE	1.00
Cost of Medical History Questionnaire	OSHA. Preliminary Regulatory Impact and Regulatory Flexibility Analysis of the Proposed Respiratory Protection Standard, 1994.	25	1.4211	CPI—Medical Care Services.	35.53
Cost of Medical Exam for Respirator Use.	OSHA. Preliminary Regulatory Impact and Regulatory Flexibility Analysis of the Proposed Respiratory Protection Standard. 1994.	75	1.4211	CPI—Medical Care Services.	106.58
Cost of Mop and Bucket	The Home Depot. Contico, 35qt Mop Bucket and Wringer. Wilen, 16oz Cotton Cut-End Mop.	62.92	1	NONE	62.92
Cost of Mop	The Home Depot. Wilen, 16oz Cotton Cut-End Mop.	62.92	1	NONE	62.92
Cost of Mobile Shower Unit (construction).	Ameri-can Engineering. Basic 828 Decontamination Trailer. 2003. 15886 Michigan Road. Argos, IN 46501.	42,960	1	NONE	42,960
Cost of Change Area per employee (construction).	Estimate	720	1	NONE	300

Source: U.S. Dept. of Labor, OSHA, Office of Regulatory Analysis, based on IT, 2004, Ex. 35–390.

Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rules

OSHA's SBREFA panel for this rule suggested that OSHA address a number of possible overlapping or conflicting rules: EPA's Maximum Achievable Control Technology (MACT) standard for chromium electroplaters; EPA's standards under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for Chromium Copper Arsenate (CCA) applicators; and state use of OSHA PELs for setting fenceline air quality standards. The Panel was also concerned that, in some cases other OSHA standards might overlap and be sufficient to assure that a new proposed standard would not be needed, or that some of the proposed standard's provisions might not be needed.

OSHA has discussed EPA's MACT standard with EPA. The standards are not duplicative or conflicting. The rules are not duplicative because they have different goals—environmental protection and protection against occupation exposure. It is quite possible, as many electroplaters are now doing, to achieve environmental protection goals without achieving occupational protection goals. The regulations are not conflicting because there exist controls that can achieve both goals without interfering with one another. However, it is possible that meeting the proposed OSHA standard would cause someone to incur additional costs for the MACT standard. If an employer has to make major changes to install LEV, this could result in significant expenses to meet EPA requirements not accounted for in OSHA's cost analysis. OSHA believes that chromium electroplaters can generally meet a PEL of 1 $\mu g/m^3$ without such major changes, and has not included costs. This issue is discussed in detail in Chapter 2 of the full PEA. However, OSHA welcomes comment on this issue.

OSHA examined the potential problem of overlapping jurisdiction for CCA applicators, and found that there would indeed be overlapping jurisdiction. For this proposed rule, OSHA had excluded CCA applicators from the scope of the coverage of the proposed rule. OSHA has been unable to find a case where a state, as a matter of law, bases fenceline standards on OSHA PELs. OSHA notes that the OSHA PEL is designed to addresses the risks associated with life long occupational exposure only. OSHA welcomes comment on this issue.

OSHA has also examined other OSHA standards, and where standards are overlapping, referred to them by reference in the proposed standard. Existing OSHA standards that may duplicate the proposed provisions in some respect include the standards addressing respiratory protection (29 CFR 1910.134); hazard communication (29 CFR 1910.1200); access to medical and exposure records (29 CFR 1910.1020); general requirements for personal protective equipment in general industry (29 CFR 1910.132), construction (29 CFR 1926.95), and shipyards (29 CFR 1915.152); and sanitation in general industry (29 CFR 1910.141), construction (29 CFR 1926.51), and shipyards (29 CFR 1915.97).

Regulatory Alternatives

This section discusses various alternatives to the proposed standard that OSHA is considering, with an emphasis on the those suggested by the SBREFA Panel as potentially alleviating impacts on small firms. (A discussion on the costs of some if these alternatives to OSHA's proposed regulatory requirements for the hexavalent chromium standard can be found in **Section III.2 Costs of Regulatory Alternatives** in the final report by OSHA's contractor, IT (IT, 2004). In the IT report, Tables III.42–III.51, costs are analyzed by regulatory alternative and major industry sector at discount rates of 7 percent and 3 percent).

Scope: The proposed standard covers exposure to all types of Cr(VI) compounds in general industry, construction, and shipyard. Cement work in construction is excluded.

OSHA considered the Panel recommendation that sectors where there is little or no known exposure to Cr(VI) be excluded from the scope of the standard. OSHA has preliminarily decided against this option. The costs for such sectors are relatively small—probably even smaller than OSHA has estimated because OSHA did not assume that any industry would use objective data to demonstrate that initial assessment was not needed. However, it is possible that changes in technology and production processes could change the exposure of employees in what are currently low exposure industries. If this happens, OSHA would need to issue a new standard to address the situation. As a result, OSHA is reluctant to exempt industries from the scope of the standard.

As stated above, the proposed standard does not cover cement work in construction. OSHA's preliminary assessment of the data indicates that the primary exposure to cement workers is dermal contact that can lead to irritant or contact allergic dermatitis. Current information indicates that the exposures in wet cement work in construction are well below 0.25 $\mu g/^3$. Moreover, unlike other exposures in construction, general industry or shipyards, exposures from cement work are most likely to be solely from dermal contact. There is little potential for airborne exposures and unlikely to be any in the future, as Cr(VI) appears in wet cement in only minute quantities naturally. Cement work also is found in the general industry setting, however the data there indicate that, because of the volume of cement involved and the nature of the work, airborne exposures are likely to be slightly higher, with 3–5% of the exposures being greater than 0.25 $\mu g/m^3$. Given these factors, the proposed standard excludes cement work in construction. OSHA has made a preliminary determination that addressing the dermal hazards from these exposures to Cr(VI) through guidance materials and enforcement of existing personal protective equipment and hygiene standards may be a more effective approach. Such guidance materials would include recommendations for specific work practices and personal protective equipment for cement work in construction.

OSHA's analysis suggests that there are 2,093 to 10,463 cases of dermatitis among cement workers annually. Using a cost of illness (COI) approach, avoiding 95 percent of these dermatoses would be valued at $2.5 to $12.6 million annually, and avoiding 50 percent of these dermatoses would be valued $1.3 million to $6.6 million annually.

The costs of including wet cement would depend on what requirements were applied to wet cement workers. OSHA estimates that adding wet cement to the scope of the standard would have costs of $33 million per year. The cost of addressing the problem through existing standards could range from $80 to $300 million per year. OSHA considered the SBREFA Panel recommendation that sectors where there is little or no known exposure to Cr(VI) be excluded from the scope of the standard. OSHA has preliminarily decided against this option. The costs for such sectors are relatively small—probably even smaller than OSHA has estimated because OSHA did not assume that any industry would use objective data to demonstrate that initial assessment was not needed. Beyond the initial exposure assessment (required only in general industry), very little would be required in workplaces where Cr(VI) exposures are below the PEL and no hazard is present from skin or eye

contact with Cr(VI). Additional requirements would generally be limited to housekeeping (in general industry) and hazard communication (warning labels on containers of Cr(VI)-contaminated materials that are consigned for disposal, training regarding the Cr(VI) standard). Where exposures in general industry exceed the Action Level, periodic monitoring would also be required. However, it is possible that changes in technology and production processes could change the exposure of employees in what are currently low exposure industries. If this happens, OSHA would need to issue a new standard to address the situation. As a result, OSHA is reluctant to exempt industries from the scope of the standard.

PELS: Section F of this preamble summary presented data on the costs and benefits of alternative PELS for all industries. The full PEA contains detailed data on the impacts of small firms at each level of PEL.

The SBREFA Panel also suggested alternatives to a uniform PEL across all industries and exposures. The Panel recommended that OSHA consider alternative approaches to industries that are intermittent users of Cr(VI). OSHA has preliminarily adopted the concept of permitting employers with intermittent exposures to meet the requirements of the standard using respirators rather than engineering controls. This approach has been used in other standards and does not require workers to routinely wear respirators.

The SBREFA Panel also recommended considering Separate Engineering Control Airborne Limits (SECALs). OSHA has preliminarily not adopted this approach because OSHA does not believe it would serve workers or small businesses well. If an approach which requires a significant number of workers to wear respirators on a regular basis were to be adopted, that approach would result in many workers wearing respirators with the associated risks, and in setting a lower PEL in accord with the QRA's estimate that there is significant risk at PELS lower than one.

The SBREFA Panel also suggested that OSHA consider different PELs for different Cr(VI) compounds leading to exposure to Cr(VI). This issue is fully discussed in the QRA. Here, it will only be noted that this would suggest lower PELs than OSHA is setting in at least some industries, and thus potentially increase impacts on small businesses.

Special Approaches to the Shipyard and Construction Industries: The SBREFA Panel was concerned that changing work conditions in the shipyard and construction industry would make it difficult to apply some of the provisions that OSHA suggested at the time of the Panel. OSHA has preliminarily decided to change its approach in these sectors. OSHA is proposing 3 separate standards, one for general industry, one for construction, and one for shipyards. In shipyard and construction, OSHA will not require exposure monitoring of any kind; will not have an action level; will require medical surveillance only for persons with signs and symptoms; and will not require regulated areas. However, employers must still meet the PEL with engineering controls and work practices where feasible.

This approach reduces the specification oriented aspects of the standard in these sectors, but may make it difficult for employers to determine how to comply with the standard. OSHA is considering a more specification oriented approach, similar to that used in the asbestos in construction standard, and in "control banding" approaches used abroad. Such an approach would require OSHA to specify what controls would need to be used in various circumstances, and employers using such controls would be considered to be in compliance with the standard. OSHA does not have the information at this time to develop or cost such an approach. OSHA welcomes comments on how it might develop such an approach.

Timing of the Standard: The SBREFA Panel also recommended considering a multi-year phase in of the standard. OSHA is examining and soliciting comment on this issue. Such a phase-in would have several advantages from a viewpoint of impacts on small businesses. First, it would reduce the one time initial costs of the standard by spreading them out over time. This would be particularly useful for small businesses that have trouble borrowing large amounts of capital in a single year. A phase-in would also be useful in the electroplating sector by allowing employers to coordinate their environmental and occupational safety and health control strategies to minimize potential costs. A differential phase-in for smaller firms would also aid very small firms by allowing them to gain from the control experience of larger firms. However a phase-in would also postpone the benefits of the standard.

SBREFA Panel

Table IX–15 lists all of the SBREFA Panel recommendations and notes OSHA responses to these recommendations.

TABLE IX–15.—SBREFA PANEL RECOMMENDATIONS AND OSHA RESPONSES

SBREFA panel recommendation	OSHA response
The Panel recommends that, as time permits, OSHA revise its economic and regulatory flexibility analyses as appropriate to reflect the SERs' comments on underestimation of costs and that the Agency compare the OSHA revised estimates to alternative estimates provided and methodologies suggested by the SERs. For those SER estimates and methodological suggestions that OSHA does not adopt, the Panel recommends that OSHA explain its reasons for preferring an alternative estimate and solicit comment on the issue.	OSHA has extensively reviewed its costs estimates, and changed many of them in response to SER comments and solicits comments on these revised cost estimates. A few examples of OSHA's cost changes are given in the responses to specific issues, below (*e.g.*, medical exams, training and familiarization).
The Panel recommends that, to the extent time permits, OSHA should carefully consider the ability of each potentially affected industry to meet any proposed PEL for CR(VI) and solicit comment on the costs and technological feasibility of the PEL.	The PEA reflects OSHA's judgment on technological feasibility and includes responses to specific issues raised by the Panel and SERs. OSHA will solicit comment on the accuracy and reasonableness of these judgments.
The Panel recommends that OSHA carefully review the basis for its estimated medical surveillance compliance costs, consider these concerns raised by the SERs, and ensure that its estimates are revised, as appropriate and time permits, to fully reflect the costs likely to be incurred by potentially affected establishments.	OSHA has increased the estimated time for a limited medical exam from 1.5 hours to 3 hours and solicits comment on all other cost projections for medical surveillance. See **Chapter IV OF THE PEA; COSTS OF COMPLIANCE, COSTS BY PROVISION**—*Medical Surveillance,* for details of OSHA's unit costs for medical surveillance.

TABLE IX–15.—SBREFA PANEL RECOMMENDATIONS AND OSHA RESPONSES—Continued

SBREFA panel recommendation	OSHA response
The Panel recommends that, as time permits, OSHA consider alternatives that would alleviate the need for extensive monitoring on construction sites, and solicit comment on this issue. If OSHA does not adopt such alternatives, then OSHA should consider increasing the estimated costs of such monitoring in construction, and solicit comment on the costs of monitoring.	OSHA revised the standard to relieve Construction and Shipyards from requirements for exposure assessment; for General Industry, OSHA believes that its unit cost estimates are realistic but will raise that as an issue. See **CHAPTER IV OF THE PEA: COSTS OF COMPLIANCE, COSTS BY PROVISION**—*Exposure Monitoring (Initial and Periodic)*, for details of OSHA's unit costs for exposure monitoring in general industry.
The Panel recommends that OSHA carefully review the basis for its estimated hygiene compliance costs, consider the concerns raised by the SERs, and, to the extent time permits, ensure that its estimates are revised, as appropriate, to fully reflect the costs likely to be incurred by potentially affected establishments.	OSHA's proposed standard will permit hand washing as a hygiene option; OSHA's analysis will also reflect, where data confirm, any cost premium related to handling contaminated waste water or laundry, or where uncertainty exists, the issue will be raised.
The Panel recommends that OSHA examine and solicit comment on this issue [possible understates in the costs of regulated areas].	OSHA has recognized costs for training and familiarization to cover a better understanding of the costs of regulated areas, and solicit comment on the issue. See **CHAPTER IV OF THE PEA; COSTS OF COMPLIANCE, COSTS BY PROVISION**—*Communication of Hazards to Employees—Training and Familiarization*, for details of OSHA's unit costs for this provision.
The Panel recommends that OSHA examine and solicit comment on these issues [costs of laundering PPE].	OSHA has examined and solicits comment on this issue and the cost OSHA has estimated. See **CHAPTER IV OF THE PEA; COSTS OF COMPLIANCE, COSTS BY PROVISION**—*Housekeeping, Protective Work Clothing and Equipments*, and Table IV–8 for details of OSHA's unit costs for laundering PPE and other related costs.
The Panel recommends that OSHA examine whether its cost estimates reflect the full costs of complying with the hazard communication standard.	OSHA's analysis assumes that employers will need time for familiarization with the standard, training on the standard, and increased initial supervision.
The Panel recommends that OSHA thoroughly review the economic impacts of compliance with a proposed Cr(VI) standard and develop more detailed feasibility analyses where appropriate. The Panel also recommends that OSHA, to the extent permitted by time and the availability of economic data, reexamine its estimates of profits and revenues in light of SER comments, and update economic data to better reflect recent changes in the economic status of the affected industries, consistent with its statutory mandate. The Panel also recommends that OSHA examine, to the extent feasible with the time available, the possibility that users will substitute non-Cr(VI) products for Cr(VI) products. The Panel recommends that OSHA solicit comment on the extent to which foreign competition may or may not impact what is feasible for the industries affected by this rule.	OSHA has reviewed and revised many of its revenue and profit estimates in the light of specific SER comments. Examples of application groups with revised revenue and profit estimates include Group 4, Chromate Production; Group 5, Chromate Pigment Producers; and Group 17, Chromium Dye Producers. However, OSHA has not updated revenue and profit impacts across the board—OSHA estimates of costs, revenues, and profits require consistent data sets which are not yet available for more recent years. OSHA's continues to examine, and will solicit comment on this issue.
The Panel recommends that OSHA consider and solicit comments on selective exemption of some industries from the proposed standard, especially those industries whose inclusion is not supported by the industry-specific data or in which inhalation exposure to Cr(VI) is minimal.	OSHA is reluctant to exempt industries where exposures are minimal because changes in technology could change exposures in the future. However, OSHA is seeking comment on the issue of the scope of the standard and data that would support not covering certain sectors.
The Panel recommends that OSHA exempt applicators of CCA given that they are already regulated by EPA as pesticide applicators under FIFRA. In addition, OSHA should clarify and seek comment as to why users of CCA-treated wood should be covered under the Cr(VI) proposal given that the use of CCA-treated wood was previously excluded by OSHA in its standard for inorganic arsenic.	OSHA has decided to exempt applicators of CCA in this proposal.
The Panel recommends that OSHA clearly explain the way that Cr(VI) exposure and risk for the worker cohort studies used in the quantitative risk assessment were calculated, and should consider and seek comment as to whether the major assumptions used in these calculations are reasonable.	The Quantitative Risk Assessment section of the Preamble addresses this issue in detail, and OSHA is seeking comments on this issue.
The Panel recommends that OSHA consider the available information on reduction of inhaled Cr(VI) to Cr(III) in the body, to determine whether exposures below a threshold concentration can be shown not to cause the genetic alterations that are believed to cause cancer. In addition, OSHA should review epidemiological analyses relevant to the question of threshold dose, to determine whether such a dose is identifiable from the available human data. OSHA should further consider and seek comment on these findings in relation to the risk assessment and the proposed PEL, allowing for a higher PEL than those presented in the draft standard if the risk assessment so indicates.	The Quantitative Risk Assessment of this Preamble addresses the issue of possible threshold effects and OSHA is seeking comments on the issue.

TABLE IX–15.—SBREFA PANEL RECOMMENDATIONS AND OSHA RESPONSES—Continued

SBREFA panel recommendation	OSHA response
The Panel recommends that OSHA should clarify the meaning of the projected lung cancer risk estimates used to support the proposed standard. In particular, OSHA should explain these estimates, which are based on a working lifetime of 45 years' exposure at the highest allowable Cr(VI) concentration, and, where appropriate, note projected excess cancers that may result from shorter periods of occupational Cr(VI) exposure.	OSHA is required by law to set health standards so that they avoid significant risk over a working lifetime. Both in the QRA and in the Benefits Chapter of the PEA, OSHA has examined alternative exposure scenarios. See **VII. Preliminary Quantitative Risk Assessment** in the Preamble and **CHAPTER VI of the PEA; BENEFITS and NET BENEFITS,** *Lung Cancers Avoided* in this PEA.
The Panel recommends that OSHA solicit information to better characterize the exposure patterns and Cr(VI) compounds encountered in the maritime environment, and should encourage input from marine chemists at appropriate points in the rulemaking.	OSHA has added information provided by firms in the shipyard industry since the Panel meeting. (See **Chapter II** of the PEA; **PROFILE OF AFFECTED INDUSTRIES, PROCESSES, AND APPLICATIONS GROUPS, AFFECTED INDUSTRIES—** ***Welding*** and ***Painting*** and **Chapter III: Technological Feasibility,** ***Welding*** and ***Painting).*** OSHA is soliciting comment on shipyard issues and from maritime chemists.
The Panel recommends that OSHA consider the appropriateness of separate PELs for specific Cr(VI) compounds, with attention to the weight and extent of the best available scientific evidence regarding their relative carcinogenic potency.	OSHA considered this possibility and preliminarily decided against it, in part, because it would require lower PELs with many persons in respirators. OSHA is soliciting comment on this issue.
The Panel recommends that OSHA solicit information to better define construction activities likely to be above and below the PEL (for initial exposure monitoring purposes) to minimize the amount of respiratory protection that would need to be used for compliance.	OSHA has eliminated the requirement for monitoring in the construction industry. OSHA has considered a control banding approach to construction, but lacks the data to fully implement this approach, and solicits comment on the issue.
The Panel recommends that OSHA provide a better explanation of how to implement an exposure assessment program for construction activities. Also, OSHA should provide further explanation on monitoring-related topics like the selection of sampling and analytical methods, the selection of plus-or-minus 25% as a confidence interval, and the use of objective data in lieu of monitoring.	OSHA has removed the requirement for exposure monitoring in construction and shipyards. The monitoring-related topics are further discussed in the Preamble, XVII. **Summary and Explanation of the Standard.**
The Panel recommends that OSHA consider less frequent monitoring for exposures above the PEL, especially in situations where the employer has already engineered down to the lowest feasible level and is not able to maintain levels below the PEL.	OSHA has preliminarily left the monitoring frequency unchanged, but has solicited comment on the issue.
The Panel recommends that OSHA review the technologies used to reduce Cr(VI) exposure to ensure that they are available or reasonably anticipated to be available in the future.	OSHA has reviewed its technological feasibility analysis and solicited comment on it.
The Panel recommends that OSHA clarify the purpose of the prohibition on the use of employee rotation to meet the PEL and take into account the needs expressed by the SERs on the issue.	The Summary and Explanation of the Preamble explains further the prohibition on employee rotation and the methods of compliance.
The Panel recommends that OSHA clarify the methods of compliance section.	
The Panel recommends that OSHA clarify how to implement the use of regulated areas particularly for construction activities. OSHA should better explain how employers would delineate boundaries for regulated areas and should better clarify the use of respiratory protection, personal protective clothing and equipment, and hygiene facilities and practices in regulated areas.	OSHA has eliminated the requirement for regulated areas in construction and shipyards. The Summary and Explanation section of the Preamble explains the regulated area requirements in General Industry.
The Panel recommends that OSHA provide a clearer explanation of why it is necessary to remove Cr(VI)-contaminated protective clothing and wash hands prior to entering non-Cr(VI) work areas and eating, drinking or smoking and take into account lost time and costs associated with conducting such activities.	These issues are addressed in the Summary and Explanation Section of the Preamble.
The Panel recommends that OSHA clarify its definition of contaminated clothing or waste, provide evidence supporting the view that "contaminated" clothing presents a hazard, and better explain the special treatment of such items and why the treatment is necessary.	
The Panel recommends that OSHA clarify its definition of reasonably anticipated skin and eye contact.	OSHA has changed the rule from SBREFA draft in order to clarify when PPE is required and to assure that it is not required except where a dermal hazard exists.
The Panel recommends that OSHA clarify the circumstances under which the proposed rule would require the use of personal protective equipment to prevent dermal exposures to solutions containing Cr(VI). In particular, OSHA should reconsider the requirements for the use of dermal protection when the PEL is exceeded; consider alternatives that are more clearly risk based; and determine whether the use of very dilute Cr(VI) solutions, as used in some laboratories, requires the use of personal protective equipment..	

TABLE IX–15.—SBREFA PANEL RECOMMENDATIONS AND OSHA RESPONSES—Continued

SBREFA panel recommendation	OSHA response
The Panel recommends that OSHA provide a clearer explanation of the benefits and the need for its proposed medical surveillance provisions.	OSHA has preliminarily dropped routine medical surveillance in the shipyard and construction industries. The Preamble Summary and Explanation clarify what is required of medical surveillance, and the extent to which the same medical examination can be used to meet the requirements of different standards.
The Panel recommends that OSHA provide a clearer guidance as to which employees are intended to be covered under the medical surveillance provisions and, in particular, how the standard is intended to cover employees who work for several different employers during the course of a year.	
The Panel recommends that OSHA clarify the qualifications necessary to provide a medical examination (including what knowledge of Cr(VI) is necessary) and what the elements of such a medical examination should be.	
The Panel recommends that OSHA design the medical surveillance provisions to be consistent with existing OSHA standards (*e.g.*, lead and arsenic) wherever possible, in order to minimize the need for duplicative medical examinations. The Panel also recommends that OSHA clarify that differences in medical surveillance requirements that may be unavoidable across OSHA standards nevertheless often will not require completely separate medical examinations.	
With respect to the EPA electroplating standards, the Panel recommends that OSHA examine whether important costs have been omitted, seek to develop alternatives that minimize these costs, and seek comment on the issue.	OSHA discusses the impact of EPA's electroplating standard in the PEA, (See **Chapter II: Technological Feasibility, Electroplating** and **Chapter VIII: Environmental Impacts)** and seeks comments on this issue.
With respect to possible dual jurisdiction with FIFRA, the Panel recommends that OSHA consider dropping CCA applicators from the scope of the rule, and seek comment on this issue.	OSHA preliminarily has decided to exclude CCA applicators from the scope of the standard.
With respect to the issue of using OSHA PELs as a basis for fenceline standards, the Panel recommends that OSHA make clear the purpose of its PELs, and explain that they are not developed or examined in terms of their validity as a basis for air quality standards.	OSHA solicits comment on the "fence line" standard issue.
The Panel recommends that OSHA examine whether existing standards are adequate to cover occupational exposure to Cr(VI), and, if not, develop the Cr(VI) standard in such a way as to eliminate duplicative and overlapping efforts on the part of employers.	OSHA has preliminarily determined that, except for CCA applicators and wet cement workers, other standards cannot provide the worker protection needed, but has sought to avoid duplication of effort between standards.
The Panel recommends that OSHA consider the scientific evidence in favor of a higher PEL, analyze the costs and economic impacts of a PEL of 20 or greater, and solicit comment on this option.	OSHA has included an analysis of the costs and benefits of a PEL of 20 in this Preamble summary, and has a full analysis of this option in the PEA.
The Panel recommends that OSHA carefully examine the entire issue of intermittent exposures, consider options that can alleviate the burden on such firms while meeting the requirements of the OSH Act, and solicit comment on such options.	OSHA preliminarily determined that intermittent users need not use engineering controls to assure compliance with the PEL.
Some SERs argued that some Cr(VI) compounds offer lesser risks of cancer than others, and should be subject to different PELs. The Panel recommends that OSHA consider these arguments and seek comment on the issue.	OSHA has preliminarily determined that all Cr(VI) compounds should have the same PEL, but seeks comment on the issue.
The Panel recommends that OSHA continue to exempt wet cement from the scope of the standard, and that if OSHA seeks comment on this option, OSHA should note the Panel's recommendation and the reasons for the recommendation. The Panel also recommends that OSHA seek ways of adapting the standard better to the dynamic working conditions of the construction industry, examine the extent to which Cr(VI) exposures are already covered by other standards, and seek comment on these issues. The Panel also recommends that OSHA consider the alternative of developing a construction standard in a separate rulemaking.	OSHA has preliminarily determined to exempt wet cement from the scope of the standard, but has sought comment on the issue. OSHA has made a number of changes to the construction standard in this proposal, including eliminating the exposure assessment requirements, the regulated area requirement, and the action level. OSHA seeks comment on its new approach.
The Panel recommends that OSHA consider, and solicit comment on, approaches to their special problems; that OSHA consider the possibility of making the maritime proposed standard more similar to the construction draft standard, or consider the alternative of developing a maritime standard in a separate rulemaking.	OSHA has made a number of changes to the shipyard standard in this proposal, including eliminating the exposure assessment requirements, the regulated area requirement, and the action level. OSHA has sought comment on its new approach.
The Panel recommends that OSHA consider and seek comment on multi-year phase-in alternatives.	This option is discussed in the regulatory alternatives section of the PEA, and OSHA is seeking comments on this alternative.
The Panel recommends that OSHA better explain the action level, including its role in ensuring workers are protected.	OSHA has eliminated the action level in the construction and shipyard standards, and explains its role in the General Industry in the Summary and Explanation of the Preamble.
The Panel recommends that OSHA consider the use of SECALs and solicit comment on whether and in what industries they are appropriate using the Cadmium standard as a model.	OSHA has preliminarily determined not to use SECALs, but solicits comments on this issue.

X. OMB Review Under the Paperwork Reduction Act of 1995

The proposed standard for chromium (VI) contains collections of information (paperwork) that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA95), 44 U.S.C. 3501 et seq, and its regulation at 5 CFR Part 1320. PRA 95 defines collection of information to mean, "the obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public of facts or opinions by or for an agency regardless of form or format" [44 U.S.C. § 3502(3)(A)].

The title, description of the need for and proposed use of the information, summary of the collections of information, description of respondents, and frequency of response of the information collection are described below with an estimate of the annual cost and reporting burden has required by § 1320.5(a) (1)(iv) and § 1320.8(d)(2). The reporting burden includes the time for reviewing instructions, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OSHA invites comments on whether each proposed collection of information:

(1) Ensures that the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Estimates the projected burden accurately, including the validity of the methodology and assumptions used;

(3) Enhances the quality, utility, and clarity of the information to be collected; and

(4) Minimizes 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 submissions of responses.

Title: Chromium (VI) Standard for General Industry (§ 1910.1026), Shipyards (§ 1915.1026); and Construction (§ 1926.1126)

Description: The proposed Cr(VI) standard is an occupational safety and health standard's information collection requirements are essential components that will assist both employers and their employees in identifying exposures as well as identifying means to take to reduce or eliminate Cr(VI) overexposures.

Summary of the Collections of Information:

• 1910.1026(d)—Exposure Assessment

Paragraph (d)(5) of this section requires the employer to notify employees of their exposure monitoring results within 15 working days after the receipt for the exposure monitoring performed in this section (§ 1910.1026(d)(2) Initial Exposure Monitoring, § 1910.1026(d)(3) Periodic Monitoring, and § 1910.1026 (d)(4) Additional Monitoring).

Employers may notify each affected employee individually in writing of the results or by posting the exposure-monitoring results in an appropriate location that is accessible to all affected employees. If the exposure monitoring results indicate that employee exposure is above the PEL, the employer must include in the written notification the corrective action being taken to reduce employee exposure to or below the PEL.

• 1910.1026(g), 1915.1026(e), 1926.1126(e)—Respiratory Protection

Paragraph (g)(2) in the general industry section, and paragraph (e)(2) in the shipyards and construction sections require the employer to institute a respiratory protection program in accordance with 29 CFR 1910.134. The Respiratory Protection Standard's (§ 1910.134) 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 administer fit-tests for employees who will use negative or positive-pressure, tight-fitting facepieces.

• 1910.1026(h), 1915.1026(f), 1926.1126(f)—Protective Work Clothing and Equipment

Paragraph (h)(3)(iii) in the general industry section and (f)(3)(iii) in the shipyards and construction sections require the employer to inform any person who launders or cleans protective clothing or equipment contaminated with chromium (VI) of the potentially harmful effects of exposure to chromium (VI) and that the clothing and equipment should be laundered or cleaned in a manner that minimizes skin or eye contact with chromium (VI) and effectively prevents the release of airborne chromium (VI) in excess of the PEL.

• 1910.1026(k), 1915.1026(h), and 1926.1126(h)—Medical Surveillance

Paragraphs (k)(4) in the general industry section and (h)(4) in the shipyards and construction sections require the employer to provide the examining PLHCP with a copy of the standard. In addition, for each employee receiving a medical examination, the employer must provide the following information:

1. A description of the affected employee's former, current, and anticipated duties as they relate to the employee's occupational exposure to chromium (VI);

2. The employee's former, current and anticipated levels of occupational exposure to chromium;

3. A description of any personal protective equipment used or to be used by the employee, including when and for how long the employee has used that equipment; and,

4. Information from records of employment-related medical examinations previously provided to the affected employee currently within the control of the employer.

Paragraphs (k)(5) in the general industry section, and (h)(5) in shipyards and construction sections require the employer to obtain a written medical opinion from the PLHCP, within 30 days for each medical examination performed on each employee. The employer must provide the employee with a copy the PLHCPs written medical opinion within two weeks of receipt. This written opinion must contain the following information:

1. The PLHCP's opinion as to whether the employee has any detected medical condition(s) that would place the employee at increased risk of material impairment to health from further exposure to chromium (VI);

2. Any recommended limitations upon the employee's exposure to chromium (VI) or upon the use of personal protective equipment such as respirators;

3. A statement that the PLHCP has explained to the employee the results of the medical examination, including any medical conditions related to chromium (VI) exposure that require further evaluation or treatment, and any special provisions for use of protective clothing or equipment.

• 1910.1026(l), 1915.1026(i), and 1926.1126(i)—Communication of Chromium (VI) Hazards to Employees

Paragraph (l)(4) of the general industry section, and (i)(3) of the shipyards and construction sections require that the employer provide

training for all employees who are exposed to airborne chromium (VI), or who have skin or eye contact with chromium (VI). Employers must maintain a record of the training provided. Also employers must provide initial training prior to or at the time of initial assignment to a job involving potential exposure to chromium (VI). However, employers do not need to provide training to a new employee, if they can demonstrate that a new employee has received training within the last 12 months that addresses the elements specified in the paragraph and that the employee can demonstrate knowledge of those elements. Employers must provide training that is understandable to the employee and must ensure that each employee can demonstrate knowledge of at least the following:

1. The health hazards associated with chromium (VI) exposure;
2. The location, manner of use, and release of chromium (VI) in the workplace and the specific nature of operations that could result in exposure to chromium (VI), especially above the PEL;
3. The engineering controls and work practices associated with the employee's job assignment;
4. The purpose, proper selection, fitting, proper use, and limitations of respirators and protective clothing;
5. Emergency procedures;
6. Measures employees can take to protect themselves from exposure to chromium (VI), including modification of personal hygiene and habits such as smoking;
7. The purpose and a description of the medical surveillance program required by paragraph (k) of the general industry section and paragraph (h) of shipyards and construction sections;
8. The contents of the standard; and
9. The employee s rights of access to records under 29 CFR 1910.1020(g).

• 1910.1026(m), 1915.1026(j), and 1926.1126(j)—Recordkeeping

Paragraph (m)(1) of the general industry section requires that employers maintain an accurate record of all employee exposure-monitoring records required in paragraph (d) of this section. The record must include at least the following information:

1. The date of measurement for each sample taken;
2. The operation involving exposure to chromium (VI) that is being monitored;
3. Sampling and analytical methods used and evidence of their accuracy;
4. Number, duration, and the results of samples taken;
5. Type of personal protective equipment, such as respirators worn; and,
6. The name, social security number, and job classification of all employees represented by the monitoring, indicating which employees were actually monitored.

Employers must maintain and make available employee exposure monitoring records in accordance with 29 CFR 1910.1020.

Paragraph (m)(2) of the general industry section requires employers who rely on historical monitoring data to maintain a record of historical data. The record must include information that reflects the following conditions:

1. The data were collected using methods that meet the accuracy requirements of paragraph (d)(6) of the general industry section;
2. The processes and work practices that were in use when the historical monitoring data were obtained are essentially the same as those to be used during the job for which initial monitoring will not be performed;
3. The characteristics of the chromium (IV) containing material being handled when the historical monitoring data were obtained are the same as those on the job for which initial monitoring will not be performed;
4. Environmental conditions prevailing when the historical monitoring data were obtained are the same as those on the job for which initial monitoring will not be performed; and
5. Other data relevant to the operations, materials, processing, or employee exposures covered by the exception.

This record must be maintained and must be made available in accordance with 29 CFR 1910.1020.

Paragraph (m)(3) of the general industry section requires employers who rely on objective data to satisfy initial monitoring requirements to establish and maintain an accurate record of the objective data relied upon. The record must include at least the following information:

1. The chromium (VI)-containing material in question;
2. The source of the objective data;
3. The testing protocol and results of testing, or analysis of the material for the release of chromium (VI);
4. A description of the operation exempted from initial monitoring and how the data support the exemption; and
5. Other data relevant to the operations, materials, processing or employee exposures covered by the exemption.

Employers must maintain this record for the duration of the employer's reliance upon such objective data and must make such records available in accordance with 29 CFR 1910.1020.

Paragraph (m)(4) of the general industry section, and paragraph (j)(1) of the shipyard and construction sections, require employers to establish and maintain an accurate record for each employee covered by medical surveillance under paragraph (k) of the general industry section, or paragraph (h) of the shipyard and construction sections. This record must include the following information about the employee:

1. Name and social security number;
2. A copy of the PLHCP's written opinions as required by paragraph (k)(5) of the general industry section, or paragraph (h)(5) for the shipyard and construction sections;
3. A copy of the information provided to the PLHCP as required by paragraph (k)(4) of the general industry section, or (h)(4) in the shipyards and construction sections; Employers must ensure that medical records are maintained and made available in accordance with 29 CFR 1910.1020.

Paragraph (m)(5) of the general industry section and paragraph (j)(2) of the shipyards and construction sections require employers to prepare a record at the completion of training that indicates the identity of the individuals trained and the date the training was completed. This record must be maintained for three years after the completion of training. The employer must provide to the Assistant Secretary or the Director, upon request, all materials relating to employee information and training.

Respondents: Employers in general industry, shipyards or construction whose employees work in jobs where there is a potential for chromium (VI) exposure (38,391 businesses).

Frequency of Response: Frequency of response varies depending on the specific collection of information.

Average Time Per Response: Varies from 5 minutes (.08 hour) for the employer to provide a copy of the written physician's opinion to the employee, to 12 hours to conduct exposure monitoring.

Total burden hours: 696,659.

Costs: (purchase of capital/startup costs): $30,793,697.

The Agency has submitted a copy of the information collection request to OMB for its review and approval. Interested persons may submit comments regarding the burden

estimates or other aspects of the information collection request to the OSHA Docket Office, Docket No. H054A, Occupational Safety and Health Administration, Room N–2625, 200 Constitution Avenue, NW., Washington, DC 20210, and to the Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street, NW., Washington, DC 20503 (Attn: OSHA Desk Officer (RIN 1218–AB45)). Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of the final information collection request, and they will also become a matter of public record.

Copies of the referenced information collection request are available for inspection and copying in the OSHA Docket Office and will be provided to persons who request copies by telephoning Todd Owen at (202) 693–1941. For electronic copies of the chromium (VI) information collection request, contact the OSHA Web page on the Internet at *http://www.osha.gov/*.

XI. Federalism

The Agency reviewed the proposed Cr(VI) standard according to the most recent Executive Order on Federalism (Executive Order 13132, 64 FR 43225, August 10, 1999). This Executive Order requires that federal agencies, to the extent possible, refrain from limiting state policy options, consult with states before taking actions that restrict their policy options, and take such actions only when clear constitutional authority exists and the problem is of national scope. The Executive Order allows federal agencies to preempt state law only with the expressed consent of Congress; in such cases, federal agencies must limit preemption of state law to the extent possible. Under section 18 of the Occupational Safety and Health Act (the "Act" or "OSH Act"), Congress expressly provides that OSHA preempt state occupational safety and health standards to the extent that the Agency promulgates a federal standard under section 6 of the Act. Accordingly, under section 18 of the Act OSHA preempts state promulgation and enforcement of requirements dealing with occupational safety and health issues covered by OSHA standards unless the state has an OSHA-approved occupational safety and health plan (i.e., is a state-plan state) [*see Gade* v. *National Solid Wastes Management Association*, 112 S. Ct. 2374 (1992)]. Therefore, with respect to states that do not have OSHA-approved plans, the Agency concludes that this proposal falls under the preemption provisions of the Act. Additionally, section 18 of the Act prohibits states without approved plans from issuing citations for violations of OSHA standards; the Agency finds that this proposed rulemaking does not expand this limitation. OSHA has authority under Executive Order 13132 to propose a Cr(VI) standard because the problems addressed by these requirements are national in scope.

As explained in section VIII of this preamble, employees face a significant risk from exposure to Cr(VI) in the workplace. These employees are exposed to Cr(VI) in general industry, construction, and shipyards. Accordingly, the proposal would establish requirements for employers in every state to protect their employees from the risks of exposure to Cr(VI). However, section 18(c)(2) of the Act permits state-plan states to develop their own requirements to deal with any special workplace problems or conditions, provided these requirements are at least as effective as the final requirements that result from this proposal.

XII. State Plans

The 26 states and territories with their own OSHA-approved occupational safety and health plans must adopt comparable provisions within six months after the Agency publishes the final hexavalent chromium standard. These states and territories are: Alaska, Arizona, California, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Virgin Islands, Washington, and Wyoming. Connecticut, New Jersey and New York have OSHA-approved State Plans that apply to state and local government employees only. Until a state-plan state promulgates its own comparable provisions, Federal OSHA will provide the state with interim enforcement assistance, as appropriate.

XIII. Unfunded Mandates

The Agency reviewed the proposed Cr(VI) standard according to the Unfunded Mandates Reform Act of 1995 (UMRA)(2 U.S.C. 1501 *et seq.*) and Executive Order 12875. As discussed in section IX of this preamble, OSHA estimates that compliance with this proposal would require private-sector employers to expend about $223 each year. However, while this proposal establishes a federal mandate in the private sector, it is not a significant regulatory action within the meaning of section 202 of the UMRA (2 U.S.C. 1532). OSHA standards do not apply to state and local governments, except in states that have voluntarily elected to adopt an OSHA-approved state occupational safety and health plan. Consequently, the proposed provisions do not meet the definition of a "Federal intergovernmental mandate" [*see* section 421(5) of the UMRA (2 U.S.C. 658(5)]. Therefore, based on a review of the rulemaking record to date, the Agency believes that few, if any, of the employers affected by the proposal are state, local, and tribal governments. Therefore, the proposed Cr(VI) requirements do not impose unfunded mandates on state, local, and tribal governments.

XIV. Protecting Children From Environmental Health and Safety Risks

Executive Order 13045 requires that Federal agencies submitting covered regulatory actions to OMB's Office of Information and Regulatory Affairs (OIRA) for review pursuant to Executive Order 12866 must provide OIRA with (1) an evaluation of the environmental health or safety effects that the planned regulation may have on children, and (2) an explanation of why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the agency. Executive Order 13045 defines "covered regulatory actions" as rules that may (1) be economically significant under Executive Order 12866 (i.e., a rulemaking that has an annual effect on the economy of $100 million or more, or would adversely effect 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), and (2) concern an environmental health risk or safety risk that an agency has reason to believe may disproportionately affect children. In this context, the term "environmental health risks and safety risks" means risks to health or safety that are attributable to products or substances that children are likely to come in contact with or ingest (*e.g.*, through air, food, water, soil, product use). The proposed Cr(VI) standard is economically significant under Executive Order 12866 (*see* section IX of this preamble). However, after reviewing the proposed Cr(VI) standard, OSHA has determined that the standard would not impose environmental health or safety risks to children as set forth in Executive Order 13045. The proposed standard would require employers to limit employee exposure to Cr(VI) and take other precautions to protect employees from adverse health effects associated with exposure to Cr(VI). To

the best of OSHA's knowledge, no employees under 18 years of age work under conditions that involve exposure to Cr(VI). However, if such conditions exist, children who are exposed to Cr(VI) in the workplace would be better protected from exposure to Cr(VI) under the proposed rule than they are currently. Based on this preliminary determination, OSHA believes that the proposed Cr(VI) standard does not constitute a covered regulatory action as defined by Executive Order 13045.

XV. Environmental Impacts

The Agency reviewed the proposed Cr(VI) standard according to the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 *et seq.*), the regulations of the Council on Environmental Quality (40 CFR part 1500), and the Department of Labor's NEPA procedures (29 CFR part 11).

As a result of this review, OSHA has made a preliminary determination that the proposed Cr(VI) standard will have no impact on air, water, or soil quality; plant or animal life; the use of land or aspects of the external environment. Therefore, OSHA concludes that the proposed Cr(VI) standard would have no significant environmental impacts.

XVI. Public Participation—Notice of Hearing

OSHA encourages members of the public to participate in this rulemaking by submitting comments on the proposal, and by providing oral testimony and documentary evidence at the informal public hearing that the Agency will convene after the comment period ends. The Agency invites interested persons having knowledge of, or experience with, occupational exposure to Cr(VI) to participate in this process, and welcomes any pertinent data and cost information that will provide it with the best available evidence on which to develop the final regulatory requirements. This section describes the procedures the public must use to submit their comments to the docket in a timely manner, and to schedule an opportunity to deliver oral testimony and provide documentary evidence at informal public hearings on the proposal. Comments, notices of intention to appear, hearing testimony, and documentary evidence will be available for inspection and copying at the OSHA Docket Office. You also should read the sections above titled **DATES** and **ADDRESSES** for additional information on submitting comments, documents, and requests to the Agency for consideration in this rulemaking.

Written Comments. OSHA invites interested persons to submit written data, views, and arguments concerning this proposal. In particular, OSHA encourages interested persons to comment on the issues raised in section II of this preamble. When submitting comments, parties must follow the procedures specified above in the sections titled **DATES** and **ADDRESSES.** The comments must clearly identify the provision of the proposal you are addressing, the position taken with respect to each issue, and the basis for that position. Comments, along with supporting data and references, received by the end of the specified comment period will become part of the record, and will be available for public inspection and copying at the OSHA Docket Office.

Informal Public Hearing. Pursuant to section 6(b)(3) of the Act, members of the public will have an opportunity to provide oral testimony concerning the issues raised in this proposal at informal public hearings. The hearings will commence at 9:30 a.m. on February 1, 2005. At that time, the presiding administrative law judge (ALJ) will resolve any procedural matters relating to the proceeding. The legislative history of section 6 of the OSH Act, as well as OSHA's regulation governing public hearings (29 CFR 1911.15), establish the purpose and procedures of informal public hearings.

Although the presiding officer at such hearings is an ALJ, and questioning by interested persons is allowed on crucial issues, the proceeding is informal and legislative in purpose. Therefore, the hearing provides interested persons with an opportunity to make effective and expeditious oral presentations in the absence of procedural restraints or rigid procedures that could impede or protract the rulemaking process. The hearing is an informal administrative proceeding, rather than adjudicative one in which the technical rules of evidence would apply; its primary purpose is to gather and clarify information. The regulations that govern public hearings, and the pre-hearing guidelines issued for this hearing, will ensure participants fairness and due process, and also will facilitate the development of a clear, accurate, and complete record. Accordingly, application of these rules and guidelines will be such that questions of relevance, procedure, and participation generally will favor development of the record. Conduct of the hearing will conform to the provisions of 29 CFR part 1911, "Rules of Procedure for Promulgating, Modifying, or Revoking Occupational Safety and Health Standards."

Although the ALJs who preside over these hearings make no decision or recommendation on the merits of OSHA's proposal, they do have the responsibility and authority to ensure that the hearing progresses at a reasonable pace and in an orderly manner. To ensure that interested persons receive a full and fair informal hearing as specified by 29 CFR part 1911, the ALJ has the authority and power to: Regulate the course of the proceedings; dispose of procedural requests, objections, and comparable matters; confine the presentations to matters pertinent to the issues raised; use appropriate means to regulate the conduct of the parties who are present at the hearing; question witnesses, and permit others to question witnesses; and limit the time for such questioning.

At the close of the hearing, the ALJ will establish a post-hearing comment period for parties who participated in the hearing. During the first part of this period, the participants may submit additional data and information to OSHA, while during the second part of this period, they may submit briefs, arguments, and summations.

Notice of Intention to Appear to Provide Testimony at the Informal Public Hearing. Interested persons who intend to provide oral testimony at the informal public hearing must file a notice of intention to appear by using the procedures specified above in the sections titled **DATES** and **ADDRESSES.** This notice must provide the: Name, address, and telephone number of each individual who will provide testimony; capacity (*e.g.*, name of the organization the individual is representing; the individual's title and position) in which each individual will testify; approximate amount of time required for each individual's testimony; specific issues each individual will address, including a brief statement of the position that the individual will take with respect to each of these issues; and any documentary evidence the individual will present, including a brief summary of the evidence. The hearings are open to the public, and all interested persons are welcome to attend. However, only a person who files a proper notice of intention to appear may ask questions and participate fully in the proceedings. While a person who did not file a notice of intention to appear may be allowed to testify at the hearing if time permits, this determination is at the discretion of the presiding ALJ.

Hearing Testimony and Documentary Evidence. Any person requesting more than 10 minutes to testify at the informal public hearing, or who intends to submit documentary evidence at the hearing, must provide the complete text

of the testimony and the documentary evidence as specified above in the **DATES** and **ADDRESSES** sections. The Agency will review each submission and determine if the information it contains warrants the amount of time requested. If OSHA believes the requested time is excessive, it will allocate an appropriate amount of time to the presentation, and will notify the participant of this action, and the reasons for the action, prior to the hearing. The Agency may limit to 10 minutes the presentation of any participant who fails to comply substantially with these procedural requirements; in such instances, OSHA may request that the participant return for questioning at a later time.

Certification of the Record and Final Determination After the Informal Public Hearing. Following the close of the hearing and post-hearing comment period, the presiding ALJ will certify the record to the Assistant Secretary of Labor for Occupational Safety and Health; the record will consist of all of the written comments, oral testimony, and documentary evidence received during the proceeding. OSHA will review the proposed Cr(VI) standard in light of all the evidence received as part of the record, and will make its decisions based on substantial evidence in the record as a whole.

XVII. Summary and Explanation of the Standards

OSHA believes that, based on currently available information, the proposed requirements set forth in this notice are necessary and appropriate to provide adequate protection to employees exposed to Cr(VI). OSHA has considered responses to the RFI as well as numerous reference works, journal articles, and other data obtained by the Agency in the development of this proposed standard.

The language of the standards and the order of the various provisions are generally consistent with drafting in other recent OSHA health standards, such as the methylene chloride, formaldehyde, and cadmium standards. OSHA believes that a similar style should be followed from standard to standard when possible in order to facilitate uniformity of interpretation of similar provisions. This approach is also consistent with Section 6(b)(5) of the OSH Act, which states that health standards shall consider "experience gained under this and other health and safety laws."

(a) Scope and Application

OSHA is proposing to issue separate standards addressing hexavalent chromium exposure in general industry, construction, and shipyards. The standard for shipyards would also apply to marine terminals and longshoring. The standards are intended to provide equivalent protection for all workers, while accounting for the different work activities, anticipated exposures, and other conditions in these sectors. The proposed standards for construction and shipyards are very similar to each other, but differ in some respects from the proposed standard for general industry. This summary and explanation will describe the proposed standard for general industry and will note differences between it and the proposed standards for construction and shipyards.

Based on the record developed to date, OSHA believes that certain activities in construction and shipyards are different enough to warrant requirements that are somewhat modified from those proposed for general industry. This preliminary determination is consistent with the recommendation of the Maritime Advisory Committee on Occupational Safety and Health (MACOSH), which has recommended that a separate standard be developed for maritime. The proposed standards do not cover the agricultural sector. OSHA is not aware of significant exposures to Cr(VI) in agriculture. The Agency is interested in any evidence indicating that significant exposures to Cr(VI) occur in sectors not covered under the proposed standards. Accordingly, the subject has been raised in the "Issues" section of this proposal.

The proposed standard applies to occupational exposures to hexavalent chromium (also referred to as chromium (VI) or Cr(VI)), that is, any chromium species with a valence of positive six, regardless of form or compound. Examples of Cr(VI) compounds include chromium oxide (CrO_2), ammonium dichromate ($(NH_4)_2Cr_2O_7$), calcium chromate ($CaCrO_4$), chromium trioxide (CrO_3), lead chromate ($PbCrO_4$), potassium chromate (K_2CrO_4), potassium dichromate ($K_2Cr_2O_7$), sodium chromate (Na_2CrO_4), strontium chromate ($SrCrO_4$), and zinc chromate ($ZnCrO_4$).

Some stakeholders have argued that specific Cr(VI) compounds should be excluded from this rulemaking and addressed in a separate standard. Notably, after OSHA was initially petitioned to issue a Cr(VI) standard, the Color Pigments Manufacturers Association (CPMA) submitted a cross-petition calling for a separate standard for lead chromate pigments (Ex. 2). CPMA argued that differences in the bioavailability and toxicity of lead chromate when compared to other Cr(VI) compounds warranted a separate standard (Ex. 2, p. 5). CPMA stated:

> Simply put, there are no studies which show a link between lead chromate pigments in a finished form and cancer caused by exposure to Chromium VI. To the contrary, studies of lead chromate workers in the manufacture of lead chromate pigments alone do not show any increased risk of cancer (Ex. 2, p. 5).

Because CPMA deemed that lead chromate pigments posed little threat to employee health, and because of concern about adverse economic impacts associated with regulation, the Association considered that "* * * no good purpose would be served by additional restrictions on lead chromate pigments" (Ex. 2, p. 6). This position was reiterated in CPMA's response to the RFI (Ex. 31–15, p. 6).

In its response to the RFI, the Boeing Company also expressed the view that OSHA should consider the bioavailability of different Cr(VI) compounds (Ex. 31–16, p. 8). Boeing indicated that exposures to strontium chromate and zinc chromate used in aerospace manufacturing are not equivalent to Cr(VI) exposures in other industries. The findings of two epidemiological studies of Cr(VI)-exposed aerospace workers were said to support this conclusion.

OSHA has proposed a rule that covers all Cr(VI) compounds because the Agency believes the evidence supports this approach. As discussed in Section VI.A of this preamble, absorption of Cr(VI) from the lung into the bloodstream is greatly dependent on the solubility of the Cr(VI) compound. Insoluble chromates are poorly absorbed and as a result remain in the lungs for a longer period of time (Ex. 35–87). While in the lungs, insoluble Cr(VI) particulates can come into contact with the epithelial cell surface, resulting in uptake into cells (Exs. 35–68; 35–67). Cellular uptake leads to DNA damage, apoptosis, and neoplastic transformation (Ex. 35–119). Less water-soluble chromates (*e.g.*, lead chromate) appear to be more potent carcinogens than more soluble chromates (*e.g.*, sodium chromate). (For a detailed discussion, see Section VI.B.8 of this preamble.)

Experimental studies involving Syrian hamster embryo cells support the belief that cytotoxicity and neoplastic transformation occur when exposures involve lead chromate pigments (Ex. 12–5). Evidence indicates that even chromates that are encapsulated in a paint matrix may be released in the lungs (Ex. 31–15, p. 2). OSHA therefore sees no reason to exempt these

compounds from the current Cr(VI) rulemaking.

OSHA believes this view is consistent with the epidemiological studies involving chromate pigment production workers and aerospace workers. While co-exposures to other Cr(VI) compounds do not allow for specific findings related to lead chromate exposure, OSHA has found that epidemiological studies of workers in the chromate pigment production industry have consistently shown excess risks for lung cancer (see Section VI.B.2 of this preamble). The studies of aerospace workers did not find an increased risk of lung cancer. However, this is not convincing evidence that aerospace workers are not at risk from Cr(VI) exposure. The small cohort size, lack of smoking data, relatively young age of the population, and number of members lost to follow-up in the study reported by Alexander *et al.* (Ex. 31–16–3) and the lack of exposure information in the report of Boice *et al.* (Ex. 31–16–4) do not allow for any broad conclusions regarding aerospace workers to be reached on the basis of these two studies. OSHA's preliminary conclusion that Cr(VI) compounds should be addressed collectively under a single standard is consistent with the findings of IARC, NTP, and NIOSH. These organizations have each found Cr(VI) compounds to be carcinogenic, without exception. Although ACGIH has issued different TLVs for soluble and insoluble Cr(VI) compounds, and for certain specific compounds, the TLV for insoluble Cr(VI) compounds is five-fold lower than the TLV for soluble Cr(VI) compounds. This is consistent with OSHA's preliminary finding that less soluble Cr(VI) compounds, to the extent that they differ from more soluble Cr(VI) compounds, are more potent carcinogens and pose a greater risk to the health of workers.

The proposed standard applies to occupational exposure in which Cr(VI), in any quantity, is present in an occupationally related context. Exposure of employees to the ambient environment, which may contain small concentrations of Cr(VI) unrelated to the job, is not subject to this standard.

The proposed standard for construction does not cover exposure to Cr(VI) in portland cement. Cement ingredients (clay, gypsum, and chalk), chrome steel grinders used to crush ingredients, refractory bricks lining the cement kiln, and ash may serve as sources of chromium that may be converted to Cr(VI) during kiln heating, leaving trace amounts of Cr(VI) in the finished product (Ex. 35–317, p. 148).

The amount of Cr(VI) in American cement is generally less than 20 µg/g (Ex. 9–57). While the Cr(VI) in cement may represent a dermal hazard, the evidence obtained by OSHA thus far indicates that the Cr(VI) concentration is generally so low that the proposed PEL could not be reached without exceeding OSHA's current PEL for Particulates Not Otherwise Regulated (PNOR). The PEL for PNOR (15 µg/m^3 for total dust) thus is at least as protective as the proposed Cr(VI) PEL in limiting the Cr(VI) inhalation exposure of cement workers. OSHA's preliminary exposure profile indicates that no employees are exposed to levels of Cr(VI) above 0.25 µg/m^3 as an 8-hour TWA during cement work in construction. Because airborne exposures to Cr(VI) during cement work in construction are expected to be minimal, and because of the economic burden of applying the ancillary provisions of the proposed standard to workers exposed to portland cement in the construction environment, OSHA has preliminarily concluded that exposures to Cr(VI) from portland cement are best addressed by providing guidance to employers rather than including portland cement in the construction rule.

OSHA has proposed to cover exposures to Cr(VI) in portland cement in general industry. The Agency's preliminary exposure profile indicates that some employees in general industry are exposed to airborne Cr(VI) levels associated with a significant risk of lung cancer as a result of work with portland cement. OSHA's preliminary findings show that nearly 2500 workers in general industry are exposed to Cr(VI) levels between 0.25 µg/m^3 and 0.5 µg/m^3 as an 8-hour TWA. Because of the evidence of higher airborne Cr(VI) exposures in general industry than in construction, and because lower burdens are anticipated in the more stable work environments found in general industry, the Agency believes it is appropriate to cover Cr(VI) exposures from portland cement under the general industry proposed standard. OSHA is interested in comments and information regarding this preliminary determination, and has included this topic in the "Issues" section of this preamble.

This proposal does not cover exposures to Cr(VI) that occur in the application of pesticides. Some Cr(VI)-containing chemicals, such as chromated copper arsenate (CCA) and acid copper chromate (ACC), are used for wood treatment and are regulated by EPA as pesticides. Section 4(b)(1) of the OSH Act precludes OSHA from regulating working conditions of employees where other Federal agencies exercise statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health. Therefore, OSHA proposes to specifically exclude those exposures regulated by EPA from coverage under the standard.

The manufacture of pesticides containing Cr(VI) is not considered pesticide application, and is covered under this proposed standard. The use of wood treated with pesticides containing Cr(VI) is also covered. In this respect, the proposed Cr(VI) standard differs from OSHA's Inorganic Arsenic standard (29 CFR 1910.1018). The Inorganic Arsenic standard explicitly exempts the use of wood treated with arsenic. When the Inorganic Arsenic standard was issued in 1978, OSHA found that the evidence in the record indicated "the arsenic in the preserved wood is bound tightly to the wood sugars, exhibits substantial chemical differences from other pentavalent arsenicals after reaction, and appears not to leach out in substantial amounts" (43 FR 19584, 19613 (5/5/78)). Based on the record in that rulemaking, OSHA did not consider it appropriate to regulate the use of preserved wood. The record in this rulemaking indicates that work with wood treated with pesticides containing Cr(VI) can involve significant Cr(VI) exposures. OSHA's exposure profile for woodworking indicates that over 30% of current employee Cr(VI) exposures exceed the proposed PEL. OSHA therefore believes it appropriate to include these activities under the scope of the proposed standard.

(b) Definitions

"Action level" is defined as an airborne concentration of Cr(VI) of 0.5 micrograms per cubic meter of air (0.5 µg/m^3) calculated as an eight-hour time-weighted average (TWA). The action level triggers requirements for exposure monitoring and medical surveillance in general industry workplaces. In this proposal, as in other standards, the action level has been set at one-half of the PEL.

Because of the variable nature of employee exposures to airborne concentrations of Cr(VI), maintaining exposures below the action level provides reasonable assurance that employees will not be exposed to Cr(VI) at levels above the PEL on days when no exposure measurements are made. Even when all measurements on a given day may fall below the PEL (but are above the action level), there is some chance that on another day, when exposures are not measured, the employee's actual exposure may exceed

the PEL. When exposure measurements are above the action level, the employer cannot be reasonably confident that employees may not be exposed to Cr(VI) concentrations in excess of the PEL during at least some part of the work week. Therefore, requiring periodic exposure measurements when the action level is exceeded provides the employer with a reasonable degree of confidence in the results of the exposure monitoring.

The action level is also intended to encourage employers to lower exposure levels in order to avoid the costs associated with the exposure monitoring and medical surveillance provisions. Some employers would be able to reduce exposures below the action level in all work areas, and other employers in some work areas. As exposures are lowered, the risk of adverse health effects among workers decreases.

OSHA s preliminary risk assessment indicates that significant risk remains at the proposed PEL of 1.0 μg/m³. Where there is continuing significant risk, the decision in the Asbestos case (Building and Construction Trades Department, *AFL–CIO* v. *Brock,* 838 F. 2d 1258, (D.C. Cir 1988)) indicated that OSHA should use its legal authority to impose additional requirements on employers to further reduce risk when those requirements will result in a greater than de minimus incremental benefit to workers' health. OSHA's preliminary conclusion is that the action level will result in a very real and necessary, but non-quantifiable, further reduction in risk beyond that provided by the PEL alone. OSHA's choice of proposing an action level of one-half of the PEL is based on the Agency's successful experience with other standards, including those for inorganic arsenic (29 CFR 1910.1018), ethylene oxide (29 CFR 1910.1047), benzene (29 CFR 1910.1028), and methylene chloride (29 CFR 1910.1052).

As discussed under the requirements for exposure monitoring, OSHA has not proposed an action level for construction and shipyards. This definition is therefore not included in the proposed standards for construction and shipyards.

"Chromium (VI) [hexavalent chromium or Cr(VI)]" means chromium with a valence of positive six, in any form or chemical compound in which it occurs. This term includes Cr(VI) in all states of matter, in any solution or other mixture, even if encapsulated by another or several other substances. The term also includes Cr(VI) when created by an industrial process, such as when welding of stainless steel generates Cr(VI) fume.

For regulatory purposes, OSHA is treating Cr(VI) generically, instead of addressing specific compounds individually. This is based on OSHA's preliminary determination that the toxicological effect on the human body is similar from Cr(VI) in any of the substances covered under the scope of this standard, regardless of the form or compound in which it occurs. As discussed in Section VI of this preamble, some variation in potency may result due to differences in the solubility of compounds. Other factors, such as encapsulation, may have some effect on the bioavailability of Cr(VI). However, OSHA believes that these factors do not result in differences that merit separate provisions for different Cr(VI) compounds. OSHA considers it appropriate to apply the requirements of the proposed standard uniformly to all Cr(VI) compounds.

"Emergency" means any occurrence that results, or is likely to result, in an uncontrolled release of Cr(VI), such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment. Every spill or leak is not necessarily an emergency. The exposure to Cr(VI) must be unexpected and significant.

If an incidental release of Cr(VI) may be safely cleaned up by employees at the time of release, it is not considered to be an emergency situation for the purposes of this section. The particular circumstances of the release itself, such as the quantity involved, confined space considerations, and the adequacy of ventilation will have an impact on employee safety. In addition, factors such as the knowledge of employees in the immediate work area, the personal protective equipment available, pre-established standard operating procedures for responding to releases, and engineering controls that employees can activate to assist them in controlling and stopping the release are all factors that must be considered in determining whether a release is incidental or an emergency. Those instances that constitute an emergency trigger certain requirements in this proposed standard (*e.g.*, medical surveillance) that are discussed later in this section.

"Employee exposure" means exposure to airborne Cr(VI) that would occur if the employee were not using a respirator. This definition is included to clarify the fact that employee exposure is measured outside any respiratory protection worn. It is consistent with OSHA's previous use of the term in other standards.

"Physician or other licensed health care professional (PLHCP)" refers to an individual who is legally permitted to provide some or all of the health care services required by this section. This definition is included because the proposed standard requires that all medical examinations and procedures be performed by or under the supervision of a PLHCP.

Any professional may perform the medical examinations and procedures provided under the standard when they are licensed by state law to do so. The Agency recognizes that this means that the personnel qualified to provide the required medical examinations and procedures may vary from state to state, depending on state licensing laws. This provision grants the employer the flexibility to retain the services of a variety of qualified licensed health care professionals, provided that these individuals are licensed to perform the specified service. OSHA believes that this flexibility will reduce cost and compliance burdens for employers and increase convenience for employees. The approach taken in this proposed standard is consistent with the approach OSHA has taken in other recent standards, such as those for methylene chloride (29 CFR 1910.1052), bloodborne pathogens (29 CFR 1910.1030), and respiratory protection (29 CFR 1910.134).

"Regulated area" means an area, demarcated by the employer, where an employee's exposure to airborne concentrations of Cr(VI) exceeds, or can reasonably be expected to exceed the PEL. This definition is consistent with the use of the term in other standards, including those for cadmium (29 CFR 1910.1027), butadiene (29 CFR 1910.1051), and methylene chloride (29 CFR 1910.1052).

OSHA has not proposed a requirement for regulated areas in construction and shipyards. This definition is therefore not included in the proposed standards for construction and shipyards.

The definitions for "Assistant Secretary", "Director", "High-efficiency particulate air [HEPA] filter", and "This section" are consistent with OSHA's previous use of these terms found in other health standards.

(c) Permissible Exposure Limit (PEL)

OSHA proposes to set an 8-hour time-weighted average (TWA) exposure limit of 1 microgram of Cr(VI) per cubic meter of air (1 μg/m³). This limit means that over the course of any 8-hour work shift, the average exposure to Cr(VI) cannot exceed 1 μg/m³. The proposed limit applies to Cr(VI), as opposed to the current PEL which is measured as CrO_3. The current PEL of 1 milligram per 10 cubic meters of air (1 μg/10 m³, or 100

μg/m³) reported as CrO_3 is equivalent to a limit of 52 μg/m³ as Cr(VI). The current PEL is enforced as a TWA in construction and as a ceiling (a level not to be exceeded at any time) in general industry.

OSHA proposes a new PEL of 1 μg/m³ because the Agency has preliminarily determined that occupational exposure to Cr(VI) at the current PEL results in a significant risk of lung cancer among exposed workers, and that compliance with the proposed standard will substantially reduce that risk. OSHA's preliminary risk assessment, presented in Section VII of this preamble, indicates that the most reliable lifetime estimate of risk from a 45 year exposure to Cr(VI) at the current PEL is 101 to 351 excess deaths from lung cancer per 1000 workers. As discussed in Section VIII of this preamble, this clearly represents a risk of material impairment of health that is significant within the context of the Benzene decision. OSHA believes that lowering the PEL to 1 μg/m³ would reduce the lifetime excess risk of death from lung cancer to between 2.1 and 9.1 per 1000 workers.

OSHA considers the level of risk remaining at the proposed PEL to be significant. However, as discussed in Section IX of this preamble, the proposed PEL is set at the lowest level that the Agency believes to be feasible in all affected industry sectors. As guided by the 1988 Asbestos decision, OSHA is proposing additional requirements to further reduce the remaining risk. OSHA anticipates that the ancillary provisions in the proposed standard will further reduce the risk beyond the reduction that would be achieved by the proposed PEL alone.

OSHA believes that it is appropriate to establish a single PEL that applies to all Cr(VI) compounds. OSHA's preferred estimates of risk supporting the proposed PEL are derived from worker cohorts that were predominantly exposed to soluble sodium chromate. The evidence reviewed by OSHA indicates that similar doses of less soluble chromates result in higher numbers of lung tumors when compared to more soluble compounds such as sodium chromate (see Section VI of this preamble). Thus, any variation in toxicological effect due to solubility is expected to result in a higher level of risk than is indicated by OSHA's preliminary risk estimates. OSHA consequently believes that the Agency's findings regarding significance of risk are valid regardless of the solubility of the Cr(VI) compound. However, the available evidence is not sufficient to make quantitative estimates of risk for each individual Cr(VI) compound. OSHA is therefore proposing a single PEL for all Cr(VI) compounds. The Agency seeks comment on whether different PELs for different Cr(VI) compounds should be set and how such determinations should be made, and has included this topic in the "Issues" section of the preamble.

(d) Exposure Monitoring

The proposed general industry standard imposes monitoring requirements pursuant to Section 6(b)(7) of the OSH Act (29 U.S.C. 655) which mandates that any standard promulgated under section 6(b) shall, where appropriate, "provide for monitoring or measuring of employee exposure at such locations and intervals, and in such manner as may be necessary for the protection of employees."

The purpose of requiring assessment of employee exposures to Cr(VI) include: determination of the extent and degree of exposure at the worksite; identification and prevention of employee overexposure; identification of the sources of exposure to Cr(VI); collection of exposure data so that the employer can select the proper control methods to be used; and evaluation of the effectiveness of those selected methods. Assessment enables employers to meet their legal obligation to ensure that their employees are not exposed to Cr(VI) in excess of the permissible exposure level and to notify employees of their exposure levels, as required by section 8(c)(3) of the Act. In addition, the availability of exposure data enables the PLHCP performing medical examinations to be informed of the extent of occupational exposures.

Paragraph (d)(1) contains proposed general requirements for exposure monitoring. Monitoring to determine employee exposures must represent the employee's time-weighted average exposure to airborne Cr(VI) over an eight-hour workday. Samples must be taken within the employee's breathing zone (i.e., "personal breathing zone samples" or "personal samples"), and must represent the employee's exposure without regard to the use of respiratory protection.

Employers must accurately characterize the exposure of each employee to Cr(VI). In some cases, this will entail monitoring all exposed employees. In other cases, monitoring of "representative" employees is sufficient. Representative exposure sampling is permitted when a number of employees perform essentially the same job under the same conditions. For such situations, it may be sufficient to monitor a fraction of these employees in order to obtain data that are "representative" of the remaining employees. Representative personal sampling for employees engaged in similar work with Cr(VI) exposure of similar duration and magnitude can be achieved by monitoring the employee(s) reasonably expected to have the highest Cr(VI) exposures. For example, this may involve monitoring the Cr(VI) exposure of the employee closest to an exposure source. This exposure result may then be attributed to the remaining employees in the group.

Exposure monitoring should include, at a minimum, one full-shift sample taken for each job function in each job classification, in each work area, for each shift. These samples must consist of at least one sample characteristic of the entire shift or consecutive representative samples taken over the length of the shift. Where employees are not performing the same job under the same conditions, representative sampling will not adequately characterize actual exposures, and individual monitoring is necessary.

OSHA proposes that employers who have workplaces covered by the general industry standard determine if any of their employees are exposed to Cr(VI) at or above the action level. Further obligations under the standard would be based on the results of this assessment. These may include obligations for periodic monitoring, establishment of regulated areas, implementation of control measures, and provision of medical surveillance.

Initial monitoring need not be conducted under two circumstances. First, where the employer has previously monitored for Cr(VI) in the past 12 months and the data were obtained during work operations conducted under workplace conditions closely resembling the processes, types of material, control methods, work practices, and environmental conditions used and prevailing in the employer's current operations, and where that monitoring satisfies all other requirements of this section, including the accuracy and confidence requirements, the employer may rely on such earlier monitoring results to satisfy the initial monitoring requirements of this section. This provision is designed to make it clear that OSHA does not intend to require employers who have recently performed appropriate employee monitoring to conduct "initial" monitoring. OSHA anticipates that this provision will reduce the compliance burden on employers, since monitoring for tasks that involve essentially the same exposures would

not be required. The Agency believes allowing the use of 12 month old data is appropriate; samples taken earlier than 12 months previously may not adequately represent current workplace conditions. The 12 month limit is consistent with the Methylene Chloride standard (29 CFR 1910.1052).

Second, where the employer has objective data demonstrating that a particular product or material containing Cr(VI) or a specific process, operation, or activity involving Cr(VI) cannot release dust, fumes, or mist in concentrations at or above the action level under any expected conditions of use, the employer may rely upon such data to satisfy initial monitoring requirements. The data must reflect workplace conditions closely resembling the processes, types of material, control methods, work practices, and environmental conditions in the employers' current operations.

Objective data demonstrate that the work operation or the product may not reasonably be foreseen to release Cr(VI) in airborne concentrations at or above the action level under the expected conditions of use that will cause the greatest possible release, or in any plausible accident. The objective data may include monitoring data, or mathematical modeling or calculations based on the chemical and physical properties of a material. For example, data collected by a trade association from its members that meet the definition of objective data may be used. When using the term "objective data", OSHA is referring to employers' reliance on manufacturers' worst case studies, laboratory studies, and other research that demonstrates, usually by means of exposure data, that meaningful exposures cannot occur. OSHA has allowed employers to use objective data in other standards such as those for formaldehyde (29 CFR 1910.1048) and asbestos (29 CFR 1910.1001) in lieu of initial monitoring and hence, from most of the provisions of these standards.

Paragraph (d)(3) contains requirements for periodic monitoring. The requirement for continued monitoring depends on the results of initial monitoring. If the initial monitoring indicates that employee exposures are below the action level, no further monitoring would be required unless changes in the workplace result in new or additional exposures. If the initial determination reveals employee exposures to be at or above the action level but below the PEL, the employer must perform periodic monitoring at least every six months. If the initial monitoring reveals employee exposures to be above the PEL, the employer must repeat monitoring at least every three months.

The proposed rule also includes provisions to adjust the frequency of periodic monitoring based on monitoring results. If periodic monitoring results indicate that employee exposures have fallen below the action level, and those results are confirmed by consecutive measurements taken at least seven days later, the employer may discontinue monitoring for those employees whose exposures are represented by such monitoring. Similarly, if periodic monitoring measurements indicate that exposures are below the PEL but above the action level, and those results are confirmed by consecutive measurements taken at least seven days later, the employer may reduce the frequency of the monitoring to at least every six months.

OSHA recognizes that exposures in the workplace may fluctuate. Periodic monitoring provides the employer with assurance that employees are not experiencing higher exposures that may require the use of additional control measures. In addition, periodic monitoring reminds employees and employers of the continued need to protect against the hazards associated with exposure to Cr(VI).

Because of the fluctuation in exposures, OSHA believes that when initial monitoring results exceed the action level but are below the PEL, employers should continue to monitor employees to ensure that exposures remain below the PEL. Likewise, when initial monitoring results exceed the PEL, periodic monitoring allows the employer to maintain an accurate profile of employee exposures. If the employer installs or upgrades controls, periodic monitoring will demonstrate whether or not controls are working properly. Selection of appropriate respiratory protection also depends on adequate knowledge of employee exposures.

In general, the more frequently periodic monitoring is performed, the more accurate the employee exposure profile. Selecting an appropriate interval between measurements is a matter of judgment. OSHA believes that the proposed frequency of six months for subsequent periodic monitoring for exposures above the action level but below the PEL, and three months for exposures above the PEL, provides intervals that are both practical for employers and protective for employees. This belief is supported by OSHA's experience with comparable monitoring intervals in other standards, including those for cadmium (29 CFR 1910.1027), methylenedianiline (29 CFR 1910.1050), methylene chloride (29 CFR 1910.1052), and formaldehyde (29 CFR 1910.1048). The proposed requirement for periodic monitoring is also consistent with OSHA's Standards Improvement Project (SIPs) proposal for monitoring frequency (67 FR 66494, 66504 (8/31/02)).

OSHA recognizes that monitoring can be a time-consuming, expensive endeavor and therefore offers employers the incentive of discontinuing monitoring for employees whose sampling results indicate exposures are below the action level. The Agency does not believe that periodic monitoring is generally necessary when monitoring results show that exposures are below the action level because there is a low probability that the results of future samples would exceed the PEL. The Agency intends for this provision to encourage employers to control their employees' exposures to Cr(VI) below the action level, thus maximizing the protection of employees' health.

Under paragraph (d)(4), employers are to perform additional monitoring when there is a change in production process, raw materials, equipment, personnel, work practices, or control methods, that may result in new or additional exposures to Cr(VI). In addition, there may be other situations which can result in new or additional exposures to Cr(VI) which are unique to an employer's work situation. In order to cover those special situations, OSHA requires the employer to perform additional monitoring whenever the employer has any reason to believe that a change has occurred which may result in new or additional exposures. This additional monitoring is necessary to ensure that monitoring results accurately represent existing exposure conditions. This is necessary so that the employer can take appropriate action to protect exposed employees, such as instituting additional engineering controls or providing appropriate respiratory protection.

Under paragraph (d)(5) of the general industry standard, employers are to notify each affected employee of their monitoring results within 15 working days after the receipt of the results. The employer shall either notify each affected employee in writing or post the monitoring results in an appropriate location accessible to all affected employees. In addition, whenever the PEL has been exceeded, the written notification must contain a description of the corrective action(s) being taken by the employer to reduce the employee's exposure to or below the PEL. The requirement to inform employees of the

corrective actions the employer is taking to reduce the exposure level to or below the PEL is necessary to assure employees that the employer is making efforts to furnish them with a safe and healthful work environment, and is required under section 8(c)(3) of the Act.

The proposal would require that all affected employees be notified of the monitoring results. When using the term "affected employees" in this context, OSHA is not referring only to the employee(s) actually subject to personal monitoring. Affected employees include all employees represented by the employee(s) sampled.

Individual notification in writing or posting would be acceptable under the proposed rule. This is consistent with other OSHA standards such as those for methylenedianiline (29 CFR 1910.1050), butadiene (29 CFR 1910.1051), and methylene chloride (29 CFR 1910.1052). In addition, the SIPs proposal (67 FR 66494, 66508 (10/31/02)) allows for employer choice of notification method. The Cr(VI) proposal is also consistent with SIPs in that SIPs specifies 15 working days after the receipt of monitoring results as the appropriate time to notify employees in general industry (67 FR 66494, 66508 (10/31/03)).

Under paragraph (d)(6), the employer would be required to use monitoring and analytical methods that can measure airborne levels of Cr(VI) to within an accuracy of plus or minus 25% (+/-25%) and can produce accurate measurements to within a statistical confidence level of 95% percent for airborne concentrations at or above the action level. Many laboratories presently have methods to measure Cr(VI) at the proposed action level with at least the required degree of accuracy. One example of an acceptable method of monitoring and analysis is OSHA method ID215. Rather than specifying a particular method that must be used, OSHA proposes to take a performance approach and instead allows the employer to use any method as long as the chosen method meets the accuracy specifications.

Paragraph (d)(7) requires the employer to provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to Cr(VI). When observation of monitoring requires entry into an area where the use of protective clothing or equipment is required, the employer must provide the observer with that protective clothing or equipment, and assure that the observer uses such clothing or equipment and complies with all other applicable safety and health procedures.

The requirement for employers to provide employees or their representatives the opportunity to observe monitoring is consistent with the OSH Act. Section 8(c)(3) of the OSH Act mandates that regulations developed under Section 6 provide employees or their representatives with the opportunity to observe monitoring or measurements. Also, Section 6(b)(7) of the OSH Act states that where appropriate, OSHA standards are to prescribe suitable protective equipment to be used in dealing with hazards. The provision for observation of monitoring and protection of the observers is also consistent with OSHA's other substance-specific health standards such as those for cadmium (29 CFR 1910.1027) and methylene chloride (29 CFR 1910.1052).

The proposed construction and shipyard standards for Cr(VI) do not include provisions for exposure monitoring. OSHA recognizes that in these sectors in many instances the results of exposure monitoring required under this proposed standard would not be available until after operations involving Cr(VI) exposure have been completed. For example, a welding task may be finished in a single day. If air monitoring is performed, the task would be completed before the employer is informed of the monitoring results. Therefore, the employer would not be in a position to make use of the monitoring results to determine appropriate control measures for that task. In other cases, the workplace conditions in construction and shipyard worksites may vary to such a great extent that it may be difficult to accurately characterize employee exposure from one day to the next. For example, a stainless steel welder may work outdoors on a windy day one day and in an enclosed environment the next day. Personal monitoring for Cr(VI) exposure on a given day may not accurately reflect these changing conditions. OSHA has therefore proposed a performance-oriented requirement for construction and shipyard employers. Rather than include specific requirements for exposure monitoring for these employers, OSHA proposes to allow construction and shipyard employers the flexibility to assess Cr(VI) exposures in any manner they choose. Thus, construction and shipyard employers could use historical data, objective data, or employee monitoring to determine employee exposures. Because the obligation to comply with the PEL would remain, whatever method the employer chooses would have to be sufficient to ensure that no employee is exposed to an airborne concentration of Cr(VI) in excess of the PEL.

In some cases, the employer may choose not to perform any monitoring. For example, certain tasks (*e.g.*, abrasive blasting of materials coated with Cr(VI); welding, cutting, or torch burning of stainless steel or of materials coated with Cr(VI); or spray application of Cr(VI) containing paints or coatings) frequently entail exposures to Cr(VI) above the proposed PEL. OSHA estimates that approximately 43% of the exposures in construction welding and 17.9% of the exposures in shipyard welding are greater than the proposed PEL of 1 $\mu g/m^3$. A construction or shipyard employer has the option of assuming the employee is exposed above the PEL and providing appropriate protective measures as prescribed by the standard.

Similarly, an employer may not find it necessary to perform exposure monitoring where exposures are well below the PEL. For example, there are several construction application groups (*e.g.*, industrial rehabilitation and maintenance, hazardous waste site work, and refractory restoration and maintenance) where a large percentage of exposures are either below 0.25 $\mu g/m^3$ or below the limit of detection for Cr(VI). In these situations, employers may be relatively assured that employees' exposure are well below the PEL and would therefore not need to conduct exposure monitoring.

This approach is consistent with OSHA's standard for air contaminants (29 CFR 1910.1000), which establishes PELs for over 400 substances, but does not include specific requirements for exposure monitoring. The Agency seeks comment as to whether this performance-oriented approach to exposure monitoring is appropriate in construction and shipyard workplaces, and has included this topic in the "Issues" section of this preamble.

(e) Regulated Areas

Under paragraph (e), general industry employers must establish regulated areas wherever an employee's exposure to airborne concentrations of Cr(VI) is, or can reasonably be expected to be, in excess of the PEL. Regulated areas are to be demarcated from the rest of the workplace in a manner that adequately establishes and alerts employees to the boundaries of these areas, and would be required to include the warning signs specified in paragraph (l)(2) of the proposed standard. Access to regulated areas is limited to persons authorized by the employer and required by work

duties to be present in the regulated area; any person entering the regulated area to observe monitoring procedures; or any person authorized by the OSH Act or regulations issued under it to be in a regulated area.

The purpose of a regulated area is to ensure that the employer makes employees aware of the presence of Cr(VI) at levels above the PEL, and to limit Cr(VI) exposure to as few employees as possible. The establishment of a regulated area is an effective means of limiting the risk of exposure to substances known to have carcinogenic effects. Because of the potentially serious results of exposure and the need for persons entering the area to be properly protected, the number of persons given access to the area should be limited to those employees needed to perform the job. Limiting access to regulated areas also has the benefit of reducing the employer's obligation to implement provisions of this proposal to as few employees as possible.

In keeping with the performance orientation of this proposed standard, OSHA has not specified how employers are to demarcate regulated areas. The demarcation should effectively warn employees not to enter the area unless they are authorized, and then only if they are using the proper personal protective equipment. The demarcation must include display of warning signs at all approaches to the regulated areas, consistent with the requirements of paragraph (l)(2) of this proposed standard. In many cases these warning signs alone will be sufficient to identify the boundaries of the regulated area.

Access to the regulated area is restricted to "authorized persons". For the purposes of this proposed standard, these are persons required by their job duties to be present in the area, as authorized by the employer. In addition, persons exercising the right to observe monitoring procedures are also allowed to enter regulated areas. Employees in some workplaces may designate a union representative to observe monitoring; this person would be allowed to enter the regulated area. Persons authorized under the OSH Act, such as OSHA compliance officers, are also allowed access to regulated areas.

OSHA has not included a requirement for regulated areas in construction and shipyard workplaces, due to the expected difficulties in establishing regulated areas in construction and shipyard workplaces. For example, several small entity representatives (SERs) from the construction and shipyard industries who participated in the SBREFA review noted that in their work settings regulated areas would be particularly problematic and might require that the entire worksite be designated as a regulated area. They also noted that due to the changing nature of the work site (namely construction sites) the demarcation of the regulated area would have to be changed each day as the work progressed (*e.g.*, Exs. 34–6, 34–14). The same rationale applies to shipyards. The Agency seeks comment as to whether a requirement for the establishment of regulated areas would be appropriate for construction or shipyard workplaces and how such areas could be established, and has included this topic in the "Issues" section of this preamble.

(f) Methods of Compliance

The proposed standard requires employers to institute effective engineering and work practice controls as the primary means to reduce and maintain employee exposures to Cr(VI) to levels that are at or below the PEL, unless the employer can demonstrate that such controls are not feasible, or if employees are not exposed above the PEL for 30 or more days per year. Employers would be required to institute engineering controls and work practices to reduce exposure to the lowest feasible level even if these measures alone would not reduce the concentration of airborne Cr(VI) to or below the PEL. The employer would then be required to supplement these controls with respirators to ensure that employees are not exposed to Cr(VI) above the PEL.

Primary reliance on engineering controls and work practices is consistent with good industrial hygiene practice and with OSHA's traditional adherence to a hierarchy of preferred controls. Engineering controls are reliable, provide consistent levels of protection to a large number of workers, can be monitored continually and inexpensively, allow for predictable performance levels, and can efficiently remove toxic substances from the workplace. Once removed, the toxic substance no longer poses a threat to employees. The effectiveness of engineering controls does not generally depend to any substantial degree on human behavior, and the operation of equipment is not as vulnerable to human error as is personal protective equipment. For these reasons, engineering controls are preferred by OSHA.

Engineering controls can be grouped into three main categories: (1) Substitution; (2) isolation; and (3) ventilation, both general and localized. Quite often a combination of these controls can be applied to an industrial hygiene control problem to achieve satisfactory air quality. It may not be necessary to apply all these measures to any specific potential hazard.

Substitution can be an ideal control measure. One of the best ways to prevent workers from being exposed to a toxic substance is to stop using it entirely. Although substitution is not always possible, replacement of a toxic material with a less hazardous alternative should always be considered.

In those cases where substitution of a less toxic material is not possible, substituting one type of process for another process may provide effective control of an air contaminant. For example, process changes from batch operations to continuous operations will usually reduce exposures. This is true primarily because the frequency and duration of workers' potential contact with process materials is reduced in continuous operations. Similarly, automation of a process can further reduce the potential hazard.

In addition to substitution, isolation should be considered as an option for controlling employee exposures to Cr(VI). Isolation can involve containment of the source of a hazard, thereby separating it from most workers. Workers can be isolated from Cr(VI) by working in a clean room or booth, or by placing some other type of barrier between the source of exposure and the employee. Employees can also be protected by being placed at a greater distance from the source of Cr(VI) emissions.

Frequently, isolation enhances the benefits of other control methods. For example, Cr(VI) compounds may be used in the formulation of certain paints. If the mixing operation is conducted in a small, enclosed room the airborne Cr(VI) potentially generated by the operation could be confined to a small area. By ensuring containment, local exhaust ventilation is more effective.

Ventilation is a method of controlling airborne concentrations of a contaminant by supplying or exhausting air. A local exhaust system is used to remove an air contaminant by capturing the contaminant at or near its source before it spreads throughout the workplace. General ventilation (dilution ventilation), on the other hand, allows the contaminant to spread throughout the work area but dilutes it by circulating large quantities of air into and out of the area. A local exhaust system is generally preferred to dilution ventilation because it provides a cleaner and healthier work environment.

Work practices controls involve adjustments in the way a task is performed. In many cases, work practice controls complement engineering controls in providing worker protection. For example, periodic inspection and maintenance of process equipment and control equipment such as ventilation systems is an important work practice control. Frequently, equipment which is in disrepair or near failure will not perform normally. Regular inspections can detect abnormal conditions so that timely maintenance can then be performed. If equipment is routinely inspected, maintained, and repaired or replaced before failure is likely, there is less chance that hazardous exposures will occur.

Workers must know the proper way to perform their job tasks in order to minimize their exposure to Cr(VI) and to maximize the effectiveness of control measures. For example, if an exhaust hood is designed to provide local ventilation and a worker performs a task that generates a contaminant away from the exhaust hood, the control measure will be of no use. Workers can be informed of proper operating procedures through information and training. Good supervision provides further support for ensuring that proper work practices are carried out by workers. By persuading a worker to follow proper procedures, such as positioning the exhaust hood in the correct location to capture the contaminant, a supervisor can do much to minimize unnecessary exposure.

Employees' exposures can also be controlled by scheduling operations with the highest exposures at a time when the fewest employees are present. For example, routine clean-up operations that involve Cr(VI) releases might be performed at night or at times when the usual production staff is not present.

OSHA has traditionally relied less on respiratory protection in the hierarchy of controls because the use and efficacy of respirators depends to a great extent on human behavior. Often work is strenuous, and the increased breathing resistance of the respirator reduces its acceptability to employees. Respirators can limit an employee's vision and ability to communicate. In some difficult and dangerous jobs, effective vision or communication is vital to a safe, efficient operation. Voice communication when using a respirator can be difficult and fatiguing. In any event, movement of the jaw in speaking can cause a temporary breaking of the face-to-facepiece seal, thereby reducing the efficiency of the respirator and decreasing the employee's protection. Skin irritation can result from wearing a respirator in hot, humid conditions. Such irritation can cause considerable distress to workers and may disrupt work schedules. To be used effectively, respirators must be individually selected; fitted and periodically refitted; conscientiously and properly worn; regularly maintained, including filter changes; and replaced as necessary. In some workplaces, these preconditions for effective respirator use can be difficult to achieve. It is more difficult to assure that each employee is wearing a respirator correctly than to ascertain that engineering controls are operational. Thus, OSHA has concluded that reliance upon respirators should be minimized when engineering and work practice controls are found to be effective.

OSHA has proposed an exception to the general requirement for primary reliance on engineering and work practice controls for those employers who do not have employee exposures above the PEL for 30 or more days per year (12 consecutive months) from a particular process or task. Thus, if an employee is exposed to Cr(VI) on only 29 days during any 12 consecutive months from a particular process or task, even if the exposure is above the PEL on all of these days, the employer would not be required by this proposed standard to implement engineering and work practice controls to control exposures to the PEL. The burden would be on the employer to show that exposures do not exceed the PEL on 30 or more days per year. OSHA believes this provision would provide needed flexibility to employers, while still protecting workers.

Under the proposed exception, the employer's obligation to implement engineering and work practice controls to comply with the PEL would not be triggered until an employee in a process or task is exposed above the PEL on 30 or more working days during a year. Where the exposure is for fewer than 30 working days, the employer could use any combination of controls to prevent employees from being exposed above the PEL, including respirators alone. The employer may use this exception if he or she has a reasonable basis for believing that employees in a process or task will not be exposed above the PEL for 30 or more days per year (12 consecutive months). OSHA intends for this exception to be process- or task-based, *i.e.*, it is specific to a process where engineering controls might be implemented to reduce exposures below the PEL. For example, an employer might have two processes, A and B, where A involved an ongoing process in the facility with exposures above the PEL for more than 30 days and another process, B, only resulted in exposures above the PEL between 10 and 29 days. The fact that the employer had employees exposed above the PEL for more than 30 days in process A would not be used to determine that engineering and work practice controls had to be used for process B. OSHA intends this exception to be similarly applied by process or task in the construction and shipyard environments where employees may move from one work site to another.

OSHA has proposed this exception because the Agency realizes that in some industries (*e.g.*, color pigment manufacturing), exposure to Cr(VI) is typically infrequent (*i.e.*, fewer than 30 days, over 12 consecutive months). For example, certain Cr(VI) processes may occur only several days a year when production of a particular product is needed. Under such conditions of exposure, it may not be economically feasible or cost effective to invest the monies needed to install engineering controls or to institute work practices to control Cr(VI) to the PEL. Without such an exception, employers would be required to implement feasible engineering controls or work practice controls wherever employees are exposed to Cr(VI) above the PEL, even if they are only exposed on one or several days a year. OSHA believes that the expense of implementing engineering and work practice controls in such circumstances may not be justified. Consequently, incorporating an exception is a reasonable way to lessen the burden on employers while still protecting employees. OSHA's proposed exception for fewer than 30 working days per year is consistent with the standards for lead (29 CFR 1910.1025) and cadmium (29 CFR 1910.1027), both of which incorporate similar provisions.

In proposing this exception, OSHA intends to provide relief exclusively to employers whose employees are exposed to Cr(VI) only for short periods (in terms of days and weeks) and otherwise are not exposed to Cr(VI) above the PEL. Where the employee has other exposures above the PEL, the employer would be obligated to achieve the PEL by means of engineering and work practice controls. The Agency believes the proposed 30-working-day exclusion would make the standard more flexible in workplaces where exposure days are extremely limited.

In order for this exception to apply, the proposed standard states that the employer must have a "reasonable basis for believing that no employees in a

process or task will be exposed above the PEL for 30 or more days". Historical data, objective data, or exposure monitoring data may all provide a reasonable basis for believing that employees will not be exposed above the PEL for 30 or more days per year. Other information, such as production orders showing that processes involving Cr(VI) exposures are conducted on fewer than 30 days per year, may also serve as a reasonable basis for believing that employees will not be exposed above the PEL for 30 or more days per year.

In order to take advantage of the proposed exception, the employer would have the burden to demonstrate that his or her employees in a process or task will not be exposed above the PEL for more than 30 days per year. The burden of proof is placed on the employer because the employer has access to needed information about employee exposure levels and processes and tasks at the worksite. Where existing information is inadequate, the employer is also in the best position to develop the necessary information. The obligation to demonstrate that a reasonable basis exists for believing that employees in a process or task will not be exposed above the PEL for more than 30 days per year is the same for general industry, construction, and shipyard employers.

Paragraph (f)(2) of the proposed rule (paragraph (d)(2) of the construction and shipyard proposals) would prohibit the employer from using employee rotation as a means of compliance with the PEL. Worker rotation reduces the exposures to individual employees, but increases the number of employees exposed. Since OSHA has made a preliminary determination that Cr(VI) is carcinogenic, the Agency considers it inappropriate to place more workers at risk. Since no threshold has been established for the carcinogenic effects of Cr(VI), it is prudent to limit the number of workers exposed at any concentration. This provision does not, however, prohibit worker rotation when it is conducted for reasons other than compliance with the PEL. For example, an employer may rotate workers in order to provide cross-training on different tasks, or to allow workers to alternate physically demanding tasks with less strenuous activities. OSHA does not intend for this provision to be interpreted as a general prohibition on employee rotation where workers are exposed to Cr(VI). This proposed provision is consistent with other OSHA standards such as those for butadiene (29 CFR 1910.1051), methylene chloride (29 CFR 1910.1052), and cadmium (29 CFR 1910.1027).

(g) Respiratory Protection

When engineering controls and work practices cannot reduce employee exposure to Cr(VI) to within the PEL, OSHA proposes that the employer must protect employees' health through the use of respirators. Specifically, respirators would be required as supplementary protection to reduce employee exposure during the installation and implementation of engineering and work practice controls; during work operations where engineering and work practice controls are not feasible; when all feasible engineering and work practice controls have been implemented, but are not sufficient to reduce exposure to or below the PEL; during work operations where employees are exposed above the PEL for fewer than 30 days per year, and the employer has elected not to implement engineering and work practice controls to achieve the PEL; and during emergencies.

These limitations on the required use of respirators are generally consistent with other OSHA health standards, such as those for butadiene (29 CFR 1910.1051) and methylene chloride (29 CFR 1910.1052). They reflect the Agency's determination, discussed in the section on methods of compliance, that respirators are inherently less reliable than engineering and work practice controls. OSHA has therefore proposed to allow reliance on respirators only in certain designated situations.

In those circumstances where engineering and work practice controls cannot be used to achieve the PEL (*e.g.*, in emergencies, or during periods when equipment is being installed), or where engineering controls may not be reasonably necessary (*e.g.*, where employees are exposed above the PEL for fewer than 30 days per year), OSHA recognizes that respirators may be essential to reduce worker exposure, and provision is made for their use as primary controls. In other circumstances, where feasible work practices and engineering controls alone cannot reduce exposure levels to the PEL, respirators also may be used for supplemental protection. In these situations, the burden of proof is placed on the employer to demonstrate that engineering and work practice controls are not feasible.

OSHA anticipates that engineering and work practice controls will be in place by the effective dates specified in paragraph (n) of this proposal (paragraph (k) for construction and shipyards). The Agency realizes that in some cases employers may commence operations that involve employee Cr(VI) exposures after that date, may install new or modified equipment, or make other workplace changes that result in new or additional exposures to Cr(VI). In these cases, a reasonable amount of time may be needed before appropriate engineering controls can be installed and proper work practices implemented. When employee exposures exceed the PEL in these situations, employers are expected to provide respiratory protection to protect workers.

Respiratory protection is also required during work operations where engineering and work practice controls are not feasible. OSHA anticipates that there will be very few situations where no engineering and work practice controls are feasible to limit employee exposure to Cr(VI). In other cases, some engineering and work practice controls may be feasible, but these controls may not be capable of lowering employee exposures to or below the PEL. For example, tasks such as stainless steel welding or abrasive blasting may present certain difficulties when performed in confined spaces. In these cases, the employer would be required to provide respiratory protection. In any event, the employer must always install engineering controls and implement work practice controls when such controls are feasible to reduce exposures, even if these controls cannot reduce exposures below the PEL.

The requirement to provide respiratory protection when feasible engineering controls are not sufficient to reduce exposures to within the PEL would also apply in instances where effective engineering controls have been installed and are being maintained or repaired. In these situations, controls may not be effective while maintenance or repair is underway. Where exposures exceed the PEL, the employer would be required to provide respirators.

As discussed earlier with regard to methods of compliance, OSHA is proposing an exemption from the general requirement for use of engineering and work practice controls where employee exposures do not exceed the PEL on 30 or more days per year. Where this exception applies, the employer would then be required to provide respiratory protection to achieve the PEL. OSHA also believes that emergencies are situations where respirators must be used to protect employees. Since an emergency, by definition, involves or is likely to involve an uncontrolled release of Cr(VI), it is important to protect

employees from the significant exposures that may occur.

Whenever respirators are used to comply with the requirements of the standard, OSHA proposes that the employer implement a comprehensive respiratory protection program in accordance with the Agency's Respiratory Protection standard (29 CFR 1910.134). The respiratory protection program is designed to ensure that respirators are properly used in the workplace, and are effective in protecting workers. The program must include procedures for selecting respirators for use in the workplace; medical evaluation of employees required to use respirators; fit testing procedures for tight-fitting respirators; procedures for proper use of respirators in routine and reasonably foreseeable emergency situations; procedures and schedules for maintaining respirators; procedures to ensure adequate quality, quantity, and flow of breathing air for atmosphere-supplying respirators; training of employees in the proper use of respirators; and procedures for evaluating the effectiveness of the program. In addition, this provision will serve as a reminder to employers covered by the Cr(VI) rule that they must also comply with the Respiratory Protection standard when respirators are provided to employees.

OSHA has proposed to revise the Respiratory Protection standard to include assigned protection factors (68 FR 34036 (6/6/03)). The proposed revision includes a table which indicates the level of respiratory protection that a given respirator or class of respirators is expected to provide, and will apply to employers whose employees use respirators for protection against Cr(VI) when it becomes a final rule (68 FR 34036, 34115 (6/6/03)).

(h) Protective Work Clothing and Equipment

The proposed standard would require that the employer provide protective clothing and equipment at no cost to employees where a hazard is present or is likely to be present from skin or eye contact with Cr(VI). The employer would also be required to ensure that employees use the clothing and equipment provided. The intent of this provision is to prevent the adverse health effects associated with dermal exposure to Cr(VI) (described in Section VI.D of this preamble) and the potential for inhalation of Cr(VI) that may be deposited on employees' street clothing. The proposed requirements for protective clothing and equipment are similar to those in other OSHA health standards such as those for cadmium (29 CFR 1910.1027) and methylenedianiline (29 CFR 1910.1050), and are based upon widely accepted principles and conventional practices of industrial hygiene. The proposed requirements are also consistent with Section 6(b)(7) of the OSH Act which states that, where appropriate, standards shall prescribe suitable protective equipment to be used in connection with hazards.

OSHA has proposed a standard that will cover payment for personal protective equipment in all workplaces (64 FR 15401 (3/31/99)). The Agency is incorporating the record of that rulemaking into the Cr(VI) rulemaking and will give due consideration to all relevant comments.

Criteria for determining when a hazard is present or is likely to be present from skin or eye contact with Cr(VI) are not specified. When evaluating the potential for hazardous eye or skin contact with Cr(VI), OSHA anticipates that the employer will assess the workplace in a manner consistent with the current requirements of the Agency's standards for use of personal protective equipment in general industry (29 CFR 1910.132) and shipyards (29 CFR 1915.152). These standards require the employer to assess the workplace to determine if hazards (including hazards associated with eye and skin contact with chemicals) are present, or are likely to be present.

As described in the non-mandatory appendices providing guidance on hazard assessment for these standards (29 CFR 1910 Subpart I Appendix B; 29 CFR 1915 Subpart I Appendix A), the employer should "exercise common sense and appropriate expertise" in assessing hazards. The recommended approach involves a walk-through survey to identify sources of hazards to workers. Review of injury/accident data is also recommended. Information obtained during this process provides a basis for the evaluation of potential hazards.

Based on the results of this assessment, the employer must determine what clothing and equipment is necessary to protect employees from Cr(VI) hazards. The proposed requirement is performance-oriented, and is designed to allow the employer flexibility in selecting the clothing and equipment most suitable for his or her particular workplace. The type of protective clothing and equipment needed to protect employees from Cr(VI) hazards will depend on the potential for exposure and the conditions of use in the workplace. Examples of protective clothing and equipment include, but are not limited to gloves, aprons, coveralls, foot coverings, and goggles. Ordinary street clothing and work uniforms or other accessories that do not serve to protect workers from Cr(VI) hazards are not considered protective clothing and equipment under this proposed standard.

The employer must exercise reasonable judgment in selecting the appropriate clothing and equipment to protect employees from Cr(VI) hazards. This provision is consistent with OSHA's current standards for provision of personal protective equipment (*e.g.*, 29 CFR 1910.132, 29 CFR 1915.152, 29 CFR 1926.95). For example, a worker who is constructing a home foundation using wood treated with chromated copper arsenate, leather gloves may be all that is necessary to prevent hazardous Cr(VI) exposure. In other situations, such as when a worker is performing abrasive blasting on a structure covered with Cr(VI)-containing paint, more extensive measures such as coveralls, head coverings, and goggles may be needed. Where exposures to Cr(VI) are minute, no protective clothing or equipment may be necessary. Many, Cr(VI) compounds are acidic or alkaline (*e.g.*, chromic acid, portland cement), and these characteristics may also influence the choice of protective clothing and equipment. For example, a chrome plater may require an apron, gloves, and goggles to protect against possible splashes of chromic acid that could result in both Cr(VI) exposure and chemical burns.

OSHA has not proposed a threshold concentration of Cr(VI) for determining when a substance would be covered under the rule. In some OSHA standards an exemption from certain requirements based on percentage composition has been included. For example, the standard for formaldehyde requires that the employer prevent eye and skin contact with liquids containing one percent or more formaldehyde (29 CFR 1910.1048(h)(1)(i)). Contact with liquids containing less than one percent formaldehyde is exempt from this provision. Such exemptions have been included so that coverage would not be extended to trivial exposures that were not associated with adverse health effects.

A similar exemption has not been included in this proposed standard because adverse health effects have been shown to occur as a result of dermal contact to relatively low concentrations of Cr(VI). For example, exposures to portland cement have been associated with allergic contact dermatitis, even though Cr(VI) concentrations in the cement were reported to be below 10 µg/

g (i.e., 0.001%) (Ex. 35–326). OSHA is not aware of any evidence that would allow establishment of a threshold concentration of Cr(VI) below which adverse dermal effects would not occur.

Paragraph (h)(2) (paragraph (f)(2) of the proposals for construction and shipyards) contains proposed requirements for removal and storage of protective clothing and equipment. The employer must ensure that all protective clothing and equipment contaminated with Cr(VI) is removed at the completion of the work shift or at the completion of tasks involving Cr(VI) exposure. Where employees must change their clothes (i.e., take off their street clothes), removal of protective clothing and equipment must occur in change rooms provided in accordance with paragraph (i) of this section (paragraph (g) of the construction and shipyard proposals). This provision is intended to reduce Cr(VI) contamination of the workplace, and limit Cr(VI) exposures outside the workplace. Wearing contaminated clothing outside the work area could lengthen the duration of exposure, and could carry Cr(VI) from regulated areas to other areas of the workplace. In addition, contamination of personal clothing could result in Cr(VI) being carried to employees' cars and homes, increasing the worker's exposure as well as exposing other individuals to Cr(VI) hazards.

Contaminated protective clothing and equipment must be removed at the end of the work shift or at the completion of tasks involving Cr(VI) exposure, whichever comes first. This language is intended to convey that protective clothing contaminated with Cr(VI) must generally not be worn when tasks involving Cr(VI) exposure have been completed for the day. For example, if employees perform work tasks involving Cr(VI) exposure for the first two hours of a work shift, and then perform tasks that do not involve Cr(VI) exposure, they must remove their protective clothing after the exposure period to avoid the possibility of increasing the duration of exposure and contamination of the work area from Cr(VI) residues on the protective clothing. If, however, employees are performing tasks involving Cr(VI) exposure intermittently throughout the day, or if employees are exposed to other contaminants where their protective clothing and equipment is needed, this provision does not prevent them from wearing the clothing and equipment until the completion of their shift.

To limit exposures outside the workplace, OSHA proposes that the employer ensure that Cr(VI)-contaminated protective clothing and equipment be removed from the workplace only by those employees whose job it is to launder, clean, maintain, or dispose of such clothing or equipment. Furthermore, the proposed standard would require that clothing and equipment that is to be laundered, cleaned, maintained, or disposed of be placed in closed, impermeable containers. This provision is intended to assure that contamination of the change room is minimized and that employees who later handle these items are protected. Those cleaning the Cr(VI)-contaminated clothing and equipment will be further protected by the requirement that warning labels be placed on containers to inform them of the potential hazards of exposure to Cr(VI).

The proposed standard requires that the employer clean, launder, repair and replace protective clothing as needed to ensure that the effectiveness of the clothing and equipment is maintained. This provision is necessary to ensure that clothing and equipment continue to serve their intended purpose of protecting workers. This would also prevent unnecessary exposures outside the workplace from employees taking contaminated clothing and equipment home for cleaning.

In keeping with the performance-orientation of the proposed rule, OSHA does not specify how often clothing and equipment should be cleaned, repaired or replaced. The Agency believes that appropriate time intervals may vary widely based on the types of clothing and equipment used, Cr(VI) exposures, and other circumstances in the workplace. The obligation of the employer, as always, is to keep the clothing and equipment in the condition necessary to perform its protective functions.

Removal of Cr(VI) from protective clothing and equipment by blowing, shaking, or any other means which disperses Cr(VI) in the air would be prohibited. Such actions would result in unnecessary exposure to airborne Cr(VI) as well as possible dermal contact.

The proposal would require that the employer inform any person who launders or cleans protective clothing or equipment contaminated with Cr(VI) of the potentially harmful effects of exposure to Cr(VI), and the need to launder or clean contaminated clothing and equipment in a manner that effectively prevents skin or eye contact with Cr(VI) or the release of airborne Cr(VI) in excess of the PEL. This provision is intended to ensure that persons who clean or launder Cr(VI)-contaminated items are aware of the associated hazards, and can then take appropriate protective measures.

The proposed standard would require employers to provide protective clothing and equipment at no cost to employees. The Agency believes that the employer is generally in the best position to select and obtain the proper type of protective clothing and equipment. OSHA also believes that by providing and owning protective clothing and equipment, the employer will be in a better position to maintain control over the inventory of protective clothing and equipment, conduct periodic inspections, and, when necessary, repair or replace it to maintain its effectiveness. The protective clothing and equipment at issue is designed and intended for work use. As discussed above, employees must remove contaminated clothing and equipment at the end of the work shift or the completion of tasks involving Cr(VI) exposure, whichever comes first. Employees may not remove contaminated clothing and equipment from the worksite, except for the employees whose job it is to launder, clean, maintain, or dispose of such clothing or equipment. The employer is responsible for cleaning or disposing of the protective clothing and equipment and retains complete control over it. The Agency is seeking comment on the proposed provision, and has included this topic in the "Issues" section of this preamble.

(i) Hygiene Areas and Practices

The proposed standard would require employers to provide hygiene facilities and to assure employee compliance with basic hygiene practices that serve to minimize exposure to Cr(VI). The proposal includes requirements for change rooms and washing facilities, ensuring that Cr(VI) exposure in eating and drinking areas is minimized, and a prohibition on certain practices that may contribute to Cr(VI) exposure. OSHA believes that strict compliance with these provisions would substantially reduce employee exposure to Cr(VI).

Several of these provisions are presently required under other OSHA standards. For example, OSHA's current standard addressing sanitation in general industry (29 CFR 1910.141) requires that whenever employees are required by a particular standard to wear protective clothing because of the possibility of contamination with toxic materials, change rooms equipped with storage facilities for street clothes and separate storage facilities for protective clothing shall be provided. The sanitation standard also includes

provisions for washing facilities, and prohibits storage or consumption of food or beverages in any area exposed to a toxic material. Similar provisions are in place for construction (29 CFR 1926.51). The hygiene provisions of this paragraph are intended to augment the requirements established under other standards with additional provisions applicable specifically to Cr(VI) exposure.

In workplaces where employees must change their clothes to use protective clothing and equipment, OSHA believes it is essential to have change rooms with separate storage facilities for street and work clothing to prevent contamination of employees' street clothes. This provision will minimize employee exposure to Cr(VI) after the work shift ends, because it reduces the duration of time they may be exposed to contaminated work clothes. Potential exposure resulting from contamination of the homes or cars of employees is also avoided. Change rooms also provide employees with privacy while changing their clothes. OSHA intends the proposed requirement for change rooms to apply to all covered workplaces where employees must change their clothes (i.e., take off their street clothes) to use protective clothing and equipment. In those situations where removal of street clothes would not be necessary (*e.g.*, in a workplace where only gloves are used as protective clothing), change rooms would not be required.

Paragraph (i)(3) (paragraph (g)(3) of the proposals for construction and shipyards) contains proposed requirements for washing facilities. The employer is to provide readily accessible washing facilities capable of removing Cr(VI) from the skin and is to ensure that affected employees use these facilities when necessary. Also, the employer is to ensure that employees who have skin contact with Cr(VI) wash their hands and faces at the end of the work shift and prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics, or using the toilet.

Washing reduces exposure by diminishing the period of time that Cr(VI) is in contact with the skin. Although engineering and work practice controls and protective clothing and equipment are designed to prevent hazardous skin and eye contact from occurring, OSHA realizes that in some circumstances these exposures will occur. For example, a worker who wears gloves to protect against hand contact with Cr(VI) may inadvertently touch his face with the contaminated glove during the course of the day. The intent of this provision is to have employees wash in order to mitigate the adverse effects when skin and eye contact does occur. At a minimum, employees are to wash their hands and faces at the end of the shift because washing is needed to remove any residual Cr(VI) contamination. Likewise, washing prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics or using the toilet also protects against further Cr(VI) exposure.

OSHA has made a preliminary determination that washing facilities would be sufficient to allow employees to remove significant levels of Cr(VI) contamination that may occur under the proposed standard. A requirement for provision and use of showers has not been included in the proposal. Some other health standards, such as the standards for cadmium (29 CFR 1910.1027) and lead (29 CFR 1910.1025), have included requirements for showers. OSHA requests information and comment as to whether provisions for showers should be included in a final Cr(VI) standard, and has included this topic in the "Issues" section of this preamble.

To minimize the possibility of food contamination and to reduce the likelihood of additional exposure to Cr(VI) through inhalation or ingestion, OSHA believes it is imperative that employees have a clean place to eat. Where the employer chooses to allow employees to eat at the facility, the proposal would require the employer to ensure that eating and drinking areas and surfaces are maintained as free as practicable of Cr(VI). Employers would also be required to assure that employees do not enter eating or drinking areas wearing protective clothing, unless properly cleaned beforehand. This is to further minimize the possibility of contamination and reduce the likelihood of additional Cr(VI) exposure from contaminated food or beverages. Employers are given discretion to choose any method for removing surface Cr(VI) from clothing and equipment that does not disperse the dust into the air or onto the employee's body. For example, if a worker is wearing coveralls for protection against Cr(VI) exposure, thorough HEPA vacuuming of the coveralls could be performed prior to entry into a lunchroom.

The employer is not required to provide eating and drinking facilities to employees. Employees may consume food or beverages off the worksite. However, where the employer chooses to allow employees to consume food or beverages at a worksite where Cr(VI) is present, OSHA intends to ensure that employees are protected from Cr(VI) exposures in these areas.

Proposed paragraph (i)(5) (paragraph (g)(5) in the construction and shipyard proposals) specifies certain activities that would be prohibited. These activities would include eating, drinking, smoking, chewing tobacco or gum, or applying cosmetics in regulated areas, or in areas where skin or eye contact occurs. Products associated with these activities, such as food and beverages, could not be carried or stored in these areas. This provision is intended to protect employees from additional sources of exposure to Cr(VI). Because the construction and shipyard proposals do not include requirements for regulated areas, reference to regulated areas is omitted in the proposed regulatory text for these standards.

(j) Housekeeping

The proposed standard includes housekeeping provisions that would require the employer to maintain surfaces as free as practicable of Cr(VI), promptly clean Cr(VI) spills and leaks, use appropriate cleaning methods, and properly dispose of Cr(VI)-contaminated waste. These provisions are exceptionally important because they minimize additional sources of exposure that engineering controls generally are not designed to address. Good housekeeping is a cost effective way to control employee exposures by removing accumulated Cr(VI) that can become entrained by physical disturbances or air currents and carried into an employee's breathing zone, thereby increasing employee exposure. Contact with contaminated surfaces may also result in dermal exposure to Cr(VI). The proposed provisions are consistent with housekeeping requirements in other OSHA standards, such as those for cadmium (29 CFR 1910.1027) and lead (29 CFR 1910.1025).

Cr(VI) deposited on ledges, equipment, floors, and other surfaces should be removed as soon as practicable, to prevent it from becoming airborne and to minimize the likelihood that skin contact will occur. When Cr(VI) is released into the workplace as a result of a leak or spill, the proposal would require the employer to promptly clean up the spill. Measures for clean-up of liquids should provide for the rapid containment of the leak or spill to minimize potential exposures. Clean-up procedures for dusts must not disperse the dust into the workplace air. These work practices aid in minimizing the number of employees exposed, as well as the extent of any potential Cr(VI) exposure.

The proposed standard would require that, where possible, surfaces contaminated with Cr(VI) be cleaned by vacuuming or other methods that minimize the likelihood of Cr(VI) exposure. OSHA believes vacuuming to be the most reliable method of cleaning surfaces on which dust accumulates, but equally effective methods may be used. Shoveling, dry or wet sweeping, and brushing would be permitted only if the employer shows that vacuuming or other methods that are usually as efficient as vacuuming are not effective under the particular circumstances found in the workplace. The proposal would also require that vacuum cleaners be equipped with HEPA filters to prevent the dispersal of Cr(VI) into the workplace. The use of compressed air for cleaning would only be allowed when used in conjunction with a ventilation system designed to capture the dust cloud created by the compressed air. This provision is also intended to prevent the dispersal of Cr(VI) into the workplace.

Cleaning equipment is to be handled in a manner that minimizes the reentry of Cr(VI) into the workplace. For example, cleaning and maintenance of HEPA-filtered vacuum equipment should be done carefully to avoid exposures to Cr(VI). Filters need to be changed and the contents of bags disposed of properly to avoid unnecessary Cr(VI) exposures.

The proposal would also require that items contaminated with Cr(VI) and consigned for disposal be collected and disposed of in sealed impermeable bags or other closed impermeable containers. These containers would include warning labels to inform individuals who handle these items of the potential hazards. By alerting employers and employees who are involved in disposal to the potential hazards of Cr(VI) exposure, they will be better able to implement protective measures.

No housekeeping provision has been included in the proposals covering construction or shipyards. OSHA has made a preliminary determination that a specific housekeeping provision is not appropriate because of the difficulties of performing housekeeping related to Cr(VI) exposure in the construction and shipyard environments. For example, in shipyard and particularly in construction work environments the generally dusty nature of outdoor work settings is likely to make it difficult to distinguish Cr(VI)—contaminated dusts from other dirt and dusts commonly found at the work site. The same control measures that apply to general industry are likely to be more difficult to implement and burdensome in these environments.

This preliminary determination differs from OSHA's determination in the standards for lead in construction (29 CFR 1926.62) and cadmium in construction (29 CFR 1926.1127), where the Agency included housekeeping provisions. In these rulemakings, OSHA did not find housekeeping provisions to present the difficulties anticipated with Cr(VI). The Agency believes that Cr(VI)-contaminated dusts will not generally be as easily identified as lead- or cadmium-contaminated dusts. Welding, in particular, could result in deposition of minute quantities of Cr(VI) that would be difficult for a construction or shipyard employer to identify. OSHA seeks comment on this preliminary finding, and has included this topic in the "Issues" section of this preamble.

Construction and shipyard employers would still need to comply with the general housekeeping requirements found at 29 CFR 1926.25 (for construction) or 29 CFR 1915.91 (for shipyards). These standards include general provisions for keeping workplaces clear of debris, but do not contain the more specific requirements found in the proposed Cr(VI) standard for general industry (such as those addressing cleaning methods) that are designed to limit Cr(VI) contamination of the workplace.

(k) Medical Surveillance

OSHA proposes to require that each employer covered by this rule make medical surveillance available at no cost, and at a reasonable time and place, for all employees who are experiencing signs or symptoms of the adverse health effects associated with Cr(VI) exposure, or who are exposed in an emergency. In addition, general industry employers would be required to provide medical surveillance for all employees exposed to Cr(VI) at or above the PEL for 30 or more days a year. The required medical surveillance must be performed by or under the supervision of a physician or other licensed health care professional.

The purpose of medical surveillance for Cr(VI) is, where reasonably possible, to determine if an individual can be exposed to the Cr(VI) present in his or her workplace without experiencing adverse health effects; to identify Cr(VI)-related adverse health effects so that appropriate intervention measures can be taken; and to determine the employee's fitness to use personal protective equipment such as respirators. The proposal is consistent with Section 6(b)(7) of the OSH Act which requires that, where appropriate, medical surveillance programs be included in OSHA health standards to aid in determining whether the health of workers is adversely affected by exposure to toxic substances. Other OSHA health standards have also included medical surveillance requirements.

The proposed standard is intended to encourage participation by requiring that medical examinations be provided by the employer without cost to employees (also required by section 6(b)(7) of the Act), and at a reasonable time and place. If participation requires travel away from the worksite, the employer would be required to bear the cost. Employees would have to be paid for time spent taking medical examinations, including travel time. OSHA is proposing that medical surveillance be provided to employees in general industry exposed at or above the PEL for 30 or more days a year in order to focus on those workers at greatest risk. Employees exposed below the PEL, or exposed for only a few days in a year, will be at lower risk of developing Cr(VI)-related disease. OSHA believes that these cutoffs, based both on exposure level and on the number of days an employee is exposed to Cr(VI), are a reasonable and administratively convenient basis for providing medical surveillance benefits to Cr(VI)-exposed workers. In past health standards, OSHA has used 30 days above the action level for triggering medical surveillance. Because of the large reduction in the PEL down to 1 μg/m^3 OSHA believes that 30 days above the PEL may be more reasonable since exposures above the PEL are more likely to result in adverse health effects that might benefit from medical surveillance. OSHA is seeking comment on the appropriateness of this trigger for medical surveillance, and whether the Agency should consider a trigger at the action level or an alternative trigger.

OSHA has not included exposure above the PEL for 30 or more days per year as a trigger for medical surveillance in the construction or shipyard Cr(VI) proposals. As discussed earlier, OSHA has not proposed to require exposure monitoring for construction or shipyard employment because of the difficulties in conducting such monitoring in these work settings. While OSHA assumes that some monitoring will be conducted in order for employers to know when or if they are above the PEL, OSHA also assumes that certain employers will not conduct exposure monitoring and may choose to presume that certain work processes or practices are above the PEL or rely on historical or objective data to show exposure levels. However, if medical surveillance for individual

employees is triggered by exposures above the PEL for 30 days or more, these employers would be forced to do monitoring in order to determine which employees are exposed above the PEL for 30 days or more. This would have the effect of re-introducing an exposure monitoring burden that the Agency is attempting to relieve.

Some employees may exhibit signs and symptoms of the adverse health effects associated with Cr(VI) exposure even when not exposed above the PEL for 30 or more days per year. These employees could be especially sensitive, may have been unknowingly exposed, or may have been exposed to greater amounts than the exposure assessment suggests. OSHA has therefore proposed that employees who experience signs or symptoms of the adverse health effects associated with Cr(VI) exposure be subject to medical surveillance. Signs and symptoms that may warrant surveillance include dermatitis, chrome holes, and nasal septum ulcers or perforations. Thus, the proposal would protect all employees exposed to Cr(VI) in unusual circumstances even if they fall outside the criteria for routine medical surveillance.

Appropriate surveillance would be required to be made available for employees exposed in an emergency regardless of the airborne concentrations of Cr(VI) normally found in the workplace. Emergency situations involve uncontrolled releases of Cr(VI), and the significant exposures that occur in these situations justify a requirement for medical surveillance. The proposed requirement for medical examinations after exposure in an emergency is consistent with the provisions of several other OSHA health standards, including the standards for methylenedianiline (29 CFR 1910.1050), butadiene (29 CFR 1910.1051), and methylene chloride (29 CFR 1910.1052).

OSHA has made a preliminary determination not to include eye or skin contact as a basis for medical surveillance. OSHA believes that compliance with the proposed provisions for protective work clothing and equipment, hygiene areas and practices, and other protective measures will minimize the potential for adverse eye and skin effects. When such health effects occur, OSHA believes that trained employees will be able to detect these conditions, report them to their employer, and obtain medical assistance. In such situations, affected employees would be provided medical surveillance on the basis that they are experiencing signs or symptoms of Cr(VI)-related health effects.

OSHA has proposed that the medical examinations provided under the rule be performed by or under the supervision of a physician or other licensed health care professional (PLHCP). The Agency considers it appropriate to allow any professional to perform medical examinations and procedures provided under the standard when they are licensed by state law to do so. This provision provides flexibility to the employer, and would reduce cost and compliance burdens. The proposed requirement is consistent with the approach of other recent OSHA standards, such as those for methylene chloride (29 CFR 1910.1052), bloodborne pathogens (29 CFR 1910.1030), and respiratory protection (29 CFR 1910.134).

The proposed standard also specifies how frequently medical examinations are to be offered to those employees covered by the medical surveillance program. Employers would be required to provide all covered employees with medical examinations whenever an employee shows signs or symptoms of Cr(VI) exposure; within 30 days after an emergency resulting in an uncontrolled release of Cr(VI); and within 30 days after a PLHCP's written medical opinion recommends an additional examination. In addition, employers in general industry would be required to provide covered employees with examinations within 30 days after initial assignment unless the employee has received a medical examination provided in accordance with the standard within the past 12 months; annually; and at the termination of employment, unless an examination has been given less than six months prior to the date of termination.

Signs or symptoms may indicate that adverse health effects attributable to Cr(VI) exposure are occurring. In such situations OSHA believes it would be appropriate to evaluate the employee's condition to determine if exposure to Cr(VI) is the cause of the condition, and to determine if protective measures are necessary. Emergency situations may involve high or unknown exposures, and OSHA believes that a medical examination is necessary to evaluate the possible adverse effects of these exposures.

In addition to medical evaluations after exposures in an emergency or when signs or symptoms occur, OSHA is proposing that additional examinations be offered following a PLHCP's recommendation that additional exams are necessary. A PLHCP may recommend additional evaluations in order to follow developments in a worker's condition, or to allow for specialized evaluation. For example, if nasal ulceration is identified in a Cr(VI)-exposed worker, a PLHCP may recommend follow-up examinations to ensure that treatment and workplace interventions are successful in addressing the condition, or a worker who exhibits dermatitis may be referred to a dermatologist for testing to determine if they are sensitized to Cr(VI).

The proposed requirement for general industry that a medical examination be offered at the time of initial assignment is intended to achieve the objective of determining if an individual will be able to work in the job involving Cr(VI) exposure without adverse effects. It also serves the useful function of establishing a health baseline for future reference. Where an examination that complies with the requirements of the standard has been provided in the past 12 months, that previous examination would serve these purposes, and an additional examination would not be needed.

OSHA believes that the provision of medical surveillance on an annual basis in general industry is an appropriate frequency for screening employees for Cr(VI)-related diseases. The main goal of periodic medical surveillance for workers is to detect adverse health effects at an early and potentially reversible stage. The proposed requirement for annual examinations is consistent with other OSHA health standards, including those for cadmium (29 CFR 1910.1027), formaldehyde (29 CFR 1910.1048), and methylene chloride (29 CFR 1910.1052). Based on the Agency's experience, OSHA believes that annual surveillance would strike a reasonable balance between the need to diagnose health effects at an early stage, and the limited number of cases likely to be identified through surveillance. The proposed requirement for general industry that the employer offer a medical examination at the termination of employment is intended to assure that no employee terminates employment while carrying an active, but undiagnosed, disease.

The examination to be provided by the PLHCP is to consist of a medical and work history; a physical examination of the skin and respiratory tract; and any additional tests considered appropriate by the PLHCP. Special emphasis is placed on the portions of the medical and work history focusing on Cr(VI) exposure, health effects associated with Cr(VI) exposure, and smoking. The physical exam focuses on organs and systems known to be susceptible to Cr(VI) toxicity. The information obtained will allow the PLHCP to assess

the employee's health status, identify adverse health effects related to Cr(VI) exposures, and determine if limitations should be placed on the employee's exposure to Cr(VI).

The proposal does not indicate specific tests that must be included in the medical examination. OSHA does not believe that any particular tests are generally applicable to all employees covered by the medical surveillance requirements, and the Agency proposes to give the examining PLHCP the flexibility to determine any appropriate tests to be selected for a given employee. For example, tests for dermal sensitization exist, but they are not recommended as a screening tool because they are capable of sensitizing persons who had not been affected previously. These tests should be considered by the PLHCP if a medical history indicating probable sensitization exists or if the employee experiences signs or symptoms indicative of sensitization. Radiological examinations and pulmonary function tests may also be useful in evaluating possible effects of Cr(VI). OSHA believes that the PLHCP is in the best position to decide which medical tests are necessary for each individual examined. Where specific tests are deemed appropriate by the PLHCP, the proposed standard would require that they be provided.

OSHA is aware that certain methods are available for evaluating Cr(VI) exposures based on analysis of chromium in urine or blood. However, the Agency is not aware of evidence indicating that these methods adequately characterize Cr(VI) exposures in most occupational environments. OSHA has also found no medical justification for routine urine or blood analysis for the detection of Cr(VI)-related health effects. Therefore, no requirement for such analysis is proposed.

The proposed standard would require the employer to ensure the PLHCP has a copy of the standard, and to provide the following information: a description of the affected employee's former and current duties as they relate to Cr(VI) exposure; the employee's former, current, and anticipated exposure level; a description of any personal protective equipment used or to be used by the employee, including when and for how long the employee has used that equipment; and information from records of employment-related medical examinations previously provided to the affected employee, currently within the control of the employer. Making this information available to the PLHCP will aid in the evaluation of the employee's health in relation to assigned duties and fitness to use personal protective equipment, when necessary.

The results of exposure monitoring are part of the information that would be supplied to the PLHCP responsible for medical surveillance. These results contribute valuable information to assist the PLHCP in determining if an employee is likely to be at risk of harmful effects from Cr(VI) exposure. A well-documented exposure history would also assist the PLHCP in determining if a condition (*e.g.*, dermatitis) may be related to Cr(VI) exposure.

The proposed rule would require employers to obtain from the examining PLHCP a written opinion containing the results of the medical examination with regard to Cr(VI) exposure, the PLHCP's opinion as to whether the employee would be placed at increased risk of material health impairment as a result of exposure to Cr(VI), and any recommended limitations on the employee's exposure or use of personal protective equipment. The PLHCP would also need to state in the written opinion that these findings were explained to the employee. The purpose of requiring the PLHCP to supply a written opinion to the employer is to provide the employer with a medical basis to aid in the determination of placement of employees and to assess the employee's ability to use protective clothing and equipment. The employer must obtain the written opinion within 30 days of the examination; OSHA believes this will provide the PLHCP sufficient time to receive and consider the results of any tests included in the examination, and allow the employer to take any necessary protective measures in a timely manner. The proposed requirement that the opinion be in written form is intended to ensure that employers and employees have the benefit of this information.

The PLHCP would not be allowed to include findings or diagnoses which are unrelated to Cr(VI) exposure in the written opinion provided to the employer. OSHA has proposed this provision to reassure employees participating in medical surveillance that they will not be penalized or embarrassed by the employer's obtaining information about them not directly pertinent to Cr(VI) exposure. The employee would be informed directly by the PLHCP of all results of his or her medical examination, including conditions of non-occupational origin. The employer would also be required to provide a copy of the PLHCP's written opinion to the employee within two weeks after receiving it, to ensure that the employee has been informed of the result of the examination in a timely manner.

In some OSHA health standards, a provision for medical removal protection (MRP) has been included. MRP typically requires that the employer temporarily remove an employee from exposure when such an action is recommended in a written medical opinion. During the time of removal, the employer is required to maintain the total normal earnings, as well as all other employee rights and benefits. However, MRP is not intended to serve as a worker's compensation system. The primary reason MRP has been included in these previous standards has been to encourage employee participation in medical surveillance. By protecting employees who are removed on a temporary basis from economic loss, this potential disincentive to participating in medical surveillance is alleviated.

The proposed rule does not include a provision for MRP, because OSHA has made a preliminary determination that MRP is not reasonably necessary or appropriate for Cr(VI)-related health effects. The Agency believes that Cr(VI)-related health effects generally fall into one of two categories: Either they are chronic conditions that temporary removal from exposure will not remedy (*e.g.*, lung cancer, respiratory or dermal sensitization), or they are conditions that can be addressed through proper application of control measures and do not require removal from exposure (*e.g.*, irritant dermatitis). Since situations where temporary removal would be appropriate are not anticipated to occur, OSHA does not believe that MRP is necessary. The Agency seeks comment on this preliminary determination, and has included this topic in the "Issues" section of this preamble.

(1) Communication of Hazards to Employees

The proposed standard includes requirements intended to ensure that the dangers of Cr(VI) exposure are communicated to employees by means of signs, labels, and employee information and training. These proposed requirements would parallel the existing requirements of OSHA's Hazard Communication standard (29 CFR 1910.1200). The hazard communication requirements of the proposed rule are designed to be substantively as consistent as possible with the Hazard Communication standard, while including additional specific requirements needed to protect employees exposed to Cr(VI).

The proposed standard would require that all approaches to regulated areas be

posted with legible and readily visible warning signs stating: Danger; Chromium (VI); Cancer Hazard; Can Damage Skin, Eyes, Nasal Passages, and Lungs; Authorized Personnel Only; Respirators Required in this Area. Such warning signs would be required wherever a regulated area exists, that is, wherever the PEL is exceeded in general industry. Because the construction and shipyard proposals do not include requirements for regulated areas, no provision is included for warning signs in the proposed regulatory text for the construction and shipyard standards.

The signs are intended to serve as a warning to employees who otherwise may not be aware that they are entering a regulated area, and to remind employees of the hazards of Cr(VI) so that they take necessary protective steps before entering the area. These signs are intended to supplement the training that employees receive regarding the hazards of Cr(VI), since even trained employees need to be reminded of the locations of regulated areas and of the precautions necessary before entering these dangerous areas.

In some instances, regulated areas are permanent, because the employer is unable to reduce Cr(VI) exposures in that area below the PEL with engineering controls. In those cases, the signs serve to warn employees not to enter the area unless they are authorized and are wearing respirators. In other cases, such as emergency situations and maintenance operations, regulated areas may be established temporarily. The use of warning signs is particularly important in these situations to make employees who are regularly scheduled to work at these sites aware of the hazards. Access is limited to authorized personnel to ensure that those entering the area are adequately trained and equipped, and to limit exposure to only those whose presence is absolutely necessary.

The proposed standard specifies the wording of the warning signs for regulated areas in order to ensure that the proper warning is given to employees. OSHA believes that the use of the word "Danger" is appropriate, based on the evidence of the toxicity and carcinogenicity of Cr(VI). "Danger" is used to attract the attention of workers in order to alert them to the fact that they are entering an area where the PEL may be exceeded and to emphasize the importance of the message that follows. The use of the word "Danger" is also consistent with other OSHA health standards dealing with carcinogens such as cadmium (29 CFR 1910.1027), methylenedianiline (29 CFR 1910.1050), asbestos (29 CFR 1910.1001), and benzene (29 CFR 1910.1028).

The proposed standard would also require that the sign indicate that respirators are required in the area. Regulated areas are areas demarcated by the employer where the employee's exposure to airborne concentrations of chromium (VI) exceeds, or can reasonably be expected to exceed the PEL (definition of a regulated area). The employer has made the determination that such areas are regulated on the basis of his/her own exposure assessments of the employees in the area. Since the employer has determined that such areas are not able to be reduced below the PEL, respirators are required as a means of control to protect the employees in those areas. The sign also serves as a means to warn other employees not in the regulated area not to enter, or if those other employees enter the area, they need to protect themselves in situations where excessive exposures can occur.

The proposal would require that warning labels be affixed to all bags or containers of contaminated clothing and equipment that are to be removed from the workplace for laundering, cleaning, or maintenance. Containers of waste, scrap, debris, and any other materials contaminated with Cr(VI) that are consigned for disposal would also need to be labeled. The labels must state: Danger; Contains Chromium (VI); Cancer Hazard; Can Damage Skin, Eyes, Nasal Passages, and Lungs. The purpose of this requirement is to ensure that all affected employees, not only those of a particular employer, are apprised of the hazardous nature of Cr(VI) exposure. These proposed requirements are consistent with the mandate of Section (6)(b)(7) of the OSH Act, which requires that OSHA health standards prescribe the use of labels or other appropriate forms of warning to apprise employees of the hazards to which they are exposed. Because the construction and shipyard proposals do not include disposal requirements, no provision is included in the construction and shipyard proposals for placing warning labels on containers of waste, scrap, debris, and other materials contaminated with Cr(VI).

Information and training is essential to inform employees of the hazards to which they are exposed and to provide employees with the necessary understanding of the degree to which they themselves can minimize potential health hazards. As part of an overall hazard communication program, training serves to explain and reinforce the information presented on labels and in material safety data sheets. These written forms of communication will be successful and relevant only when employees understand the information presented and are aware of the actions to be taken to avoid or minimize exposures, thereby reducing the possibility of experiencing adverse health effects.

OSHA proposes that employers provide training for all employees who are exposed to airborne Cr(VI) or who have skin or eye contact with Cr(VI), ensure that employees participate in the training, and maintain a record of the training provided. Training would be provided to all employees exposed to Cr(VI), and would not be limited to only those exposed above the PEL or action level. This proposed requirement is consistent with the Hazard Communication standard (29 CFR 1910.1200), which requires training for all employees exposed to hazardous chemicals and defines this to include potential (*e.g.*, accidental or possible) exposure. This training would allow employees to make efforts to avoid exposures altogether or mitigate those exposures that do occur.

The employer is to provide initial training prior to or at the time of initial assignment to a job involving potential exposure to Cr(VI). An employer who is able to demonstrate that a new employee has received training within the last 12 months is allowed to use that training for purposes of initial training required by the standard, provided the previous training has addressed the elements specified in the training provisions of the proposal, and the employee is able to demonstrate knowledge of those elements. In cases where understanding of some elements is lacking or inadequate, the employer would be required to provide training only in those elements. This allowance for prior training is intended to ensure that employees receive sufficient training, without requiring unnecessary repetition of that training.

The training requirements in this standard are performance-oriented. The proposed standard lists the subjects that must be addressed in training, but not the specific ways that this is to be accomplished. Hands-on training, videotapes, slide presentations, classroom instruction, informal discussions during safety meetings, written materials, or any combination of these methods may be appropriate. Such performance-oriented requirements are intended to encourage employers to tailor training to the needs of their workplaces, thereby resulting in the most effective training program in each specific workplace.

OSHA believes that the employer is in the best position to determine how the training can most effectively be accomplished. The Agency has therefore laid out the objectives to be met to ensure that employees are made aware of the hazards associated with Cr(VI) in their workplace and how they can help to protect themselves. The specifics regarding how this is to be achieved are left up to the employer.

In order for the training to be effective, the employer must ensure that it is provided in a manner that the employee is able to understand. Employees have varying educational levels, literacy, and language skills, and the training must be presented in a language and at a level of understanding that accounts for these differences in order to meet the proposed requirement that individuals being trained understand the specified elements. This may mean, for example, providing materials, instruction, or assistance in Spanish rather than English if the workers being trained are Spanish-speaking and do not understand English. The employer would not be required to provide training in the employee's preferred language if the employee understood both languages; as long as the employee is able to understand the language used, the intent of the proposed standard would be met.

In order to ensure that employees comprehend the material presented during training, it is critical that trainees have the opportunity to ask questions and receive answers if they do not fully understand the material that is presented to them. When videotape presentations or computer-based programs are used, this requirement may be met by having a qualified trainer available to address questions after the presentation, or providing a telephone hotline so that trainees will have direct access to a qualified trainer.

Under the proposal, the employer would be required to ensure that each employee can demonstrate knowledge of the specified elements. This could be determined through methods such as discussion of the required training subjects, written tests, or oral quizzes.

The frequency of training under the proposed standard would be determined by the needs of the workplace. Individuals would need to be trained sufficiently to understand the specified elements. Additional training is needed periodically to refresh and reinforce the memories of individuals who have previously been trained, and to ensure that these individuals are informed of new developments in the workplace that may result in new or additional exposures to Cr(VI). For example, training after new control measures are implemented would generally be necessary in order to ensure that employees are able to properly use the new controls that are introduced. Employees would likely be unfamiliar with new work practices undertaken, with the operation of new engineering controls, or the use of new personal protective equipment; training would rectify this lack of understanding. Additional training would ensure that employees are able to actively participate in protecting themselves under the conditions found in the workplace, even if those conditions change.

(m) Recordkeeping

The proposed standard for general industry would require employers to maintain exposure monitoring, medical surveillance, and training records. Because the proposed construction and shipyard standards do not include requirements for exposure monitoring, no provision for retention of exposure monitoring records is included in the proposed regulatory texts for construction and shipyards. However, the record retention requirements of OSHA's standard on access to medical and exposure records (29 CFR 1910.1020) apply to any exposure records that construction and shipyard employers produce.

The recordkeeping requirements are proposed in accordance with section 8(c) of the OSH Act, which authorizes OSHA to require employers to keep and make available records as necessary or appropriate for the enforcement of the Act or for developing information regarding the causes and prevention of occupational injuries and illnesses. The proposed recordkeeping provisions are also consistent with the OSHA's standard addressing access to employee exposure and medical records (29 CFR 1910.1020).

The proposal would require that records be kept of environmental monitoring results that identify the monitored employee and accurately reflect the employee's exposure. The employer would be required to keep records for each exposure measurement taken. Specifically, records must include the following information: The date of measurement for each sample taken; the operation involving exposure to Cr(VI) that was monitored; sampling and analytical methods used and evidence of their accuracy; the number, duration, and results of samples taken; the type of personal protective equipment used; and the name, social security number, and job classification of all employees represented by the monitoring, indicating which employees were actually monitored.

Most of OSHA's substance-specific standards require that exposure monitoring and medical surveillance records include the employee's social security number. OSHA has included this requirement in the past because social security numbers are particularly useful in identifying employees, since each number is unique to an individual for a lifetime and does not change when an employee changes employers. When employees have identical or similar names, identifying employees solely by name makes it difficult to determine to which employee a particular record pertains. However, based on privacy concerns, OSHA is examining alternatives to requiring social security numbers for employee identification. In its Standards Improvement Project proposal, the Agency requested public comment on the necessity, usefulness, and effectiveness of social security numbers as a means of identifying employee records, and any privacy concerns or issues raised by this requirement, as well as the availability of other effective methods of identifying employees for OSHA recordkeeping purposes (67 FR 66493 (19/31/02)). OSHA intends for the requirements of the Cr(VI) standard to conform with any final determination made through the Standards Improvement Project.

The proposal would allow the employer to rely on Cr(VI) monitoring results obtained in the past 12 months when the data were obtained during operations conducted under workplace conditions closely resembling the employer's current operations. Where historical monitoring data are used, the proposal would require that records of these data be maintained. The records of historical data must demonstrate that exposures on a particular job will be below the action level by showing that the work being performed, Cr(VI)-containing material being handled, and environmental conditions at the time the historical data were obtained are the same as those on the job for which monitoring was not performed. The records must also demonstrate that the data were obtained using a method sufficiently accurate to be allowed under the standard. Other data relevant to operations, materials, processing, or employee exposures must also be included in records.

A provision allowing the use of objective data in place of initial monitoring is included in this proposed standard. Objective data are information demonstrating that a particular product or material cannot release Cr(VI) in

concentrations at or above the action level under any expected conditions of use, even under conditions of worst-case release. Where objective data are used to satisfy initial monitoring requirements, the proposal would require employers to establish and maintain accurate records of the objective data relied upon. Since the use of objective data exempts the employer from requirements for conducting periodic monitoring and certain other provisions of the proposal due to the low level of potential exposure, it is critical that this determination be carefully documented. The record would be required to include identification of the Cr(VI)-containing material in question; the source of the objective data; the testing protocol and results of testing, or analysis of the material for the release of Cr(VI); a description of the operation exempted from initial monitoring and how the data support the exemption; and any other data relevant to the operations, materials, processing or employee exposures covered by the exemption.

Compliance with the requirement to maintain a record of objective data protects the employer at later dates from the contention that initial monitoring was not conducted in an appropriate manner. The record would also be available to employees so that they can examine the determination made by the employer. The employer would be required to maintain the record for the duration of the employer's reliance upon the objective data.

In addition to records relating to employee exposures to Cr(VI), the proposal would require the employer to establish and maintain an accurate medical surveillance record for each employee subject to the medical surveillance requirements of the standard. OSHA believes that medical records, like exposure records, are necessary and appropriate both to the enforcement of the standard and to the development of information regarding the causes and prevention of occupational illnesses. Good medical records, including the record of the examination at termination of employment itself, can be useful to the Agency and others in enumerating illnesses and deaths attributable to Cr(VI), in evaluating compliance programs, and in assessing the accuracy of the Agency's risk estimates. Furthermore, medical records are necessary for the proper evaluation of the employee's health.

The medical surveillance records would be required to include the following information: The name, social security number, and job classification of the employee; a copy of the PLHCP's written opinions; and a copy of the information provided to the PLHCP. This information includes the employee's duties as they relate to Cr(VI) exposure, Cr(VI) exposure levels, and descriptions of personal protective equipment used by the employee.

The employer would be required under the proposal to maintain records of employees' Cr(VI)-related training. At the completion of training, the employer would be required to prepare a record that indicates the identity of the individuals trained and the date the training was completed. The record would need to be maintained for three years after the completion of training. In addition, the employer would need to provide materials relating to employee information and training to OSHA or NIOSH, if requested.

OSHA believes that a three year retention period for training records is reasonable. Since OSHA is not proposing specific intervals for periodic retraining, but is making retraining contingent upon the need to maintain employee understanding of safe use and handling of Cr(VI) and workplace changes which result in significant increases in employee exposures to Cr(VI), it is appropriate to have records of training to allow employers to determine when and how employees have been trained. The proposed requirement to provide training materials upon request is necessary to allow for evaluation of training programs, and is consistent with the other OSHA standards such as those for bloodborne pathogens (29 CFR 1910.1030) methylene chloride (29 CFR 1910.1052), butadiene (29 CFR 1910.1051), and methylenedianiline (29 CFR 1910.1050).

All medical and exposure records developed under the Cr(VI) rule would be made available to employees and their designated representatives in accordance with OSHA's standard on access to records (29 CFR 1910.1020). The medical and exposure records standard requires that exposure records be kept for at least 30 years and that medical records be kept for the duration of employment plus thirty years. It is necessary to keep these records for extended periods because of the long latency period commonly associated with cancer. Cancer often cannot be detected until 20 or more years after first exposure. The extended record retention period is therefore needed because diagnosis of disease in employees is assisted by, and in some cases can only be made by, having present and past exposure data as well as the results of present and past medical examinations.

(n) Dates

OSHA proposes that the final Cr(VI) rule become effective 60 days after its publication in the **Federal Register**. This period is intended to allow affected employers the opportunity to familiarize themselves with the standard. Employer obligations to comply with most requirements of the final rule would begin 90 days after the effective date (150 days after publication of the final rule). This is designed to allow employers sufficient time to complete initial exposure assessments, establish regulated areas, obtain appropriate work clothing and equipment, and comply with other provisions of the rule.

Additional time would be allowed for the employer to establish change rooms and to implement engineering controls. Change rooms would be required no later than one year after the effective date of the standard, and engineering controls would need to be in place within two years after the effective date. This is to allow affected employers sufficient time to design and construct change rooms (where necessary), and to design, obtain, and install the necessary control equipment. OSHA solicits comment on the adequacy of these proposed start-up dates. In particular, the Agency is aware that in some cases employers may be required to reevaluate modified ventilation systems for compliance with regulations governing discharges of Cr(VI) to the environment. OSHA would like to ensure that employers are provided sufficient time to complete this process, and has included this topic in the "Issues" section of this preamble.

XVIII. Authority and Signature

This document was prepared under the direction of John L. Henshaw, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

The Agency issues the proposed sections under the following authorities: Sections 4, 6(b), 8(c), and 8(g) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); section 107 of the Contract Work Hours and Safety Standards Act (the Construction Safety Act) (40 U.S.C. 333); section 41, the Longshore and Harbor Worker's Compensation Act (33 U.S.C. 941); Secretary of Labor's Order No. 5–2002 (67 FR 65008); and 29 CFR Part 1911.

List of Subjects in 29 CFR Parts 1910, 1915, 1917, 1918, and 1926

Cancer, Chemicals, Hazardous substances, Health, Occupational safety and health, Reporting and recordkeeping requirements.

Signed at Washington, DC, this 21st day of September, 2004.

John L. Henshaw,

Assistant Secretary of Labor.

XIX. Proposed Standards

Chapter XVII of Title 29 of the Code of Federal Regulation is proposed to be amended as follows:

PART 1910—[AMENDED]

Subpart Z—[Amended]

1. The authority citation for Subpart Z of Part 1910 is revised to read as follows:

Authority: Secs. 4, 6, 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 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), 3–2000 (65 FR 50017), or 5–2002 (67 FR 65008), as applicable; and 29 CFR part 1911.

All of subpart Z issued under section 6(b) of the Occupational Safety and Health Act, —except those substances that have exposure limits listed in Tables Z–1, Z–2, and Z–3 of 29 CFR 1910.1000. The latter were issued under Sec. 6(a) (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, Section 1910.1000 Tables Z–1, Z–2, and Z–3 not issued under 29 CFR part 1911 except for the arsenic (organic compounds), benzene, and cotton dust listings.

Section 1910.1001 also issued under Sec. 107 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 3704) 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 and 1910.1200 also issued under 29 U.S.C. 653.

Section 1910.1030 also issued under Pub. L. 106–430, 114 Stat. 1901.

§ 1910.1000 [Amended]

2. In § 1910.1000, Table Z–2, the entry for Chromic acid and chromates 1.0 mg/10 m^3 is removed and the following entry added in its place:

§ 1910.1000 Air contaminants.

* * * * *

TABLE Z–2

Substance	8-hour time weighted average	Acceptable ceiling concentration	Acceptable maximum peak above the acceptable ceiling average concentration for an 8-hr shift	
			Concentration	Maximum duration
* * * * * * *				
Chromium (VI) compounds (as Cr); see 1910.1026.				
* * * * * * *				

* * * * *

3. A new § 1910.1026 is added to read as follows:

§ 1910.1026 Chromium (VI).

(a) *Scope.* This standard applies to occupational exposures to chromium (VI) in all forms and compounds in general industry, except exposures that occur in the application of pesticides (*e.g.*, the treatment of wood with preservatives).

(b) *Definitions.* For the purposes of this section the following definitions apply:

Action level means a concentration of airborne chromium (VI) of 0.5 microgram per cubic meter of air (0.5 µg/m^3) calculated as an 8-hour time-weighted average (TWA).

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

Chromium (VI) [hexavalent chromium or Cr(VI)] means chromium with a valence of positive six, in any form and in any compound.

Director means the Director of the National Institute for Occupational Safety and Health (NIOSH), U.S. Department of Health and Human Services, or designee.

Emergency means any occurrence that results, or is likely to result, in an uncontrolled release of chromium (VI). If an incidental release of chromium (VI) can be controlled at the time of release by employees in the immediate release area, or by maintenance personnel, it is not an emergency.

Employee exposure means the exposure to airborne chromium (VI) that would occur if the employee were not using a respirator.

High-efficiency particulate air [HEPA] filter means a filter that is at least 99.97 percent efficient in removing mono-dispersed particles of 0.3 micrometers in diameter or larger.

Physician or other licensed health care professional [PLHCP] is an individual whose legally permitted scope of practice (i.e., license, registration, or certification) allows him or her to independently provide or be delegated the responsibility to provide some or all of the particular health care services required by paragraph (k) of this section.

Regulated area means an area, demarcated by the employer, where an employee's exposure to airborne concentrations of chromium (VI) exceeds, or can reasonably be expected to exceed, the PEL.

This section means this chromium (VI) standard.

(c) *Permissible exposure limit (PEL).* The employer shall ensure that no employee is exposed to an airborne concentration of chromium (VI) in excess of 1 microgram per cubic meter of air (1 µg/m^3), calculated as an 8-hour time-weighted average (TWA).

(d) *Exposure assessment.* (1) *General.* The employer shall determine the 8-hour TWA exposure for each employee on the basis of a sufficient number of personal breathing zone air samples to accurately characterize full shift exposure on each shift, for each job classification, in each work area. Where an employer does representative sampling instead of sampling all employees in order to meet this requirement, the employer shall sample the employee(s) expected to have the highest chromium (VI) exposures.

(2) *Initial exposure monitoring.* (i) Except as provided for in paragraphs (d)(2)(ii) and (d)(2)(iii) of this section, each employer who has a workplace or work operation covered by this section shall determine if any employee may be

exposed to chromium (VI) at or above the action level.

(ii) Where the employer has monitored for chromium (VI) in the past 12 months, and the data were obtained during work operations conducted under workplace conditions closely resembling the processes, types of material, control methods, work practices, and environmental conditions used and prevailing in the employer's current operations, and where that monitoring satisfies all other requirements of this section, including the accuracy and confidence levels of paragraph (d)(6) of this section, the employer may rely on such earlier monitoring results to satisfy the requirements for initial monitoring.

(iii) Where the employer has objective data demonstrating that a material containing chromium (VI) or a specific process, operation, or activity involving chromium (VI) cannot release dust, fumes, or mist of chromium (VI) in concentrations at or above the action level under any expected conditions of use, the employer may rely upon such data to satisfy initial monitoring requirements. The data must reflect workplace conditions closely resembling the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations.

(3) *Periodic monitoring.* (i) If initial monitoring or periodic monitoring indicates that employee exposures are below the action level, the employer may discontinue monitoring for those employees whose exposures are represented by such monitoring.

(ii) If initial monitoring or periodic monitoring reveals employee exposures to be at or above the action level, the employer shall perform periodic monitoring at least every six months.

(iii) If initial monitoring reveals employee exposures to be at or above the PEL, the employer shall perform periodic monitoring at least every three months.

(iv) If periodic monitoring indicates that employee exposures are below the action level, and the result is confirmed by the result of another monitoring taken at least seven days later, the employer may discontinue the monitoring for those employees whose exposures are represented by such monitoring.

(4) *Additional monitoring.* The employer shall perform additional monitoring when there has been any change in the production process, raw materials, equipment, personnel, work practices, or control methods that may result in new or additional exposures to chromium (VI), or when the employer has any reason to believe that new or additional exposures have occurred.

(5) *Employee notification of monitoring results.* (i) Within 15 working days after the receipt of the results of any monitoring performed under this section, the employer shall either notify each affected employee individually in writing of the results or shall post the results of the exposure monitoring in an appropriate location that is accessible to all affected employees.

(ii) Whenever monitoring results indicate that employee exposure is above the PEL, the employer shall describe in the written notification the corrective action being taken to reduce employee exposure to or below the PEL.

(6) *Accuracy of measurement.* The employer shall use a method of monitoring and analysis that can measure chromium (VI) to within an accuracy of plus or minus 25 percent (+/− 25%) and can produce accurate measurements to within a statistical confidence level of 95 percent for airborne concentrations at or above the action level.

(7) *Observation of monitoring.* (i) The employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to chromium (VI).

(ii) When observation of monitoring requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide the observer with clothing and equipment and shall assure that the observer uses such clothing and equipment and complies with all other applicable safety and health procedures.

(e) *Regulated areas.* (1) *Establishment.* The employer shall establish a regulated area wherever an employee's exposure to airborne concentrations of chromium (VI) is, or can reasonably be expected to be, in excess of the PEL.

(2) *Demarcation.* The employer shall ensure that regulated areas are demarcated from the rest of the workplace in a manner that adequately establishes and alerts employees of the boundaries of the regulated area, and shall include the warning signs required under paragraph (l)(2) of this section.

(3) *Access.* The employer shall limit access to regulated areas to:

(i) Persons authorized by the employer and required by work duties to be present in the regulated area;

(ii) Any person entering such an area as a designated representative of employees for the purpose of exercising the right to observe monitoring procedures under paragraph (d) of this section; or

(iii) Any person authorized by the Occupational Safety and Health Act or regulations issued under it to be in a regulated area.

(f) *Methods of compliance.* (1) *Engineering and work practice controls.* (i) Except as permitted in paragraph (f)(1)(ii) of this section, the employer shall use engineering and work practice controls to reduce and maintain employee exposure to chromium (VI) to or below the PEL unless the employer can demonstrate that such controls are not feasible. Wherever feasible engineering and work practice controls are not sufficient to reduce employee exposure to or below the PEL, the employer shall use them to reduce employee exposure to the lowest levels achievable, and shall supplement them by the use of respiratory protection that complies with the requirements of paragraph (g) of this section.

(ii) Where the employer has a reasonable basis for believing that no employee in a process or task will be exposed above the PEL for 30 or more days per year (12 consecutive months), the requirement to implement engineering and work practice controls to achieve the PEL does not apply to that process or task.

(2) *Prohibition of rotation.* The employer shall not rotate employees to different jobs to achieve compliance with the PEL.

(g) *Respiratory protection.* (1) *General.* The employer shall provide respiratory protection for employees during:

(i) Periods necessary to install or implement feasible engineering and work practice controls;

(ii) Work operations, such as maintenance and repair activities, for which engineering and work practice controls are not feasible;

(iii) Work operations for which an employer has implemented all feasible engineering and work practice controls and such controls are not sufficient to reduce exposures to or below the PEL;

(iv) Work operations where employees are exposed above the PEL for fewer than 30 days per year, and the employer has elected not to implement engineering and work practice controls to achieve the PEL; or

(v) Emergencies.

(2) *Respiratory protection program.* Where respirator use is required by this section, the employer shall institute a respiratory protection program in accordance with 29 CFR 1910.134.

(h) *Protective work clothing and equipment.* (1) *Provision and use.* Where a hazard is present or is likely to be present from skin or eye contact with chromium (VI), the employer shall provide appropriate personal protective

clothing and equipment at no cost to employees, and shall ensure that employees use such clothing and equipment.

(2) *Removal and storage.* (i) The employer shall ensure that employees remove all protective clothing and equipment contaminated with chromium (VI) at the end of the work shift or at the completion of their tasks involving chromium (VI) exposure, whichever comes first.

(ii) The employer shall ensure that no employee removes chromium (VI)-contaminated protective clothing or equipment from the workplace, except for those employees whose job it is to launder, clean, maintain, or dispose of such clothing or equipment.

(iii) When contaminated protective clothing or equipment is removed for laundering, cleaning, maintenance, or disposal, the employer shall ensure that it is stored and transported in sealed, impermeable bags or other closed, impermeable containers.

(iv) Bags or containers of contaminated protective clothing or equipment that are removed from change rooms for laundering, cleaning, maintenance, or disposal shall be labeled in accordance with paragraph (l) of this section.

(3) *Cleaning and replacement.* (i) The employer shall clean, launder, repair and replace all protective clothing and equipment required by this section as needed to maintain its effectiveness.

(ii) The employer shall prohibit the removal of chromium (VI) from protective clothing and equipment by blowing, shaking, or any other means that disperses chromium (VI) into the air or onto an employee's body.

(iii) The employer shall inform any person who launders or cleans protective clothing or equipment contaminated with chromium (VI) of the potentially harmful effects of exposure to chromium (VI) and that the clothing and equipment should be laundered or cleaned in a manner that minimizes skin or eye contact with chromium (VI) and effectively prevents the release of airborne chromium (VI) in excess of the PEL.

(i) *Hygiene areas and practices.* (1) *General.* Where protective clothing and equipment is required, the employer shall provide change rooms in conformance with 29 CFR 1910.141. Where skin contact with chromium (VI) occurs, the employer shall provide washing facilities in conformance with 29 CFR 1910.141. Eating and drinking areas provided by the employer shall also be in conformance with § 1910.141.

(2) *Change rooms.* The employer shall assure that change rooms are equipped with separate storage facilities for protective clothing and equipment and for street clothes, and that these facilities prevent cross-contamination.

(3) *Washing facilities.* (i) The employer shall provide readily accessible washing facilities capable of removing chromium (VI) from the skin, and shall ensure that affected employees use these facilities when necessary.

(ii) The employer shall ensure that employees who have skin contact with chromium (VI) wash their hands and faces at the end of the work shift and prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics, or using the toilet.

(4) *Eating and drinking areas.* (i) Whenever the employer allows employees to consume food or beverages at a worksite where chromium (VI) is present, the employer shall ensure that eating and drinking areas and surfaces are maintained as free as practicable of chromium (VI).

(ii) The employer shall ensure that employees do not enter eating and drinking areas with protective work clothing or equipment unless surface chromium (VI) has been removed from the clothing and equipment by methods that do not disperse chromium (VI) into the air or onto an employee's body.

(5) *Prohibited activities.* The employer shall ensure that employees do not eat, drink, smoke, chew tobacco or gum, or apply cosmetics in regulated areas, or in areas where skin or eye contact with chromium (VI) occurs; or carry the products associated with these activities, or store such products in these areas.

(j) *Housekeeping.* (1) *General.* The employer shall ensure that:

(i) All surfaces are maintained as free as practicable of accumulations of chromium (VI).

(ii) All spills and releases of chromium (VI) containing material are cleaned up promptly.

(2) *Cleaning methods.* (i) The employer shall ensure that surfaces contaminated with chromium (VI) are cleaned by HEPA-filter vacuuming or other methods that minimize the likelihood of exposure to chromium (VI).

(ii) Shoveling, sweeping, and brushing may be used only where HEPA-filtered vacuuming or other methods that minimize the likelihood of exposure to chromium (VI) have been tried and found not to be effective.

(iii) The employer shall not allow compressed air to be used to remove chromium (VI) from any surface unless the compressed air is used in conjunction with a ventilation system designed to capture the dust cloud created by the compressed air.

(iv) The employer shall ensure that cleaning equipment is handled in a manner that minimizes the reentry of chromium (VI) into the workplace.

(3) *Disposal.* The employer shall ensure that:

(i) Waste, scrap, debris, and any other materials contaminated with chromium (VI) and consigned for disposal are collected and disposed of in sealed, impermeable bags or other closed, impermeable containers.

(ii) Bags or containers of waste, scrap, debris, and any other materials contaminated with chromium (VI) that are consigned for disposal are labeled in accordance with paragraph (l) of this section.

(k) *Medical surveillance.* (1) *General.* (i) The employer shall make medical surveillance available at no cost to the employee, and at a reasonable time and place, for all employees:

(A) Who are or may be occupationally exposed to chromium (VI) above the PEL for 30 or more days a year;

(B) Experiencing signs or symptoms of the adverse health effects associated with chromium (VI) exposure; or

(C) Exposed in an emergency.

(ii) The employer shall assure that all medical examinations and procedures required by this section are performed by or under the supervision of a PLHCP.

(2) *Frequency.* The employer shall provide a medical examination:

(i) Within 30 days after initial assignment, unless the employee has received a chromium (VI) related medical examination, provided in accordance with this standard, within the last twelve months;

(ii) Annually;

(iii) Within 30 days after a PLHCP's written medical opinion recommends an additional examination;

(iv) Whenever an employee shows signs or symptoms of the adverse health effects associated with chromium (VI) exposure;

(v) Within 30 days after exposure during an emergency which results in an uncontrolled release of chromium (VI); or

(vi) At the termination of employment, unless the last examination that satisfied the requirements of paragraph (k) of this section was less than six months prior to the date of termination.

(3) *Contents of examination.* A medical examination consists of:

(i) A medical and work history, with emphasis on: past, present, and anticipated future exposure to chromium (VI); any history of respiratory system dysfunction; any

history of asthma, dermatitis, skin ulceration, or nasal septum perforation; and smoking status and history;

(ii) A physical examination of the skin and respiratory tract; and

(iii) Any additional tests deemed appropriate by the examining PLHCP.

(4) *Information provided to the PLHCP.* The employer shall ensure that the examining PLHCP has a copy of this standard, and shall provide the following information:

(i) A description of the affected employee's former, current, and anticipated duties as they relate to the employee's occupational exposure to chromium (VI);

(ii) The employee's former, current, and anticipated levels of occupational exposure to chromium (VI);

(iii) A description of any personal protective equipment used or to be used by the employee, including when and for how long the employee has used that equipment; and

(iv) Information from records of employment-related medical examinations previously provided to the affected employee, currently within the control of the employer.

(5) *PLHCP's written medical opinion.* (i) The employer shall obtain a written medical opinion from the PLHCP, within 30 days for each medical examination performed on each employee, which contains:

(A) The PLHCP's opinion as to whether the employee has any detected medical condition(s) that would place the employee at increased risk of material impairment to health from further exposure to chromium (VI);

(B) Any recommended limitations upon the employee's exposure to chromium (VI) or upon the use of personal protective equipment such as respirators;

(C) A statement that the PLHCP has explained to the employee the results of the medical examination, including any medical conditions related to chromium (VI) exposure that require further evaluation or treatment, and any special provisions for use of protective clothing or equipment.

(ii) The PLHCP shall not reveal to the employer specific findings or diagnoses unrelated to occupational exposure to chromium (VI).

(iii) The employer shall provide a copy of the PLHCP's written medical opinion to the examined employee within two weeks after receiving it.

(l) *Communication of chromium (VI) hazards to employees.*

(1) *General.* In addition to the requirements of the Hazard Communication Standard, 29 CFR 1910.1200, for labels, material safety data sheets, and training, employers shall comply with the following requirements.

(2) *Warning signs.* (i) The employer shall ensure that legible and readily visible warning signs are displayed at all approaches to regulated areas so that an employee may read the signs and take necessary protective steps before entering the area.

(ii) Warning signs required by paragraph (l)(2)(i) of this section shall include at least the following information:

DANGER
CHROMIUM (VI)
CANCER HAZARD
CAN DAMAGE SKIN, EYES, NASAL PASSAGES, AND LUNGS
AUTHORIZED PERSONNEL ONLY
RESPIRATORS REQUIRED IN THIS AREA

(3) *Warning labels.* The employer shall ensure that bags or containers of contaminated clothing and equipment to be removed for laundering, cleaning, or maintenance, and containers of waste, scrap, debris, and any other materials contaminated with chromium (VI) that are consigned for disposal, bear appropriate warning labels that include at least the following information:

DANGER
CONTAINS CHROMIUM (VI)
CANCER HAZARD
CAN DAMAGE SKIN, EYES, NASAL PASSAGES, AND LUNGS

(4) *Employee information and training.* (i) For all employees who are exposed to airborne chromium (VI), or who have skin or eye contact with chromium (VI), the employer shall provide training, ensure employee participation in training, and maintain a record of training provided.

(ii) The employer shall provide initial training prior to or at the time of initial assignment to a job involving potential exposure to chromium (VI). An employer who is able to demonstrate that a new employee has received training within the last 12 months that addresses the elements specified in paragraph (l)(4)(iii) of this section is not required to repeat such training provided that the employee can demonstrate knowledge of those elements.

(iii) The employer shall provide training that is understandable to the employee and shall ensure that each employee can demonstrate knowledge of at least the following:

(A) The health hazards associated with chromium (VI) exposure;

(B) The location, manner of use, and release of chromium (VI) in the workplace and the specific nature of operations that could result in exposure to chromium (VI), especially exposure above the PEL;

(C) The engineering controls and work practices associated with the employee's job assignment;

(D) The purpose, proper selection, fitting, proper use, and limitations of respirators and protective clothing;

(E) Emergency procedures;

(F) Measures employees can take to protect themselves from exposure to chromium (VI), including modification of personal hygiene and habits such as smoking;

(G) The purpose and a description of the medical surveillance program required by paragraph (k) of this section;

(H) The contents of this section; and

(I) The employee's rights of access to records under 29 CFR 1910.1020(g).

(iv) The employer shall provide additional training when:

(A) Training is necessary to ensure that each employee maintains an understanding of the safe use and handling of chromium (VI) in the workplace.

(B) Workplace changes (such as modification of equipment, tasks, or procedures) result in an increase in employee exposures to chromium (VI), and those exposures exceed or can reasonably be expected to exceed the action level or result in a hazard from skin or eye contact with chromium (VI).

(v) The employer shall make a copy of this section and its appendices readily available without cost to all affected employees.

(m) *Recordkeeping.* (1) *Exposure measurements.* (i) The employer shall maintain an accurate record of all measurements taken to monitor employee exposure to chromium (VI) as prescribed in paragraph (d) of this section.

(ii) This record shall include at least the following information:

(A) The date of measurement for each sample taken;

(B) The operation involving exposure to chromium (VI) that is being monitored;

(C) Sampling and analytical methods used and evidence of their accuracy;

(D) Number, duration, and the results of samples taken;

(E) Type of personal protective equipment, such as respirators worn; and

(F) Name, social security number, and job classification of all employees represented by the monitoring, indicating which employees were actually monitored.

(iii) The employer shall ensure that exposure records are maintained and made available in accordance with 29 CFR 1910.1020.

(2) *Historical monitoring data.* (i) Where the employer has monitored for chromium (VI) in the past 12 months, and has relied on this historical monitoring data to demonstrate that exposures on a particular job will be below the action level, the employer shall establish and maintain an accurate record of the historical monitoring data relied upon.

(ii) The record shall include information that reflects the following conditions:

(A) The data were collected using methods that meet the accuracy requirements of paragraph (d)(6) of this section;

(B) The processes and work practices that were in use when the historical monitoring data were obtained are essentially the same as those to be used during the job for which initial monitoring will not be performed;

(C) The characteristics of the chromium (VI) containing material being handled when the historical monitoring data were obtained are the same as those on the job for which initial monitoring will not be performed;

(D) Environmental conditions prevailing when the historical monitoring data were obtained are the same as those on the job for which initial monitoring will not be performed; and

(E) Other data relevant to the operations, materials, processing, or employee exposures covered by the exception.

(iii) The employer shall ensure that historical exposure records are maintained and made available in accordance with 29 CFR 1910.1020.

(3) *Objective data.* (i) Where an employer uses objective data to satisfy initial monitoring requirements, the employer shall establish and maintain an accurate record of the objective data relied upon.

(ii) This record shall include at least the following information:

(A) The chromium (VI)-containing material in question;

(B) The source of the objective data;

(C) The testing protocol and results of testing, or analysis of the material for the release of chromium (VI);

(D) A description of the operation exempted from initial monitoring and how the data support the exemption; and

(E) Other data relevant to the operations, materials, processing or employee exposures covered by the exemption.

(iii) The employer shall maintain this record for the duration of the employer's reliance upon such objective data and shall make such records available in accordance with 29 CFR 1910.1020.

(4) *Medical surveillance.* (i) The employer shall establish and maintain an accurate record for each employee covered by medical surveillance under paragraph (k) of this section.

(ii) The record shall include the following information about the employee:

(A) Name and social security number;

(B) A copy of the PLHCP's written opinions;

(C) A copy of the information provided to the PLHCP as required by paragraph (k)(4) of this section.

(iii) The employer shall ensure that medical records are maintained and made available in accordance with 29 CFR 1910.1020.

(5) *Training.* (i) At the completion of training, the employer shall prepare a record that indicates the identity of the individuals trained and the date the training was completed. This record shall be maintained for three years after the completion of training.

(ii) The employer shall provide to the Assistant Secretary or the Director, upon request, all materials relating to employee information and training.

(n) *Dates.* (1) *Effective date.* This section shall become effective [60 days after publication of the final rule in the **Federal Register**].

(2) *Start-up dates.* All obligations of this section commence 90 days after the effective date except as follows:

(i) Change rooms required by paragraph (i) of this section shall be provided no later than one year after the effective date.

(ii) Engineering controls required by paragraph (f) of this section shall be implemented no later than two years after the effective date.

PART 1915—[AMENDED]

4. The authority citation for 29 CFR part 1915 is revised to read as follows:

Authority: Sec. 41, Longshore and Harbor Workers' Compensation Act (33 U.S.C. 941); secs. 4, 6, 8, Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 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), 3–2000 (65 FR 50017) or 5–2002 (67 FR 65008), as applicable.

Sections 1915.120, 1915.152 and 1915.1026 also issued under 29 CFR part 1911.

5. In § 1915.1000, Table Z, the entry for "Chromic acid and chromates (as CrO(3)) 0.1" is removed and the following entry added in its place:

§ 1915.1000 Air contaminants.

* * * * *

TABLE Z—SHIPYARDS

Substance	CAS No.[d]	ppm [a] *	mg/m [3] [b] *	Skin designation
*	*	*	*	*
Chromium (VI) compounds (as Cr); see 1915.1026.			
*	*	*	*	*

* * * * * * *

[3] Use Asbestos Limit § 1915.1001.

* * * * * * *

* The PELS are 8-hour TWAs unless otherwise noted; a (C) designation denotes a ceiling limit. They are to be determined from breathing-zone air samples.

[a] Parts of vapor or gas per million parts of contaminated air by volume at 25° C and 760 torr.

[b] Milligrams of substance per cubic meter of air. When entry is in this column only, the value is exact; when listed with a ppm entry, it is approximate.

* * * * * * *

[d] The CAS number is for information only. Enforcement is based on the substance name. For an entry covering more than one metal compound, measured as the metal, the CAS number for the metal is given—not CAS numbers for the individual compounds.

* * * * *

6. A new § 1915.1026 is added, to read as follows:

§ 1915.1026 Chromium (VI).

(a) *Scope.* This standard applies to occupational exposures to chromium (VI) in all forms and compounds in shipyards, marine terminals, and longshoring.

(b) *Definitions.* For the purposes of this section the following definitions apply:

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

Chromium (VI) [hexavalent chromium or Cr(VI)] means chromium with a valence of positive six, in any form and in any compound.

Director means the Director of the National Institute for Occupational Safety and Health (NIOSH), U.S. Department of Health and Human Services, or designee.

Emergency means any occurrence that results, or is likely to result, in an uncontrolled release of chromium (VI). If an incidental release of chromium (VI) can be controlled at the time of release by employees in the immediate release area, or by maintenance personnel, it is not an emergency.

Employee exposure means the exposure to airborne chromium (VI) that would occur if the employee were not using a respirator.

High-efficiency particulate air [HEPA] filter means a filter that is at least 99.97 percent efficient in removing mono-dispersed particles of 0.3 micrometers in diameter or larger.

Physician or other licensed health care professional [PLHCP] is an individual whose legally permitted scope of practice (i.e., license, registration, or certification) allows him or her to independently provide or be delegated the responsibility to provide some or all of the particular health care services required by paragraph (h) of this section.

This section means this chromium (VI) standard.

(c) *Permissible exposure limit (PEL).* The employer shall ensure that no employee is exposed to an airborne concentration of chromium (VI) in excess of 1 microgram per cubic meter of air (1 $\mu g/m^3$), calculated as an 8-hour time-weighted average (TWA).

(d) *Methods of compliance.* (1) *Engineering and work practice controls.* (i) Except as permitted in paragraph (d)(1)(ii) of this section, the employer shall use engineering and work practice controls to reduce and maintain employee exposure to chromium (VI) to or below the PEL unless the employer can demonstrate that such controls are not feasible. Wherever feasible engineering and work practice controls are not sufficient to reduce employee exposure to or below the PEL, the employer shall use them to reduce employee exposure to the lowest levels achievable, and shall supplement them by the use of respiratory protection that complies with the requirements of paragraph (e) of this section.

(ii) Where the employer has a reasonable basis for believing that no employee in a process or task will be exposed above the PEL for 30 or more days per year (12 consecutive months), the requirement to implement engineering and work practice controls to achieve the PEL does not apply to that process or task.

(2) *Prohibition of rotation.* The employer shall not rotate employees to different jobs to achieve compliance with the PEL.

(e) *Respiratory protection.* (1) *General.* The employer shall provide respiratory protection for employees during:

(i) Periods necessary to install or implement feasible engineering and work practice controls;

(ii) Work operations, such as maintenance and repair activities, for which engineering and work practice controls are not feasible;

(iii) Work operations for which an employer has implemented all feasible engineering and work practice controls and such controls are not sufficient to reduce exposures to or below the PEL;

(iv) Work operations where employees are exposed above the PEL for fewer than 30 days per year, and the employer has elected not to implement engineering and work practice controls to achieve the PEL; or

(v) Emergencies.

(2) *Respiratory protection program.* Where respirator use is required by this section, the employer shall institute a respiratory protection program in accordance with 29 CFR 1910.134.

(f) *Protective work clothing and equipment.* (1) *Provision and use.* Where a hazard is present or is likely to be present from skin or eye contact with chromium (VI), the employer shall provide appropriate personal protective clothing and equipment at no cost to employees, and shall ensure that employees use such clothing and equipment.

(2) *Removal and storage.* (i) The employer shall ensure that employees remove all protective clothing and equipment contaminated with chromium (VI) at the end of the work shift or at the completion of their tasks involving chromium (VI) exposure, whichever comes first.

(ii) The employer shall ensure that no employee removes chromium (VI)-contaminated protective clothing or equipment from the workplace, except for those employees whose job it is to launder, clean, maintain, or dispose of such clothing or equipment.

(iii) When contaminated protective clothing or equipment is removed for laundering, cleaning, maintenance, or disposal, the employer shall ensure that it is stored and transported in sealed, impermeable bags or other closed, impermeable containers.

(iv) Bags or containers of contaminated protective clothing or equipment that are removed from change rooms for laundering, cleaning, maintenance, or disposal shall be labeled in accordance with paragraph (i) of this section.

(3) *Cleaning and replacement.* (i) The employer shall clean, launder, repair and replace all protective clothing and equipment required by this section as needed to maintain its effectiveness.

(ii) The employer shall prohibit the removal of chromium (VI) from protective clothing and equipment by blowing, shaking, or any other means that disperses chromium (VI) into the air or onto an employee's body.

(iii) The employer shall inform any person who launders or cleans protective clothing or equipment contaminated with chromium (VI) of the potentially harmful effects of exposure to chromium (VI) and that the clothing and equipment should be laundered or cleaned in a manner that minimizes skin or eye contact with chromium (VI) and effectively prevents the release of airborne chromium (VI) in excess of the PEL.

(g) *Hygiene areas and practices.* (1) *General.* Where protective clothing and equipment is required, the employer shall provide change rooms in conformance with 29 CFR 1910.141. Where skin contact with chromium (VI) occurs, the employer shall provide washing facilities in conformance with 29 CFR 1915.97. Eating and drinking areas provided by the employer shall also be in conformance with § 1915.97.

(2) *Change rooms.* The employer shall assure that change rooms are equipped with separate storage facilities for protective clothing and equipment and for street clothes, and that these facilities prevent cross-contamination.

(3) *Washing facilities.* (i) The employer shall provide readily accessible washing facilities capable of removing chromium (VI) from the skin, and shall ensure that affected employees use these facilities when necessary.

(ii) The employer shall ensure that employees who have skin contact with chromium (VI) wash their hands and faces at the end of the work shift and prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics, or using the toilet.

(4) *Eating and drinking areas.* (i) Whenever the employer allows employees to consume food or beverages at a worksite where chromium (VI) is present, the employer shall ensure that eating and drinking areas and surfaces are maintained as free as practicable of chromium (VI).

(ii) The employer shall ensure that employees do not enter eating and drinking areas with protective work clothing or equipment unless surface chromium (VI) has been removed from the clothing and equipment by methods that do not disperse chromium (VI) into the air or onto an employee's body.

(5) *Prohibited activities.* The employer shall ensure that employees do not eat, drink, smoke, chew tobacco or gum, or apply cosmetics in areas where skin or eye contact with chromium (VI) occurs; or carry the products associated with these activities, or store such products in these areas.

(h) *Medical surveillance.* (1) *General.* (i) The employer shall make medical surveillance available at no cost to the employee, and at a reasonable time and place, for all employees:

(A) Experiencing signs or symptoms of the adverse health effects associated with chromium (VI) exposure; or

(B) Exposed in an emergency.

(ii) The employer shall assure that all medical examinations and procedures required by this section are performed by or under the supervision of a PLHCP.

(2) *Frequency.* The employer shall provide a medical examination:

(i) Whenever an employee shows signs or symptoms of the adverse health effects associated with chromium (VI) exposure;

(ii) Within 30 days after exposure during an emergency which results in an uncontrolled release of chromium (VI); or

(iii) Within 30 days after a PLHCP's written medical opinion recommends an additional examination.

(3) *Contents of examination.* A medical examination consists of:

(i) A medical and work history, with emphasis on: Past, present, and anticipated future exposure to chromium (VI); any history of respiratory system dysfunction; any history of asthma, dermatitis, skin ulceration, or nasal septum perforation; and smoking status and history;

(ii) A physical examination of the skin and respiratory tract; and

(iii) Any additional tests deemed appropriate by the examining PLHCP.

(4) *Information provided to the PLHCP.* The employer shall ensure that the examining PLHCP has a copy of this standard, and shall provide the following information:

(i) A description of the affected employee's former, current, and anticipated duties as they relate to the employee's occupational exposure to chromium (VI);

(ii) The employee's former, current, and anticipated levels of occupational exposure to chromium (VI);

(iii) A description of any personal protective equipment used or to be used by the employee, including when and for how long the employee has used that equipment; and

(iv) Information from records of employment-related medical examinations previously provided to the affected employee, currently within the control of the employer.

(5) *PLHCP's written medical opinion.* (i) The employer shall obtain a written medical opinion from the PLHCP, within 30 days for each medical examination performed on each employee, which contains:

(A) The PLHCP's opinion as to whether the employee has any detected medical condition(s) that would place the employee at increased risk of material impairment to health from further exposure to chromium (VI);

(B) Any recommended limitations upon the employee's exposure to chromium (VI) or upon the use of personal protective equipment such as respirators;

(C) A statement that the PLHCP has explained to the employee the results of the medical examination, including any medical conditions related to chromium (VI) exposure that require further evaluation or treatment, and any special provisions for use of protective clothing or equipment.

(ii) The PLHCP shall not reveal to the employer specific findings or diagnoses unrelated to occupational exposure to chromium (VI).

(iii) The employer shall provide a copy of the PLHCP's written medical opinion to the examined employee within two weeks after receiving it.

(i) *Communication of chromium (VI) hazards to employees.*

(1) *General.* In addition to the requirements of the Hazard Communication Standard, 29 CFR 1910.1200, for labels, material safety data sheets, and training, employers shall comply with the following requirements.

(2) *Warning labels.* The employer shall ensure that bags or containers of contaminated clothing and equipment to be removed for laundering, cleaning, or maintenance, bear appropriate warning labels that include at least the following information:

DANGER
CONTAINS CHROMIUM (VI)
CANCER HAZARD
CAN DAMAGE SKIN, EYES, NASAL PASSAGES, AND LUNGS

(3) *Employee information and training.* (i) The employer shall provide training for all employees who are potentially exposed to chromium (VI), ensure employee participation in training, and maintain a record of training provided.

(ii) The employer shall provide initial training prior to or at the time of initial assignment to a job involving potential exposure to chromium (VI). An employer who is able to demonstrate that a new employee has received training within the last 12 months that addresses the elements specified in paragraph (l)(4)(iii) of this section is not required to repeat such training provided that the employee can demonstrate knowledge of those elements.

(iii) The employer shall provide training that is understandable to the employee and shall ensure that each employee can demonstrate knowledge of at least the following:

(A) The health hazards associated with chromium (VI) exposure;

(B) The location, manner of use, and release of chromium (VI) in the workplace and the specific nature of operations that could result in exposure to chromium (VI), especially exposure above the PEL;

(C) The engineering controls and work practices associated with the employee's job assignment;

(D) The purpose, proper selection, fitting, proper use, and limitations of respirators and protective clothing;

(E) Emergency procedures;

(F) Measures employees can take to protect themselves from exposure to chromium (VI), including modification of personal hygiene and habits such as smoking;

(G) The purpose and a description of the medical surveillance program required by paragraph (h) of this section;

(H) The contents of this section; and

(I) The employee's rights of access to records under 29 CFR 1910.1020(g).

(iv) The employer shall provide additional training when:

(A) Training is necessary to ensure that each employee maintains an understanding of the safe use and handling of chromium (VI) in the workplace.

(B) Workplace changes (such as modification of equipment, tasks, or procedures) result in an increase in employee exposures to chromium (VI), and those exposures exceed or can reasonably be expected to exceed the PEL or result in a hazard from skin or eye contact with chromium (VI).

(v) The employer shall make a copy of this section and its appendices readily available without cost to all affected employees.

(j) *Recordkeeping.* (1) *Medical surveillance.* (i) The employer shall establish and maintain an accurate record for each employee covered by medical surveillance under paragraph (h) of this section.

(ii) The record shall include the following information about the employee:

(A) Name and social security number;

(B) A copy of the PLHCP's written opinions;

(C) A copy of the information provided to the PLHCP as required by paragraph (h)(4) of this section.

(iii) The employer shall ensure that medical records are maintained and made available in accordance with §1910.1020.

(2) *Training.* (i) At the completion of training, the employer shall prepare a record that indicates the identity of the individuals trained and the date the training was completed. This record shall be maintained for three years after the completion of training.

(ii) The employer shall provide to the Assistant Secretary or the Director, upon request, all materials relating to employee information and training.

(k) *Dates.* (1) *Effective date.* This section shall become effective [60 days after publication of the final rule in the **Federal Register**].

(2) *Start-up dates.* All obligations of this section commence 90 days after the effective date except as follows:

(i) Change rooms required by paragraph (g) of this section shall be provided no later than one year after the effective date.

(ii) Engineering controls required by paragraph (d) of this section shall be implemented no later than two years after the effective date.

PART 1917—[AMENDED]

7. The authority citation for 29 CFR Part 1917 is revised to read as follows:

Authority: Sec. 41, Longshore and Harbor Workers' Compensation Act (33 U.S.C. 941); secs. 4, 6, 8, Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order Nos. 12–71 (36 FR 8754). 8–76 (41 FR 25059), 9–83 (48 FR 35736), 6–96 (62 FR 111), or 5–2002 (67 FR 65008), as applicable; 29 CFR part 1911.

Section 1917.28 also issued under 5 U.S.C. 553.

8. New paragraphs (a)(2)(xiii)(E) and (b) are added to § 1917.1, to read as follows:

§ 1917.1 Scope and applicability.

* * * * *

(a) * * *

(2) * * *

(xiii) * * *

(E) Hexavalent chromium § 1910.1026 (See § 1915.1026)

* * * * *

(b) Section 1915.1026 applies to any occupational exposures to hexavalent chromium in workplaces covered by this part.

PART 1918—[AMENDED]

9. The authority citation for 29 CFR Part 1918 is revised to read as follows:

Authority: Secs. 4, 6, 8, Occupational Safety and Health Act of 1970, 29 U.S.C. 653, 655, 657; Walsh-Healey Act, 41 U.S.C. 35 *et seq.*; Service Contract Act of 1965, 41 U.S.C. 351 et seq,; Sec. 107, Contract Work Hours and Safety Standards Act (Construction Safety Act), 40 U.S.C. 333; Sec. 41, Longshore and Harbor Workers' Compensation Act, 33 U.S.C. 941; National Foundation of Arts and Humanities Act, 20 U.S.C. 951 *et seq.*; Secretary of Labor's Order Nos. 6–96 (62 FR 111) or 5–2002 (67 FR 65008), as applicable; and 29 CFR part 1911.

10. New paragraphs (b)(9)(v) and (c) are added to § 1918.1 to read as follows:

§ 1918.1 Scope and application.

* * * * *

(b) * * *

(9) * * *

(v) Hexavalent chromium § 1910.1026 (See § 1915.1026)

* * * * *

(c) Section 1915.1026 applies to any occupational exposures to hexavalent chromium in workplaces covered by this part.

PART 1926—[AMENDED]

Subpart D—[Amended]

11. The authority citation for subpart D of 29 CFR Part 1926 is revised to read as follows:

Authority: Sec. 107, Contract Work Hours and Safety Standards Act (40 U.S.C. 333); secs. 4, 6, 8, Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order Nos. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 6–96 (62 FR 111), or 5–2002 (67 FR 65008), as applicable; and 29 CFR part 1911.

§ 1926.55 [Amended]

12. In Appendix A to § 1926.55, the entry for "Chromic acid and chromates (as CrO_3) 0.1" is removed and the following entry added in its place:

§ 1926.55 Gases, vapors, fumes, dusts, and mists.

* * * * *

THRESHOLD LIMIT VALUES OF AIRBORNE CONTAMINANTS FOR CONSTRUCTION

Substance	CAS No.[d]	ppm [a]	mg/m [3] [b]	Skin Designation
*	*	*	*	*
Chromium (VI) compounds (as Cr); see 1926.1126.				
*	*	*	*	*

[3] Use Asbestos Limit§ 1915.1001

* * * * * * *

[a] Parts of vapor or gas per million parts of contaminated air by volume at 25 ° C and 760 torr.

[3b] Milligrams of substance per cubic meter of air. When entry is in this column only, the value is exact; when listed with a ppm entry, it is approxiate

* * * * * * *

[d] The CAS number is for information only. Enforcement is based on the substance name. For an entry covering more than one metal compound, measured as the metal, the CAS number for the metal is given—not CAS numbers for the individual compounds.

* * * * *

Subpart Z—[Amended]

13. The authority citation for subpart Z of 29 CFR Part 1926 is revised to read as follows:

Authority: Sec. 107, Contract Work Hours and Safety Standards Act (40 U.S.C. 333); secs. 4, 6, 8, Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order Nos. 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 5–2002 (67 FR 65008), as applicable; and 29 CFR part 1911.

Section 1926.1102 not issued under 29 U.S.C. 655 or 29 CFR part 1911; also issued under 5 U.S.C. 553.

14. A new § 1926.1126 is added to subpart Z of 29 CFR Part 1926 to read as follows:

§ 1926.1126 Chromium (VI).

(a) *Scope.* This standard applies to occupational exposures to chromium (VI) in all forms and compounds in construction, except for exposures to portland cement.

(b) *Definitions.* For the purposes of this section the following definitions apply:

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

Chromium (VI) [hexavalent chromium or Cr(VI)] means chromium with a valence of positive six, in any form and in any compound.

Director means the Director of the National Institute for Occupational Safety and Health (NIOSH), U.S. Department of Health and Human Services, or designee.

Emergency means any occurrence that results, or is likely to result, in an uncontrolled release of chromium (VI). If an incidental release of chromium (VI) can be controlled at the time of release by employees in the immediate release area, or by maintenance personnel, it is not an emergency.

Employee exposure means the exposure to airborne chromium (VI) that would occur if the employee were not using a respirator.

High-efficiency particulate air [HEPA] filter means a filter that is at least 99.97 percent efficient in removing mono-dispersed particles of 0.3 micrometers in diameter or larger.

Physician or other licensed health care professional [PLHCP] is an individual whose legally permitted scope of practice (i.e., license, registration, or certification) allows him or her to independently provide or be delegated the responsibility to provide some or all of the particular health care services required by paragraph (h) of this section.

This section means this chromium (VI) standard.

(c) *Permissible exposure limit (PEL).* The employer shall ensure that no employee is exposed to an airborne concentration of chromium (VI) in excess of 1 microgram per cubic meter of air (1 $\mu g/m^3$), calculated as an 8-hour time-weighted average (TWA).

(d) *Methods of compliance.* (1) *Engineering and work practice controls.* (i) Except as permitted in paragraph (d)(1)(ii) of this section, the employer shall use engineering and work practice controls to reduce and maintain employee exposure to chromium (VI) to or below the PEL unless the employer can demonstrate that such controls are not feasible. Wherever feasible engineering and work practice controls are not sufficient to reduce employee exposure to or below the PEL, the employer shall use them to reduce employee exposure to the lowest levels achievable, and shall supplement them by the use of respiratory protection that complies with the requirements of paragraph (e) of this section.

(ii) Where the employer has a reasonable basis for believing that no employee in a process or task will be exposed above the PEL for 30 or more days per year (12 consecutive months), the requirement to implement engineering and work practice controls to achieve the PEL does not apply to that process or task.

(2) *Prohibition of Rotation.* The employer shall not rotate employees to different jobs to achieve compliance with the PEL.

(e) *Respiratory Protection.* (1) *General.* The employer shall provide respiratory protection for employees during:

(i) Periods necessary to install or implement feasible engineering and work practice controls;

(ii) Work operations, such as maintenance and repair activities, for which engineering and work practice controls are not feasible;

(iii) Work operations for which an employer has implemented all feasible engineering and work practice controls and such controls are not sufficient to reduce exposures to or below the PEL;

(iv) Work operations where employees are exposed above the PEL for fewer than 30 days per year, and the employer has elected not to implement engineering and work practice controls to achieve the PEL; or

(v) Emergencies.

(2) *Respiratory protection program.* Where respirator use is required by this section, the employer shall institute a respiratory protection program in accordance with 29 CFR 1910.134.

(f) *Protective work clothing and equipment.* (1) *Provision and use.* Where a hazard is present or is likely to be present from skin or eye contact with chromium (VI), the employer shall provide appropriate personal protective clothing and equipment at no cost to employees, and shall ensure that employees use such clothing and equipment.

(2) *Removal and storage.* (i) The employer shall ensure that employees remove all protective clothing and equipment contaminated with chromium (VI) at the end of the work shift or at the completion of their tasks involving chromium (VI) exposure, whichever comes first.

(ii) The employer shall ensure that no employee removes chromium (VI)-contaminated protective clothing or equipment from the workplace, except for those employees whose job it is to launder, clean, maintain, or dispose of such clothing or equipment.

(iii) When contaminated protective clothing or equipment is removed for laundering, cleaning, maintenance, or disposal, the employer shall ensure that it is stored and transported in sealed, impermeable bags or other closed, impermeable containers.

(iv) Bags or containers of contaminated protective clothing or equipment that are removed from change rooms for laundering, cleaning, maintenance, or disposal shall be labeled in accordance with paragraph (i) of this section.

(3) *Cleaning and replacement.* (i) The employer shall clean, launder, repair and replace all protective clothing and equipment required by this section as needed to maintain its effectiveness.

(ii) The employer shall prohibit the removal of chromium (VI) from protective clothing and equipment by blowing, shaking, or any other means that disperses chromium (VI) into the air or onto an employee's body.

(iii) The employer shall inform any person who launders or cleans protective clothing or equipment contaminated with chromium (VI) of the potentially harmful effects of exposure to chromium (VI) and that the clothing and equipment should be laundered or cleaned in a manner that minimizes skin or eye contact with chromium (VI) and effectively prevents the release of airborne chromium (VI) in excess of the PEL.

(g) *Hygiene areas and practices.* (1) *General.* Where protective clothing and equipment is required, the employer shall provide change rooms in conformance with 29 CFR 1926.51.

Where skin contact with chromium (VI) occurs, the employer shall provide washing facilities in conformance with 29 CFR 1926.51. Eating and drinking areas provided by the employer shall also be in conformance with § 1926.51.

(2) *Change rooms.* The employer shall assure that change rooms are equipped with separate storage facilities for protective clothing and equipment and for street clothes, and that these facilities prevent cross-contamination.

(3) *Washing facilities.* (i) The employer shall provide readily accessible washing facilities capable of removing chromium (VI) from the skin, and shall ensure that affected employees use these facilities when necessary.

(ii) The employer shall ensure that employees who have skin contact with chromium (VI) wash their hands and faces at the end of the work shift and prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics, or using the toilet.

(4) *Eating and drinking areas.* (i) Whenever the employer allows employees to consume food or beverages at a worksite where chromium (VI) is present, the employer shall ensure that eating and drinking areas and surfaces are maintained as free as practicable of chromium (VI).

(ii) The employer shall ensure that employees do not enter eating and drinking areas with protective work clothing or equipment unless surface chromium (VI) has been removed from the clothing and equipment by methods that do not disperse chromium (VI) into the air or onto an employee's body.

(5) *Prohibited activities.* The employer shall ensure that employees do not eat, drink, smoke, chew tobacco or gum, or apply cosmetics in areas where skin or eye contact with chromium (VI) occurs; or carry the products associated with these activities, or store such products in these areas.

(h) *Medical Surveillance.* (1) *General.* (i) The employer shall make medical surveillance available at no cost to the employee, and at a reasonable time and place, for all employees:

(A) Experiencing signs or symptoms of the adverse health effects associated with chromium (VI) exposure; or

(B) Exposed in an emergency.

(ii) The employer shall assure that all medical examinations and procedures required by this section are performed by or under the supervision of a PLHCP.

(2) *Frequency.* The employer shall provide a medical examination:

(i) Whenever an employee shows signs or symptoms of the adverse health effects associated with chromium (VI) exposure;

(ii) Within 30 days after exposure during an emergency which results in an uncontrolled release of chromium (VI); or

(iii) Within 30 days after a PLHCP's written medical opinion recommends an additional examination.

(3) *Contents of examination.* A medical examination consists of:

(i) A medical and work history, with emphasis on: Past, present, and anticipated future exposure to chromium (VI); any history of respiratory system dysfunction; any history of asthma, dermatitis, skin ulceration, or nasal septum perforation; and smoking status and history;

(ii) A physical examination of the skin and respiratory tract; and

(iii) Any additional tests deemed appropriate by the examining PLHCP.

(4) *Information provided to the PLHCP.* The employer shall ensure that the examining PLHCP has a copy of this standard, and shall provide the following information:

(i) A description of the affected employee's former, current, and anticipated duties as they relate to the employee's occupational exposure to chromium (VI);

(ii) The employee's former, current, and anticipated levels of occupational exposure to chromium (VI);

(iii) A description of any personal protective equipment used or to be used by the employee, including when and for how long the employee has used that equipment; and

(iv) Information from records of employment-related medical examinations previously provided to the affected employee, currently within the control of the employer.

(5) *PLHCP's Written Medical Opinion.* (i) The employer shall obtain a written medical opinion from the PLHCP, within 30 days for each medical examination performed on each employee, which contains:

(A) The PLHCP's opinion as to whether the employee has any detected medical condition(s) that would place the employee at increased risk of material impairment to health from further exposure to chromium (VI);

(B) Any recommended limitations upon the employee's exposure to chromium (VI) or upon the use of personal protective equipment such as respirators;

(C) A statement that the PLHCP has explained to the employee the results of the medical examination, including any medical conditions related to chromium (VI) exposure that require further evaluation or treatment, and any special provisions for use of protective clothing or equipment.

(ii) The PLHCP shall not reveal to the employer specific findings or diagnoses unrelated to occupational exposure to chromium (VI).

(iii) The employer shall provide a copy of the PLHCP's written medical opinion to the examined employee within two weeks after receiving it.

(i) *Communication of chromium (VI) hazards to employees.* (1) *General.* In addition to the requirements of the Hazard Communication Standard, 29 CFR 1910.1200, for labels, material safety data sheets, and training, employers shall comply with the following requirements.

(2) *Warning labels.* The employer shall ensure that bags or containers of contaminated clothing and equipment to be removed for laundering, cleaning, or maintenance, bear appropriate warning labels that include at least the following information:

DANGER
CONTAINS CHROMIUM (VI)
CANCER HAZARD
CAN DAMAGE SKIN, EYES, NASAL PASSAGES, AND LUNGS

(3) *Employee information and training.* (i) The employer shall provide training for all employees who are potentially exposed to chromium (VI), ensure employee participation in training, and maintain a record of training provided.

(ii) The employer shall provide initial training prior to or at the time of initial assignment to a job involving potential exposure to chromium (VI). An employer who is able to demonstrate that a new employee has received training within the last 12 months that addresses the elements specified in paragraph (l)(4)(iii) of this section is not required to repeat such training provided that the employee can demonstrate knowledge of those elements.

(iii) The employer shall provide training that is understandable to the employee and shall ensure that each employee can demonstrate knowledge of at least the following:

(A) The health hazards associated with chromium (VI) exposure;

(B) The location, manner of use, and release of chromium (VI) in the workplace and the specific nature of operations that could result in exposure to chromium (VI), especially exposure above the PEL;

(C) The engineering controls and work practices associated with the employee's job assignment;

(D) The purpose, proper selection, fitting, proper use, and limitations of respirators and protective clothing;

(E) Emergency procedures;

(F) Measures employees can take to protect themselves from exposure to chromium (VI), including modification of personal hygiene and habits such as smoking;

(G) The purpose and a description of the medical surveillance program required by paragraph (h) of this section;

(H) The contents of this section; and

(I) The employee's rights of access to records under 29 CFR 1910.1020(g).

(iv) The employer shall provide additional training when:

(A) Training is necessary to ensure that each employee maintains an understanding of the safe use and handling of chromium (VI) in the workplace.

(B) Workplace changes (such as modification of equipment, tasks, or procedures) result in an increase in employee exposures to chromium (VI), and those exposures exceed or can reasonably be expected to exceed the PEL or result in a hazard from skin or eye contact with chromium (VI).

(v) The employer shall make a copy of this section and its appendices readily available without cost to all affected employees.

(j) *Recordkeeping.* (1) *Medical surveillance.* (i) The employer shall establish and maintain an accurate record for each employee covered by medical surveillance under paragraph (h) of this section.

(ii) The record shall include the following information about the employee:

(A) Name and social security number;

(B) A copy of the PLHCP's written opinions;

(C) A copy of the information provided to the PLHCP as required by paragraph (h)(4) of this section.

(iii) The employer shall ensure that medical records are maintained and made available in accordance with §1910.1020.

(2) *Training.* (i) At the completion of training, the employer shall prepare a record that indicates the identity of the individuals trained and the date the training was completed. This record shall be maintained for three years after the completion of training.

(ii) The employer shall provide to the Assistant Secretary or the Director, upon request, all materials relating to employee information and training.

(k) *Dates.* (1) *Effective date.* This section shall become effective [60 days after publication of the final rule in the **Federal Register**].

(2) *Start-up dates.* All obligations of this section commence 90 days after the effective date except as follows:

(i) Change rooms required by paragraph (g) of this section shall be provided no later than one year after the effective date.

(ii) Engineering controls required by paragraph (d) of this section shall be implemented no later than two years after the effective date.

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Part III

Department of Housing and Urban Development

Notice of Final Order; Government Sponsored Enterprises Mortgage Data and Annual Housing Activities Report Information: Proprietary Information/ Public Use Data; Notice

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4796–N–01]

RIN 2502–AH96

Notice of Final Order; Government Sponsored Enterprises Mortgage Data and Annual Housing Activities Report Information: Proprietary Information/ Public Use Data

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing. Commissioner, HUD.

ACTION: Notice of final order.

SUMMARY: This notice sets forth a final order of the Department of Housing and Urban Development (HUD or Department) which provides that certain loan-level mortgage data elements submitted to HUD by the Federal National Mortgage Association (Fannie Mae) and the Federal Home Loan Mortgage Corporation (Freddie Mac) (collectively, the government-sponsored enterprises, or GSEs) are classified as non-proprietary and shall be made available to the public. After careful review of the previous proprietary orders, the Department is making a number of changes to the proprietary classification of certain GSE single-family and multifamily mortgage data elements. The list of data elements that HUD is making available to the public is described in the following sections. In addition, the Department is setting forth in the Appendix to this final order the loan-level data elements that the Department has determined to classify as proprietary and non-proprietary. The final order implements the Department's prior determination that the unpaid principal balance (UPB) of mortgages in the single-family Census Tract File shall be released, subject to a top-code expressed as a ratio to the current conforming loan limit for one-family properties. In releasing these data, the Department will use the top-coding convention already employed for the years 1993 through 1995. The Department will release the reclassified data elements beginning in 2005, via the Department's public use database covering the GSEs' 2004 mortgage purchases, and in all future public use databases. Finally, the Department is making four technical changes with respect to the disclosure of data elements previously determined by HUD to be non-proprietary. This final order supersedes the final order of October 17, 1996 (1996 Order).

EFFECTIVE DATE OF THE FINAL ORDER: The Final Order set forth in this notice is effective on October 4, 2004.

FOR FURTHER INFORMATION CONTACT: Sandra Fostek, Director, Office of Government Sponsored Enterprises Oversight, Office of Housing, Room 3150, telephone (202)708–2224. For questions on data or methodology, contact John L. Gardner, Director, Financial Institutions Regulation Division, Office of Policy Development and Research, Room 8212, telephone (202) 708–1464. For legal questions, contact Paul S. Ceja, Deputy Assistant General Counsel for Government Sponsored Enterprises/RESPA, and Ronnie Shorenstein, Senior GSE/RESPA Division Attorney, Office of the General Counsel, Room 9262, telephone (202) 708–3137. The address for all of these persons is Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410. Persons with hearing and speech impairments may access the phone numbers through TTY by calling the Federal Information Relay Service at (800) 877–8399.

SUPPLEMENTARY INFORMATION:

A. The Final Order

Pursuant to sections 1323 and 1326 of the Federal Housing Enterprises Financial Safety and Soundness Act (FHEFSSA), codified at 12 U.S.C. 4543 and 4546, the Department has determined that certain loan-level mortgage data elements, as detailed in the attached Appendix and contained in the annual loan-level data files that will be submitted by Fannie Mae and Freddie Mac to the Department in accordance with sections 309(m) and (n) of the Federal National Mortgage Association Charter Act (Fannie Mae Charter Act), codified at 12 U.S.C. 1723a(m) and 1723a(n), and sections 307(e) and (f) of the Federal Home Loan Mortgage Corporation Act (Freddie Mac Act), codified at 12 U.S.C. 1456(e) and 1456(f), respectively, shall be treated as non-proprietary information. The Appendix further identifies data elements that lose their proprietary character when categorized in ranges, adjusted, or recoded in other ways. The data so identified in the Appendix shall be made available for public disclosure under sections 1323 and 1326 of FHEFSSA and HUD's regulations at 24 CFR part 81, subpart F.

This final order concerns whether loan-level data elements are proprietary. It is not applicable to aggregated information on activities that has been or will be submitted by the GSEs in their Annual Housing Activities Reports (AHARs) and Mortgage Reports. It is not applicable to aggregations of information above the loan-level that the Department may produce for various reasons, including fulfilling its responsibilities to inform the public about the GSEs' activities.

A detailed discussion of HUD's determinations in this Final Order is set forth in Section D below.

B. Background

1. Statutory Requirements and Legislative History Regarding Proprietary Data.

The Federal Housing Enterprises Financial Safety and Soundness Act of 1992, enacted as Title XIII of the Housing and Community Development Act of 1992, (FHEFSSA) (Pub. L. 102–550, approved October 28, 1992), codified generally at 12 U.S.C. 4501–4561, requires the Secretary of Housing and Urban Development to establish and monitor the performance of Fannie Mae and Freddie Mac in meeting annual goals for purchases of mortgages on housing for low- and moderate-income families; housing located in central cities, rural areas, and other underserved areas; and special affordable housing (*i.e.*, housing meeting the needs of and affordable to low income families in low-income areas and very low-income families).

Section 1323 of FHEFSSA, codified at 12 U.S.C. 4543, provides that the Secretary shall make available to the public the data submitted by the GSEs in the data reports required under section 309(m) of the Fannie Mae Charter Act and section 307(e) of the Freddie Mac Act, except data that the Secretary determines, by regulation or order pursuant to section 1326, codified at 12 U.S.C. 4546, are proprietary. Section 1323(b)(2) of FHEFSSA, codified at 12 U.S.C. 4543(b)(2), specifically provides that the Secretary may not restrict access to data consisting of income, census tract location, race, and gender of mortgagors of single-family properties.

In addition, section 1326 of FHEFSSA provides that the Secretary may, by regulation or order, provide that certain information shall be treated as proprietary information and not subject to disclosure under section 1323 of FHEFSSA, section 309(n)(3) of the Fannie Mae Charter Act or section 307(f)(3) of the Freddie Mac Act. Section 1326 of FHEFSSA also states that the Secretary shall not provide public access to, or disclose to the public, any information required to be submitted by a GSE under section 309(n) of the Fannie Mae Charter Act or section 307(f) of the Freddie Mac Act that the Secretary determines is proprietary. Pending the issuance of a final decision on the matter, such

information may not be disclosed to the public or a representative of any person or agency.

The legislative history of FHEFSSA provides that "* * * every effort should be made to provide public disclosure of the information required to be collected and/or reported to the regulator consistent with the exemption for proprietary data * * *" S. Rep. 102–282, 102d Cong., 2d Sess. 40 (1992). In addition, the legislative history indicates that Congress intended that the GSE public use database help fill the "information vacuum" on GSE mortgage activities and complement the database established under the Home Mortgage Disclosure Act (HMDA) (*see* S. Rep. 102–282, 102d Cong., 2d Sess. 33, 39 (1992).)

2. Regulatory and Administrative Actions.

On October 13, 1993, the Department published in the **Federal Register** Notices of Interim Housing Goals which required, among other things, that each GSE provide data and other information on mortgages purchased, in the form of Annual and Quarterly Reports, on their respective performance under the Interim Housing Goals, and, after the end of each year, loan-level computerized data files providing details on each mortgage purchased (*see* 58 FR 53048 for Fannie Mae and 58 FR 53072 for Freddie Mac).

On June 7, 1994, the Department published in the **Federal Register** a Notice of Temporary Order that identified certain information contained in the GSEs' loan-level data files submitted to HUD that the Department had determined to be proprietary information (*see* 59 FR 29514) (the 1994 Temporary Order). The 1994 Temporary Order identified, in its Exhibit A, the specific loan-level data elements that were covered by the Temporary Order and provided that these data elements were to be withheld from public disclosure. The Department solicited public comments in connection with this Temporary Order and indicated that it would consider these comments during its development of a subsequent proposed rulemaking to implement its statutory authority under FHEFSSA.

As part of its 1995 proposed and final rules to establish regulations governing the GSEs, the Department developed regulations governing the use of the public use database to make available to the public loan-level data on the GSEs' single-family and multifamily mortgage purchases.

In the Department's December 1, 1995 final GSE rule (1995 Final Rule) (60 FR 61846, 61897–8) which implemented the Secretary's GSE regulatory authorities, HUD required, for 1996 and future years, each GSE to provide data and other information on mortgages purchased in two forms—Annual Housing Activities Reports (AHARs) that discuss each GSE's performance under the housing goals, and quarterly Mortgage Reports that include aggregate data on mortgage purchases and, in the second and fourth quarter reports, loan-level computerized data files that provide details on each mortgage purchased by each GSE. The data required in the loan-level data files include, for each mortgage purchased by the GSEs: the borrower(s) annual income, race, and gender; census tract location; other geographic identifiers; loan-to-value (LTV) ratio; number of units; owner-occupancy status; and other details about the mortgage, the property, and the borrower(s). The information required for the Mortgage Reports includes aggregate data concerning: the amount of mortgage purchases that qualify towards each housing goal, classified by number of units and dollar volume; borrower(s) income and race; location of property; and various other categories. (*See* 24 CFR part 81, subpart E.)

In addition, the Department's regulation at 24 CFR 81.74, set forth in the 1995 Final Rule, established six factors for the Secretary to consider and procedures to be followed when the Secretary determines whether or not to accord proprietary treatment to mortgage data or AHAR information.

Section 81.75, which was set forth in the 1995 Final Rule provided, in part, that: Following a determination by the Secretary that mortgage data or AHAR information is proprietary information under FHEFSSA, the Secretary shall expeditiously issue a temporary order, final order, or regulation withholding the mortgage data or AHAR information from the public use database and from public disclosure by HUD in accordance with 12 U.S.C. 4546.

Section 81.75 further provided that the Secretary "may, from time-to-time, by regulation or order, issue a list entitled 'GSE Mortgage Data and AHAR Information: Proprietary Information/Public-Use Data' providing that certain information shall be treated as proprietary information" and expressly authorized the Secretary to "modify the list by regulation or order."

The Department set forth in Appendix F to the 1995 Final Rule a final order identifying the list of data elements that HUD had determined under section 1326 of FHEFSSA to be proprietary (and, thus, not available to the public) and those data elements that it had determined to be non-proprietary and available to the public. (See 60 FR 62001–62005.) The 1995 Final Rule stated that Appendix F contained the most current listing of data and information determined by HUD to be proprietary and that it superseded the 1994 Temporary Order.

The 1995 Final Rule also identified in Appendix F the structure of the public use database, including that GSE single-family data would be released to the public in three separate files: a Census Tract File that identified the census tract location of the mortgaged property, a National File A (with mortgage-level data on owner-occupied one-unit properties but without census tract identifiers), and a National File B (with unit-level data on all single-family properties also without census tract identifiers). The GSE multifamily data are disclosed in two files, the Census Tract File, which identifies the census tract location of the mortgaged property and the National file, which does not identify the location of mortgaged properties but contains mortgage level data and unit class level data on all multifamily properties.

In 1996, based upon a review of the 1995 order and comments provided by the GSEs, HUD determined that the issuance of a new order was needed. Therefore, on October 17, 1996, the Department issued a new order (see 61 FR 54322) (1996 Order) releasing some new data and reconfiguring files to protect proprietary information. In the 1996 Order, the Department's changes included the following: For the single-family files: (1) Add an indicator for served or underserved areas to the Census Tract File; (2) in certain cases recode area median family income and borrower(s) annual income to protect proprietary information in the Census Tract File; (3) specify properties included in National File A and the presentation of unit-level information in National File B; (4) recode the borrower income ratio for rental units in National File B to provide the public with affordability information; (5) provide information on whether mortgages were originated in the same or a previous year, consistent with HMDA, in National File B; and (6) revise the reporting of the occupancy code in National File B. For the multifamily files, release the type of seller institution in the Census Tract File, and release data on the affordability of units in the National File.

Subsequently, as part of its GSE housing goals proposed rule of March 9, 2000 (65 FR 12660) (the 2000 Proposed Rule), the Department included several additional changes to its classifications of certain GSE mortgage data. As part of

this rulemaking, HUD proposed to treat as non-proprietary, and to release to the public, the following single-family data elements:

(1) A code distinguishing loans on properties in metropolitan areas from loans on properties in non-metropolitan areas in the two single-family National Files;

(2) A code distinguishing home purchase, refinance, second, and rehabilitation loans in the single-family Census Tract File and National File A;

(3) An identifier for federally guaranteed loans (with type of guarantee) in the single-family Census Tract File;

(4) Identification of the borrower's and co-borrower's race/national origin in the two single-family National Files; and

(5) A code distinguishing owner-occupied from investor properties in the single-family Census Tract File and National File A.

In addition, HUD proposed two changes to the GSE multifamily files that would allow the release to the public of:

(1) A code in the National File that would distinguish loans originated in the year of purchase by the GSE from loans originated in prior years; and

(2) A code in the National File identifying the type of seller institution.

HUD also proposed four technical recoding and definitional changes concerning: (1) the borrower(s) annual income in the single-family database; (2) the Purpose of Loan in the Census Tract File; (3) the Purpose of Loan in the multifamily database; and (4) the Occupancy Code in the single-family database. (*See* Section 1.C. of the 2000 Proposed Rule, 65 FR 12668–12670.)

In the final GSE rule that HUD published on October 31, 2000 (65 FR 65044) (the 2000 Final Rule), HUD decided not to make a final determination with regard to which GSE data elements would be designated as proprietary or non-proprietary. Instead, the Department decided, after referencing its authority under section 1326 of FHEFSSA and § 81.75 of its regulations, that it would issue an order setting forth its determinations regarding the proprietary or non-proprietary status of the subject data elements following publication of the 2000 Final Rule. The Department stated that its decision would be issued in accordance with its regulations at §§ 81.72 to 81.74. (See 65 FR 65801–65802.)

In 2003, the Department prepared and submitted to the Office of Management and Budget (OMB) a draft final order in which it stated determinations with respect to each of the changes that it had proposed in the 2000 Proposed Rule (the Draft Final Order). The Department also included in the Draft Final Order items that were not discussed in the 2000 proposed rulemaking, including:

(1) The designation as non-proprietary in National Files A and B of the borrower's and co-borrower's gender (information which previously was made available in the National files only as a combined borrower/co-borrower data element); and

(2) Increasing the top-coding of the unpaid principal balance (UPB) of mortgage loans at the time of acquisition by a GSE to reflect increases in the conforming loan limit.

In May 2003, the GSEs requested a copy of the Department's submission to OMB and, in response, the Department provided Fannie Mae and Freddie Mac with a copy of the list of proprietary and non-proprietary determinations from its Draft Final Order (the 2003 List). The 2003 List reflected the Department's initial views about the proprietary and non-proprietary status of each of the data elements that had been included in the 2000 Proposed Rule, as well as items (1) and (2) above.

In May 2003 HUD representatives met separately with Fannie Mae and Freddie Mac staff to discuss the proposed treatment of the data elements in the 2003 List. The Department informed the GSEs that they could each submit written comments reflecting the views that they had expressed at the May 2003 meetings. On June 24, 2003, the GSEs submitted written comments. The Department has reviewed and considered these comments.

As described further below, the Department has concluded that the GSE data elements that were identified in the 2000 Proposed Rule and 2003 administrative proceedings, when released in certain files and with certain modifications as described below, may be treated as non-proprietary and may be released to the public via the public use database.

C. Public Comments on the 2000 Proposed Rule and the 2003 List

In making its determinations, the Department considered the public comments submitted on the 2000 Proposed Rule and the GSEs' comments (described below) on the 2003 List. HUD received comments on the 2000 Proposed Rule from both GSEs and from trade organizations, advocacy groups, researchers, and lenders. The Department discussed the comments in the 2000 Final Rule (see 65 FR 65044, 65081–65082) and incorporates that discussion herein. The Department is further discussing, in this final order, Freddie Mac's comments on the 2003 List.

Freddie Mac asserted that a portion of its June 24, 2003, comment letter is confidential and proprietary. In this final order, the Department discusses only those Freddie Mac comments that were not designated as proprietary. Fannie Mae asserted that the entire contents of its June 24, 2003, comment letter are confidential and proprietary.

Although the Department fully considered all the comments raised by the GSEs in their June 24, 2003 letters, due to the confidentiality concerns raised by the GSEs regarding those letters, only those portions of Freddie Mac's comments that it has not designated as confidential and proprietary are discussed herein. Because Fannie Mae requested confidential treatment of all issues raised in its comments, the Department has considered, but is not discussing, these comments in this final order.

Prior to publication of this final order, the Department sent to the GSEs a copy of this final order, together with separate determination letters in which the Department responded to the comments that each GSE contended are confidential and proprietary.

In its comments on the 2003 List, Freddie Mac asserted that the Department's administrative process for changing the treatment of the items of proprietary data in the 2003 List was inadequate. Freddie Mac agreed that the Department could modify its designations of proprietary and non-proprietary data in the public use database by regulation or order, but stated that neither the process for a regulation nor for an order had been followed. Freddie Mac did not elaborate further on the process it considered proper for issuing an order.

The Department has considered Freddie Mac's comments relating to the administrative process it used in making the determinations set forth in this final order and has determined that it followed the appropriate administrative process under section 1326 of FHEFSSA, HUD's regulations at 24 CFR 81.74 and 81.75, and the Administrative Procedure Act. The Department has provided various opportunities to the GSEs to have their views considered during both the 2000 and 2003 administrative proceedings, and the GSEs did, in fact, avail themselves of each of these opportunities by submitting written comments and meeting with HUD representatives. Moreover, the Department has fully considered the GSEs' oral and written comments. Accordingly, the Department

believes that the administrative process it has afforded the GSEs fully satisfies the requirements and procedural protections afforded in its regulations and in the Administrative Procedure Act.

HUD's determinations, including a specific discussion of each change to the 1996 Order, are set forth below in Section D.

D. Changes Included in This Order

The Department is issuing this final order setting forth its determinations of proprietary and non-proprietary status with respect to the data element changes HUD proposed in its 2000 Proposed Rule, and the two additional items proposed by the Department in the 2003 List. The following section sets forth HUD's determinations and how those determinations change the 1996 Order.

In making its determinations, HUD has considered all of the the public and non-public comments regarding its proposed changes to the public use database, and acted pursuant to its regulations at 24 CFR 81.71–81.75. Further, in making its determination, the Department specifically employed the six factors listed for making proprietary determinations of mortgage data or AHAR information set forth in 24 CFR 81.74(b), including a consideration of any effect that disclosure of GSE data may have on the GSEs' financial or competitive positions. In this final order, the Department is making the following changes to the treatment of the following single-family loan level data elements:

1. Treatment of Single-Family Data

1. MSA Code/Metropolitan and Non-Metropolitan Location

In the 2000 Proposed Rule, HUD proposed to add an identifier to National Files A and B that would identify only whether a mortgaged property is located in a metropolitan area or is located in a non-metropolitan area, or that the information is missing, without revealing the specific Metropolitan Statistical Areas (MSAs) of the property by disclosing the MSA code. MSA Codes for specific MSAs will continue to be available only in the Census Tract File.

HUD has determined that its proposal should be implemented and that data identifying whether a property is in a metropolitan or non-metropolitan area should not be accorded proprietary treatment in the National Files. The incremental amount of information made available to the public through the release of metropolitan/non-metropolitan data is necessary in order to accurately characterize GSE purchases, to fully understand the ability of the GSEs to lead the mortgage market, and to help to fill the "information vacuum" related to the GSEs" mortgage purchase activities as noted by Congress when it enacted FHEFSSA in 1992.

In addition, separately identifying data on metropolitan and non-metropolitan activities of the GSEs is of critical importance in order to accurately compare the GSEs to the primary mortgage market. By allowing analysis of the GSEs' purchases of mortgages on properties in metropolitan areas, as opposed to non-metropolitan areas, HUD's release of this data would allow comparisons with market data, reported in accordance with HMDA, which contain information on newly originated mortgages in metropolitan areas at the census tract level. National File B also separates the GSEs' mortgage purchases into prior-year and current-year originations. The market analysis, comparing GSE purchases with HMDA-reported originations in the primary market, will allow HUD and others to accurately evaluate GSE leadership capabilities relative to the conventional conforming mortgage market, one of the statutory factors that Congress mandated that HUD consider in setting the housing goals.

2. Purpose of Loan

In the 2000 Proposed Rule, HUD proposed to add Purpose of Loan to the Census Tract File and National File A by releasing data on whether a mortgage was for home purchase, refinance, or was a second mortgage. HUD further proposed to add a previously unreleased indicator for rehabilitation loans to the coded values of Purpose of Loan, and to redefine code "9" as "information not applicable/not available."

HUD has determined not to accord proprietary treatment to Purpose of Loan data if Purpose of Loan data are released in the Census Tract File and National File A in two categories, either "home purchase" or "all other", the latter of which would include refinance, second, and rehabilitation mortgages combined into one element. For National File B, the public use database would retain the existing level of detail, although an additional element would be provided to indicate whether a loan is a code 4, which indicates rehabilitation loans. The public use database will redefine code 9 from "Not Applicable" to "Not Applicable/Not Available."

By making these changes, the Census Tract File and National File A of the public use database will clearly identify home purchase mortgages, which are central to the GSEs' missions and important to the formulation of regulatory policy toward the GSEs while addressing any concerns relating to the public release of this information. Meanwhile, National File B of the public use database will continue to report greater detail on loan purpose, including information on second mortgages and rehabilitation loans.

The need to distinguish home purchase loans in the Census Tract File has been conveyed to HUD by researchers who have attempted to use the GSE public use database in conjunction with HMDA data (which separately identifies home purchase and refinance loans). These researchers indicate that the usefulness of the Census Tract File is severely limited because it does not separately identify home purchase loans.

The level of down payment is a major factor in determining access to homeownership for lower-income families. With respect to National File A, separately identifying the distribution of home purchase loans across LTVs would allow users of the public use database to perform analyses of the GSEs' contributions to homeownership opportunities for those lower-income families that find it most difficult to raise cash. Such identification would permit the public to consider whether the GSEs are purchasing sufficient low down payment loans to serve the needs of lower-income borrowers. Currently, questions such as these cannot be answered using the GSE public use database. Including Purpose of Loan in National File A will enable HUD and others to analyze the GSEs' contributions to expanding homeownership opportunities.

3. Federal Guarantee

Federal Guarantee is already disclosed in National Files A and B. HUD proposed to add it to the Census Tract File. This data element identifies whether the loan is a Federal Housing Administration (FHA) loan or Veterans Administration (VA) loan, a Rural Housing Service (RHS) guaranteed rural housing loan, a home equity conversion mortgage (HECM), a Title I–FHA loan, or a loan without any federal guarantee. Federal Guarantee (FHA, VA, RHS) is disclosed in the HMDA database.

HUD has determined that proprietary restrictions will not be violated if the Census Tract File reports the Federal Guarantee in one of three categories—"FHA/VA," "other federal guarantee," or "no federal guarantee." HUD has

determined that its proposal should be implemented and data identifying "federal guarantee," as described herein, should not be accorded proprietary treatment in the Census Tract File.

HUD previously determined in the 1996 Order that the Federal Guarantee data element specifying whether a loan is an FHA or a VA loan, an RHS-guaranteed rural housing loan, a HECM, a Title I FHA loan, or a loan without any federal guarantee, is not proprietary when released in the National Files A and B, as specified in that Order. On the other hand, HUD also determined, with regard to the Census Tract File, that this element is proprietary. However, since HMDA does make available to the public information on whether current year loans are conventional, FHA, VA, or RHS, the Department believes that a revocation of its prior proprietary determination with regard to the Census Tract File is warranted.

The public benefit of being able to distinguish FHA/VA, Other Federal Guarantee and No Federal Guarantee loans by geographical location is substantial. As noted earlier, HMDA reports such information for most loans originated in the primary market in metropolitan areas and for most loans sold to the GSEs. This addition to the Census Tract File will make the data in that file consistent with the primary market data reported by HMDA. By including the Federal Guarantee information in the Census Tract File, HUD will enable users of the GSE public use database to analyze the GSEs' mortgage purchases with more precision.

4. Race/National Origin

Section 1323(b)(2) of FHEFSSA, codified at 12 U.S.C. 4543(b)(2), provides that the Secretary shall not restrict access to certain data elements listed in the GSEs' respective Charter Acts; these data elements include the race of mortgagors. The race/national origin of the borrower and co-borrower are already made public in the Census Tract File. This data element also includes designations for why information is not available. The race/national origin of the borrower and co-borrower are also made public in National Files A and B as a combined data element which presents data on the race/national origin of the borrower and co-borrower, including whether they are of a different race/national origin from each other. There is no designation for why information is missing in National Files A and B.

In the 2000 Proposed Rule, HUD proposed to change the presentation in National Files A and B to provide a separate race/national origin data element for the borrower and co-borrower, and to detail reasons for missing race data currently provided only in the Census Tract File (specifically whether information was not provided by the applicant in a mail or telephone application, the field is not applicable, or the information is not available). HUD has determined that its proposal should be implemented and that data identifying "race/national origin," as described herein, should not be accorded proprietary treatment in National Files A and B.

HUD previously determined in the 1995 Final Rule, and reaffirmed in the 1996 Order, that the race/national origin data element is non-proprietary when released for the borrower and co-borrower in the Census Tract File, and that combined race/national origin data for both the borrower and co-borrower are non-proprietary in the form in which these have been released in the National Files A and B. Thus, the Department has not previously made available to the public, via the public use database, separate data on race/national origin for the borrower and the co-borrower in National Files A and B. However, since HMDA does make available to the public separate data on the race/national origin of the borrower and the co-borrower, as does the Census Tract File, the Department believes that a revocation of its prior proprietary determination is warranted.

5. Gender of the Borrower and Co-Borrower

Section 1323(b)(2) of FHEFSSA, codified at 12 U.S.C. 4543(b)(2), provides that the Secretary shall not restrict access to certain data elements listed in the GSEs' respective Charter Acts. These data elements include the gender of single-family mortgagors. The gender of the borrower and co-borrower are already present in the Census Tract File, and as a combined data element in National Files A and B. There is no designation for why information is missing in National Files A and B.

HUD is now changing the presentation in National Files A and B to provide borrower and co-borrower information separately. In addition, HUD will include in National Files A and B additional information on the reasons why data are missing, *i.e.*, information was not provided by the applicant in mail or telephone application, the field is not applicable, or the information is not available. This information currently is provided only in the Census Tract File. HUD has determined that this change should be implemented and that data identifying the gender of the borrower and co-borrower, as described herein, should not be accorded proprietary treatment in the National Files A and B.

The disclosure, on a disaggregated basis in the National Files, of separate gender information for borrowers and co-borrowers, would not affect the financial or competitive position of either GSE. As noted above, the two National Files already report gender information on an aggregated basis (combining the primary borrower and co-borrower information). The Department would be providing separate gender information for the borrower and the co-borrower in the form in which gender information is already provided in the Census Tract File.

HUD previously determined in the 1996 Order that gender qualifies for proprietary treatment when released in the form of separate borrower and co-borrower gender data elements in the two National Files. As a result, the Department has not previously made this information available to the public via the public use database. Information on the gender of the borrower and co-borrower for GSE-purchased loans is readily available from the Census Tract File (for all single-family loans) and from HMDA (for most home purchase and refinance loans sold to the GSEs).

The Department's release of separate information on borrower and co-borrower race/national origin (as discussed in the preceding section) will have the effect of revealing, in National Files A and B, information on whether the number of borrowers is one or at least two. Given this information with the existing combined borrower/co-borrower gender data element, the level of gender information in National Files A and B will become substantively equivalent to the level of gender information provided if the borrower and co-borrower information are provided separately. (In some cases there are three or more borrowers; information on the total number of borrowers for a loan will continue to be excluded from the GSE public use database.) To make this as clear as possible for users of the public use database, HUD will code borrower and co-borrower information separately as is done with HMDA data.

For these reasons, HUD has determined that it is appropriate to release this augmented disclosure of information on gender in the National Files.

6. Top-Coding of Unpaid Principal Balance (UPB)

The Department uses "top-coding" in the public use database to present the maximum unpaid principal balance of a mortgage at the time of acquisition by a GSE as a number less than the conforming loan limit. In this way, users of the public use database can gain information on the unpaid principal balance of GSE mortgage purchases without being able to discern whether a unit is a one-unit or a two-to-four unit property. The top-code for a single-family mortgage is calculated by applying a fixed ratio to the conforming loan limit.

The first year for which HUD collected proprietary data on UPB was 1993, when the conforming loan limit for one-unit properties (except in Alaska and Hawaii) was $203,150. For that year, HUD top-coded UPB at $200,000, or 98.45 percent of the conforming loan limit.

Under the 1994 Temporary Order, UPB was designated as proprietary and not released. Under Appendix F of the 1995 Rule, data on UPB were allowed to be released as either less than or greater than $200,000 in the single-family Census Tract File, but not in National File A or B. The 1996 Order did not change the treatment of this data element.

After the 1996 Order was published, HUD released UPB data, top-coded at $200,000 for the years 1993 through 1995. For subsequent years, HUD has continued to apply a $200,000 top-code, even as the conforming loan limit has risen. For 2004, with a conforming loan limit of $333,700, a $200,000 top-code means that information on the distribution of UPB that HUD has asserted to be relevant for public purposes and non-proprietary is being masked.

Accordingly, HUD will henceforth adjust annually the top-code UPB for all single-family properties by applying the fixed ratio (200/207) to the then-current single-family conforming loan limit. Therefore, consistent with the top-coding convention already employed for 1993 through 1995, HUD is ordering the top-coding convention for each year to be 98.4 percent of the conforming loan limit, rounded to the nearest $500. This will result in a top-code for the year 2004, in which the conforming loan limit is $333,700, of $328,500.

HUD has determined that there is no adverse consequence from annually re-specifying the top-code of UPB, as it only restores the level of disclosure established in the Final Order that is set forth in Appendix F to the 1995 Final Rule and in the 1996 Order. HUD previously determined in those Orders that the Acquisition UPB data element qualifies for proprietary treatment, but may be released to the public after applying top-coding to this data. In those Orders, the Department indicated that the purpose of top-coding was to mask two-to four-unit properties by combining them with one-unit properties within approximately 1.5 percentage points below the conforming loan limit. Over time, the top-code set in 1996 has decreased to 59.93 percent of the conforming loan limit in 2004, as the conforming loan limit has risen.

Because the Department has already determined that the Acquisition UPB data element can be released to the public when a top-code is applied, and since the effect of the current modification is limited to adjusting the top-code to reflect annual changes in the conforming loan limit, the Department believes this clarification of HUD's prior proprietary determination is warranted.

7. Occupancy Code

Occupancy Code (identifying whether the unit is owner-occupied, a rental unit in an owner-occupied property, a unit in an investment property, or information not available) is already provided in National File B of the public use database. In the 2000 Proposed Rule, HUD proposed to add this data element to the Census Tract File and to National File A (identifying whether the property is owner-occupied, is an investment property, or that the information is not available). The Census Tract File currently does not distinguish mortgages on owner-occupied properties from mortgages on investor-owned properties. Separately identifying mortgages on owner-occupied and investor-owned properties in the Census Tract File of the public use database would make the Census Tract File comparable with HMDA, which distinguishes between mortgages on owner-occupied and non-owner-occupied properties. This change would permit comparison of the GSEs' purchases of mortgages on owner-occupied properties with HMDA-reported mortgages on owner-occupied properties originated in the conventional conforming primary market. (In the public use database second homes are included in the "owner-occupied" category while in HMDA they are included in the "non-owner-occupied" category.)

HUD has determined that its proposal should be implemented and that occupancy code information in the Census Tract File should not be accorded proprietary treatment. HUD previously determined in the 1996 Order that the Occupancy Code data element is not proprietary in National File B when recoded to mask whether the property is the second home, but that the data element is accorded proprietary treatment in the Census Tract File and National File A. However, since HMDA does make available to the public the occupancy code data element, and for the other reasons set forth in this final order, the Department believes that a revocation of its prior proprietary determination with respect to the Census Tract File is warranted. (HUD has further determined that because National File A contains only mortgage data on owner-occupied one-unit properties, release of information on investor-owned properties is not applicable to this File.)

Under HMDA, lenders report information for most loans originated in the primary market in metropolitan areas and for most loans sold to the GSEs. This addition to the single-family Census Tract File would make the data in that file consistent with the primary market data reported by HMDA, thus allowing for comparisons of the characteristics of loans on owner-occupied properties that are originated in the primary market and loans that are bought by the GSEs. This would provide a better understanding of the role of the GSEs in purchasing mortgages in the owner-occupied portions of the metropolitan housing markets. In addition, single-family rental properties provide an important source of financing for low-income housing, particularly in inner cities, but more needs to be known about the GSEs' activities in this important market. For these reasons, the public benefit of being able to distinguish, by geographical location, between mortgages on owner-occupied and investor-owned properties is substantial.

2. Treatment of Multifamily Data

Under the 2000 Proposed Rule, HUD proposed to add the following data elements to the GSE public use database for multifamily properties:

1. Date of Mortgage Note

Date of Mortgage Note was proposed by HUD in the 2000 Proposed Rule to be released in the multifamily National File only, showing whether the mortgage was originated in the same year as acquired by the GSE, or in a prior year, or whether this information is missing.

HUD has determined that its proposal should be implemented and that data on the Date of Mortgage Note in the

multifamily National File should not be accorded proprietary treatment.

HUD previously determined in the 1996 Final Order that the Date of Mortgage Note data element qualifies for proprietary treatment in both the Census Tract File and the National File. As a result, the Department has not previously made this information available to the public via the public use database. However, since HMDA does make available to the public the Date of Mortgage Note data element, the Department believes that a revocation of its prior proprietary determination is warranted. This will permit public analyses of GSE purchases of multifamily loans originated in prior years and also facilitate comparisons between data in the GSE public use database and HMDA data.

2. Type of Seller Institution

Type of Seller Institution (showing whether the loan seller is a mortgage company, Savings Association Insurance Fund (SAIF)-insured depository institution, Bank Insurance Fund (BIF)-insured depository institution, National Credit Union Administration (NCUA)-insured credit union, or some other type of institution) is already provided to users in the Census Tract File of the public use database. In the 2000 Proposed Rule, HUD proposed to release this information in the National File as well.

HUD has determined that data on the Type of Seller Institution in the National File should not be accorded proprietary treatment and that its proposal should be implemented with one change: SAIF-insured depository institution and BIF-insured depository institution will be recoded as a combined data element in the National File.

HUD previously determined in the 1996 Order that the Type of Seller Institution data element is not proprietary when released in the Census Tract File and is proprietary when released in the National File. As a result, the Department has not previously made this information available to the public via the public use database. However, since HMDA does make available to the public the Type of Seller Institution data element, the Department believes that a revocation of its prior proprietary determination is warranted. This will facilitate comparisons between data contained in the GSE and HMDA databases and will also facilitate analyses by members of the public of affordability, property and size characteristics, as well as other key characteristics by type of seller at the national level.

E. Other Technical Changes

In the 2000 Proposed Rule, HUD proposed the following additional changes, of a minor technical or definitional nature, to the public use database:

1. Borrower(s) Annual Income

HUD proposed to change the "not available" code for borrower(s) annual income from "999999" to "9999999." No objection was raised to this change. Accordingly, it will be implemented.

2. Purpose of Loan—Single-Family

HUD proposed to add code "4" for rehabilitation loans as a code under Purpose of Loan in the single-family GSE public use database, and to change code "9" from "not applicable" to "not applicable/not available." No objection was raised to this change. Accordingly, it will be implemented.

3. Purpose of Loan—Multifamily

HUD proposed to change code "9" under Purpose of Loan in the multifamily GSE public use database from "not applicable" to "not applicable/not available." No objection was raised to this change. Accordingly, it will be implemented.

4. Occupancy Code in National File A

In the preamble to the 2000 Proposed Rule, HUD proposed that Occupancy Code be disclosed in National File A. In seeming contradiction to this proposal, HUD's matrix in Appendix E to the 2000 Proposed Rule indicated that this data element would continue not to be disclosed. The issue is, however, substantively immaterial given that National File A is limited to mortgages on owner-occupied one-unit properties, all of which would have an Occupancy Code of "1" under the proposal. In order to economize on space in the data file, and since the code is unnecessary, HUD will continue to omit this data element from National File A.

F. Summary of Revised Public Use Database Structure

An appendix is attached to this Final Order that summarizes the structure of the single-family and multifamily GSE public use database files incorporating the changes that will be implemented based on HUD's determinations in this Final Order. For GSE single-family mortgage data, changes are reflected in data fields 4, 15, 18, 22, 27, 41, 42, 43, 44, and 47. For GSE multifamily mortgage data, changes are reflected in data fields 19, 21, and 33.

Conclusion

The Department is complying fully with the requirements of FHEFSSA and will not restrict access to the data submitted by the GSEs to HUD under sections 309(m) and (n) of the Fannie Mae Charter Act and sections 307(e) and (f) of the Freddie Mac Act, other than as described in this final order and the attached Appendix. Also, the Department has considered the assertions of the GSEs and other commenters that certain data should be treated as proprietary and has concluded that revising the 1996 Order is necessary to release GSE information that is reported to HUD to the public, to complement the HMDA database, and to fill the "information vacuum" on GSE mortgage purchase activities, while at the same time protecting the GSEs' proprietary information, in accordance with FHEFSSA and its legislative history.

Pursuant to sections 1323 and 1326 of FHEFSSA, codified at 12 U.S.C. 4543 and 4546, and HUD's regulations at 24 CFR part 81, the Department has determined that certain loan-level mortgage data elements, as detailed in the attached Appendix and contained in the annual loan-level data files submitted by Fannie Mae and Freddie Mac to the Department in accordance with sections 309(m) and (n) of the Fannie Mae Charter Act (12 U.S.C. 1723a(m) and 1723a(n)) and sections 307(e) and (f) of the Freddie Mac Act (12 U.S.C. 1456(e) and 1456(f)), shall not be accorded proprietary treatment and shall be made available for public use via the public use database established by section 1323 of FHEFSSA. The Appendix further identifies those data elements for which HUD has made these determinations.

Finally, this final order provides that the Department also will revise the top-coding convention on the unpaid principal balance (UPB) of mortgages in the single-family Census Tract File beginning with the year 2004 and consistent with the top-coding convention already employed for the years 1993 through 1995.

The Department will release the reclassified data elements, as set forth in this Final Order, beginning in 2005, through the Department's public use database covering the GSEs' 2004 mortgage purchases, and in all future public use databases.

The Department also has determined to make the technical changes to its implementation of the public use database, as originally described in the 2000 Proposed Rule and as described in

this final order. These technical changes will take effect immediately.

Expiration and Modification of this Final Order

This final order supersedes the final order of October 17, 1996 (61 FR 54322) and shall be effective until such time as the Department determines that it is necessary and/or appropriate to withdraw or modify it.

Dated: September 28, 2004.

John C. Weicher,

Assistant Secretary for Housing-Federal Housing Commissioner.

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APPENDIX

GSE MORTGAGE DATA AND AHAR INFORMATION: PROPRIETARY INFORMATION/PUBLIC-USE DATA

Notes: The following matrices distinguish proprietary from public-use mortgage data elements. A "YES" designation indicates that the data element is proprietary and not included in the public use data base in the format indicated. A "NO", "NO, Added field", "Yes, but recode", and "YES, but redefine and recode as" indicate that the data element is included in the public use data base. Certain data are coded as missing or not available either because the data was not submitted or because the data is proprietary.

GSE Single-Family Mortgage Data
Owner- and Renter-Occupied 1- to 4-Unit Properties
Proprietary Information/Public-Use Data

The "Census Tract File" contains mortgage-level data on all single-family properties.
The "National File A" contains mortgage-level data on owner-occupied 1-unit properties.
The "National File B" contains unit-level data on all single-family properties.

#	Field Description	Values	Census Tract File	National File A	National File B
0	Agency Flag	1=Fannie Mae 2=Freddie Mac	NO	NO	NO
1	Loan Number		Yes, but recode as a Random Number*	Yes, but recode as a Random Number*	Yes, but recode as a Random Number*
2	US Postal State	0=Missing	NO	YES	YES
3	US Postal Zip Code		YES	YES	YES
4	MSA Code	0=Missing	NO	YES but recode as: 1= metropolitan area 0=non-metropolitan area	YES but recode as: 1= metropolitan area 0=non-metropolitan area
5	Place Code - FIPS		YES	YES	YES
6	County - 1990 Census	0=Missing	NO	YES	YES
7	Census Tract/BNA - 1990 Census	0=Missing	NO	YES	YES
8**	Census Tract Geographic Designation	1=Tract Entirely Within Central City 2=Tract Entirely Outside Central City 3=Central City Split Tract 9=Not Able To Code	NO	YES	YES
9**	Central City Flag 1	9999=Not Able To Code	NO	YES	YES
10**	Central City Flag 2	9998=Not Available 9999=Not Applicable	NO	YES	YES
11	1990 Census Tract - Percent Minority	9999=Not Available	NO	YES, but recode as: 1=0- <10% 2=10- <30% 3=30- 100% 9=Missing	YES, but recode as: 1=0-<10% 2=10- <30% 3=30- 100% 9=Missing
12	1990 Census Tract - Median Income	999999=Not Available	NO	YES	YES
13	1990 Local Area Median Income	999999=Not Available	NO	YES	YES
14	Tract Income Ratio	9999=Not Applicable	NO	YES, but recode as: 1=0-<=80% 2=80-<=120% 3= >120% 9=Missing	YES, but recode as: 1=0-<=80% 2=80-<=120% 3= >120% 9=Missing
15	Borrower(s) Annual Income	9999999=Not Available	YES, but recode in terms of dollars for year of acquisition.	YES	YES
16	Area Median Family Income	999999=Not Available or Withheld as Proprietary	YES, but recode in terms of dollars for year of acquisition.	YES	YES
17***	Borrower Income Ratio	9999=Not Applicable, Not Available, or Withheld as Proprietary	YES, but recode proprietary data as 9999.	YES, but recode as: 1=0- <=60% 2=60 - <=100% 3= >100 9=Not Applicable	YES, but redefine and recode as:*** 1=0- <=60% 2=60- <=100% 3= >100 9=Not Applicable
18	Acquisition UPB		YES, but recode as: Actual values if < top-code 999998= >=top-code 999999=Missing (top-code based on conforming loan limit-see note)	YES	YES
19	LTV at Origination	999=Not Applicable	YES	YES, but recode as: 1=0- <=60% 2=60- <=80% 3=80- <=90% 4=90- <=95% 5= > 95% 9=Missing	YES
20	Date of Mortgage Note		YES	YES	YES, but recode as: 1=Originated same calendar year as acquired 2=Originated prior to calendar year of acquisition 9=Missing
21	Date of Acquisition		YES	YES	YES
22	Purpose of Loan	1=Purchase 2=Refinancing 3=Second Mortgage 4=Rehabilitation 9=Not Applicable/Not Available	YES but recode as: 1=purchase 8=other 9=not applicable/not available	YES but recode as: 1=purchase 8=other 9=not applicable/not available	NO

#	Field Description	Values	Census Tract File	National File A	National File B
23	Cooperative Unit Mortgage	1=Yes 2=No 8=Not Available 9=Not Applicable	YES	YES	YES
24**	Refinancing Loan from Own Portfolio	1=Yes 2=No 9=Not Applicable	YES	YES	YES
25	Special Affordable, Seasoned Loan: Are Proceeds Recycled?	1=Yes 2=No 9=Not Applicable	YES	YES	YES
26	Product Type	01=Fixed Rate 02=ARM 03=Balloon 04=GPM/GEM 05=Reverse Annuity Mortgage 06=Other 07...98=List Other Distinct Products 99=Not Available	YES	YES	YES
27	Federal Guarantee	1=FHA/VA 2=RHS-Guaranteed Rural Housing Loan 3=HECMs 4=No Federal Guarantee 5=Title 1-FHA	YES, but recode as: 1=FHA/VA 4=No Federal Guarantee 8=Other Federal Guarantee	NO	NO
28	RTC/FDIC	1=Yes 2=No	YES	YES	YES
29	Term of Mortgage at Origination		YES	YES	YES
30	Amortization Term	998=Non-Amortizing Loan 999=Not Available	YES	YES	YES
31****	Lender Institution Name		YES	YES	YES
32****	Lender City		YES	YES	YES
33****	Lender State		YES	YES	YES
34	Type of Seller Institution	1=Mortgage Company 2=SAIF Insured Depository Institution 3=BIF Insured Depository Institution 4=NCUA Insured Credit Union 5=Other	YES	YES	NO
35	Number of Borrowers	99=Missing	NO	YES	YES
36	First-Time Home Buyer	1=Yes 2=No 9=Not Available	NO	YES	YES
37	Mortgage Purchased under GSE's Community Lending Program	1=FNMA's Community Homebuyer Program 2=FNMA's Community Lending Other 3=FNMA's Other Housing Impact Programs OR 1=FHLMC's Affordable Gold 2=FHLMC's Alternative Qualifying 9=Not Applicable (either GSE)	YES	YES	YES
38	Acquisition Type	1=Cash 2=SWAP 3=Other 4=Credit Enhancement 5=Bond or Debt Purchase 6=REMIC 7=Reinsurance 8=Risk Sharing 9=REIT	YES	YES	YES
39	GSE's Real Estate Owned	1=Yes 2=No 3=Not Available	YES	YES	YES
40**	Public Subsidy Programs	1=Federal only 2=State or Local only 3=Other/Private Subsidy only 4=Federal and State or Local 5=Federal and Other 6=State or Local and Other 7=Federal, State or Local and Other 9=Data Not Provided	YES	YES	YES
41	Borrower Race or National Origin	1=American Indian or Alaskan Native 2=Asian or Pacific Islander 3=Black 4=Hispanic 5=White 6=Other 7=Information Not Provided by Applicant In Mail or Telephone Application 8=Not Applicable 9=Not Available	NO	NO	NO
42	Co-Borrower Race or National Origin	1=American Indian or Alaskan Native 2=Asian or Pacific Islander 3=Black 4=Hispanic 5=White 6=Other 7=Information Not Provided by Applicant In Mail or Telephone Application 8=Not Applicable 9=Not Available	NO	NO	NO

#	Field Description	Values	Census Tract File	National File A	National File B
43	Borrower Gender	1=Male 2=Female 3=Information Not Provided by Applicant In Mail or Telephone Application 4=Not Applicable 9=Not Available	NO	NO	NO
44	Co-Borrower Gender	1=Male 2=Female 3=Information Not Provided by Applicant In Mail or Telephone Application 4=Not Applicable 9=Not Available	NO	NO	NO
45	Age of Borrower	999=Data Not Provided	NO	YES	YES
46	Age of Co-Borrower	999=Data Not Provided	NO	YES	YES
47*****	Occupancy Code	1=Principal Residence/Owner-Occupied 2=Second Home 3=Investment Property (Rental) 9=Not Available	YES, but redefine and recode as: 1=Owner-Occupied property 2=Investment Property 9=Not Available	YES	YES, but redefine and recode as:***** 1=Owner-Occupied 2=Rental Unit in an Owner-Occupied Property 3=Investment Property (Rental) 9=Not Available
48	Number of Units		YES	NO	NO
49	Unit - Number of Bedrooms	99=Data Not Provided	YES	YES	YES
50	Unit - Owner Occupied	1=Yes 2=No	YES	YES	NO
51	Unit - Affordability Category	1=Low-Income Family (but not Very Low-Income) in a Low-Income Area 2=Very Low-Income Family, in a Low-Income Area 3=Very Low-Income Family, Not in a Low-Income Area 4=Other 9=Not Available 0=Missing	YES	NO	NO
52	Unit - Reported Rent Level	99999=Not Applicable	YES	YES	YES
53	Unit - Reported Rent Plus Utilities	99999=Not Applicable	YES	YES	YES
54	Fannie Mae Exclusions	1=Excluded from Goal Reporting	YES	YES	YES
55****	Geographically Targeted Indicator	1=Yes 2=No 9=Not Applicable	NO, Added Field	NO, Added Field	NO, Added Field

Note: The top-code for field 18 is 98.4 percent of the conforming loan limit, rounded to the nearest $500.

* Different random number on each of the tract and national files.

** Not applicable to 1996 and beyond data sets. Central city is as defined by the Office of Management and Budget.

*** The borrower income ratio field is defined for rental units on National File B to reflect the affordability of units based on rent data submitted by the GSEs to the Secretary.

**** Not applicable to 1993-1995 data sets.

***** National File B is recoded so that rental and owner-occupied units of 2-4 unit properties can be distinguished.

GSE Multifamily Mortgage Data
Property Level
Proprietary Information/Public-Use Data

The "Census Tract File" contains mortgage-level date on all multifamily properties.
The "National File" consists of two parts: one part contains mortgage level data and the other consists of unit-class-level data for all multifamily properties.

#	Field Description	Values	Census Tract File	National File
0	Agency Flag	1=Fannie Mae 2=Freddie Mac	NO	NO
1	Loan Number		Yes, but recode as a Random Number*	Yes, but recode as a Random Number*
2	US Postal State	0=Missing	NO	YES
3	US Postal Zip Code		YES	YES
4	MSA Code	0=Missing	NO	YES
5	Place Code - FIPS		YES	YES
6	County - 1990 Census	0=Missing	NO	YES
7	Census Tract/BNA - 1990 Census	0=Missing	NO	YES
8**	Census Tract Geographic Designation	1=Tract Entirely Within Central City 2=Tract Entirely Outside Central City 3=Central City Split Tract 9=Not Able To Code	NO	YES
9**	Central City Flag 1	9999=Not Able To Code	NO	YES
10**	Central City Flag 2	9998=Not Available 9999=Not Applicable	NO	YES
11	1990 Census Tract - Percent Minority	9999=Not Available	NO	YES, but recode as: 1=0-<10% 2=10- <30% 3=30- 100% 9=Missing
12	1990 Census Tract - Median Income	999999=Not Available	NO	YES
13	1990 Local Area Median Income	999999=Not Available	NO	YES
14	Tract Income Ratio	9999=Not Applicable	NO	YES, but recode as: 1=0-<=80% 2=80-<=120% 3= >120% 9=Missing
15	Aree Median Family Income	999999=Not Available	NO	YES
16	Affordability Category	1= >=20% are especially-low-income <40% are very-low-income 2= <20% & >=40% 3= >=20% & >=40% 4= <20% & <40% 8=Not Available 9=Not Eligible 0=Missing	YES	NO
17	Acquisition UPB		YES, but recode as: 1= <= $500,000 2= $500,000-<=$1m 3= $1m-<=$2m 4= $2m-<=$4m 5= > $4m 9=Missing	YES
18	Participation Percent		YES	YES
19	Date of Mortgage Note		YES	YES but recode as: 1 same year as acquired by GSE 2 in a prior year 9 missing
20	Date of Acquisition		YES	YES
21	Purpose of Loan	1=Purchase 2=Refinancing 3=New Construction 4=Rehabilitation 9=Not Applicable/Not Availeble	YES	NO
22	Cooperative Project Loan	1=Yes 2=No 8=Not Available 9=Not Applicable	YES	YES
23**	Refinancing Loan from Own Portfolio	1=Yes 2=No 9=Not Applicable	YES	YES
24	Special Affordable, Seasoned Loan: Are Proceeds Recycled?	1=Yes 2=No 9=Not Applicable	YES	YES
25	Mortgagor Type	1=Individual 2=For Profit Entity 3=Nonprofit Entity 4=Public Entity 5=Other	YES	YES

#	Field Description	Values	Census Tract file	National File
26	Term of Mortgage at Origination		YES	YES
27	Loan Type	1=Fixed Rate 2=ARM 3=GPM	YES	YES
28	Construction Loan	1=Yes 2=No	YES	YES
29	Amortization Term	998=Non-Amortizing Loan 999=Not Available	YES	YES
30***	Lender Institution		YES	YES
31***	Lender City		YES	YES
32***	Lender State		YES	YES
33	Type of Seller Institution	1=Mortgage Company 2=SAIF Insured Depository Institution 3=BIF Insured Depository Institution 4=NCUA Insured Credit Union 5=Other	NO	YES but recode as: 1=Mortgage Company 2=SAIF- or BIF-Insured depository institution 3=NCUA Insured Credit Union 4=Other
34	Government Insurance	1=Yes 2=No 3=FHA Risk Sharing 9=Not Availeble	YES	NO
35	FHA Risk Shere Percent		YES	YES
36	Acquisition Type	1=Cash 2=Swap 3=Other 4=Credit Enhancement 5=Bond/Debt Purchased 6=REMIC 7=Reinsurance 8=Risk Shering 9=REIT	YES	YES
37	GSE Real Estate Owned	1=Yes 2=No 3=Not Available	YES	YES
38	Public Subsidy Program	1=Federal only 2=Stete or Local only 3=Other/Private Subsidy only 4=Federal and State or Local 5=Federal and Other 6=Stete or Local and Other 7=Federal, State or Local and Other 9=Data Not Provided	YES	YES
39	Total Number of Units		YES	NO
40**	Special Affordable - 45 Percent	0=Missing or Not Applicable	YES	NO
41**	Special Affordable - 55 Percent	0=Missing or Not Applicable	YES	NO
42	Fannie Mae Exclusions	1=Excluded from Goal Reporting	YES	YES
43***	Geographically Targeted Indicator	1=Yes 2=No 9=Not Applicable	NO, Added Field	NO, Added Field

* Different random numbers on tract and netional files
** Not applicable to 1996 and beyond data sets.
*** Not applicable to 1993-1995 data sets.

GSE Multifamily Mortgage Data
Unit Class Level
Proprietary Information/Public-Use Data

0	Agency Flag		YES	NO
1	Loan Number		YES	Yes, but recode as e Rendom Number****
44	Unit Type XX-Number of Bedrooms		YES	YES, but recode as: 1=0-1 Bedroom 2= 2 or more Bedrooms
45	Unit Type XX-Number of Units		YES	NO
46	Unit Type XX-Average Rent Level		YES	YES
47	Unit Type XX-Average Rent Plus Utilities		YES	YES
48	Unit Type XX-Affordability Level		YES	YES, but recode as: 1=0- <=50% 2=50- <=60% 3=60- <=80% 4=80- <=100% 5= > 100% 9=Not Availeble
49	Unit Type XX-Tenant Income Indicator	0=No or Not Provided 1=Yes	YES	NO

**** This number will match the property level random number on the netional file.

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October 4, 2004

Part IV

Department of Transportation

Federal Aviation Administration

14 CFR Part 13
Civil Penalty Assessment Procedures; Final Rule

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 13

[Docket No. 27854; Amendment No. 13–32]

RIN 2120–AE84

Civil Penalty Assessment Procedures

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: The Federal Aviation Administration (FAA) is adopting procedures for administratively assessing civil penalties for violations of the laws and regulations the agency enforces. These procedures pertain to initiating and adjudicating a civil penalty against an individual acting as a pilot, flight engineer, mechanic, or repairman. These procedures are needed because the National Transportation Safety Board now reviews these civil penalty actions and the FAA's existing rules for civil penalty actions are not sufficiently flexible to adequately address the procedural differences that review in a different forum entails. This final rule also makes other minor modifications to the FAA's procedures for assessing civil penalties against persons other than individuals acting as pilots, flight engineers, mechanics, or repairmen.

DATES: Effective Date: This rule is effective on November 3, 2004.

FOR FURTHER INFORMATION CONTACT: Joyce Redos, Attorney, Enforcement Division (AGC–300), Federal Aviation Administration, 800 Independence Ave., SW., Washington, DC 20591; telephone (202) 267–3137.

SUPPLEMENTARY INFORMATION:

Availability of This Action

You can get an electronic copy of this action using the Internet by:

(1) Searching the Department of Transportation's electronic Docket Management System (DMS) Web page at *http://dms.dot.gov/search;*

(2) Visiting the Office of Rulemaking's Web page at *http://www.faa.gov/avr/arm/index.cfm;* or

(3) Accessing the Government Printing Office's Web page at *http://www.access.gpo.gov/su_docs/aces/aces140.html.*

You can also get a copy of this action if you submit a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue, SW., Washington, DC 20591, or by calling (202) 267–9680. Make sure to identify the docket number, notice number, or amendment number of this rulemaking.

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), or you may visit *http://dms.dot.gov.*

Small Business Regulatory Enforcement Fairness Act

The Small Business Enforcement Fairness Act (SBREFA) of 1996 requires FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. If you are a small entity and you have a question regarding this document, you may contact a local FAA official or the person listed under **FOR FURTHER INFORMATION CONTACT.** You can find out more about SBREFA on the Internet at *http://www.faa.gov/avr/arm/sbrefa.cfm* or by e-mailing us at *AWA–SBREFA@faa.gov.*

Background [1]

The FAA has authority to assess civil penalties for certain violations of the FAA's governing statute and regulations or orders issued under that statute as well as other statutes, regulations, or orders the agency enforces. This authority formerly covered all civil penalty actions involving a civil penalty of $50,000 or less.

In 49 U.S.C. 46301(d)(5), Congress transferred the authority to review the FAA's administrative civil penalty actions against individuals acting as pilots, flight engineers, mechanics, or repairmen to the National Transportation Safety Board (NTSB). Proceedings against individuals acting as pilots, flight engineers, mechanics and repairmen, therefore, are adjudicated under the NTSB's Rules of Practice in Air Safety Proceedings, located in 49 CFR part 821.

This rulemaking adopts procedures under a new section of the FAA's regulations, 14 CFR 13.18, for initiating civil penalty actions adjudicated by the NTSB. It amends existing 14 CFR 13.16 to exclude actions covered under new § 13.18. It adds a new section, 14 CFR 13.14, that lists those provisions that, if violated, may result in a civil penalty being sought or assessed administratively. Section 13.14(c) also states that the amounts of civil penalties are periodically adjusted for inflation under the formula set by Congress in 28 U.S.C. 2461 note. We implemented this formula in 14 CFR part 13, subpart H. This regulation also makes other clarifying changes to part 13.

Although the FAA published the notice of proposed rulemaking (NPRM) almost 10 years ago, the final rule adopts procedural rules and publishes informational regulations. Therefore, another opportunity for notice and comment is not warranted.

Disposition of Comments

Three commenters responded to the NPRM, which the FAA issued on July 29, 1994 (59 FR 40192, Aug. 5, 1994). The first commenter questioned two aspects of the NPRM. Those aspects related to (1) which forum has jurisdiction of security screening cases involving pilots and (2) why the penalty for disrupting a flight crewmember's duties is less than the penalty for tampering with a smoke alarm device. The first comment is moot because Congress transferred responsibility for aviation security to the Department of Homeland Security. The second comment is beyond the scope of the NPRM because Congress set the penalty amounts in question, not the agency. In any event, in 49 U.S.C. 46318, Congress set a maximum penalty of $25,000 for certain violations involving interference with a crewmember.

The second commenter raised a number of concerns about the fairness of the proposed rule and the FAA's authority to assess civil penalties. All but one of this commenter's concerns were unresponsive to, or otherwise beyond the scope of, the rulemaking. The remaining comment was "[t]he way the system looks now, the first a person hears of a problem is when the government sends him/her a notice specifying a violation of the FARs with the amount they owe the gov[ernmen]t. That just is [not] fair and is not right." The commenter seemingly misunderstood the intent of the notice of proposed assessment. Contrary to the comment, the notice of proposed assessment does not constitute a finding of a violation. Nor does the notice impose a civil penalty. The notice of proposed assessment gives an alleged

[1] On December 12, 2003, Public Law 108–176, "Vision 100—Century of Aviation Reauthorization Act," (Vision 100) was signed into law. Among other things, Vision 100 modified the maximum amount of civil monetary penalties the FAA can administratively assess under 49 U.S.C. 46301(d). For violations occurring on or after December 12, 2003, the FAA now has authority to assess administratively a maximum civil penalty of $400,000 against persons other than individuals or small business concerns. For individuals and small business concerns, the maximum civil penalty the FAA can assess administratively remains $50,000.

violator notice of a violation being charged and the proposed sanction for that violation. Following the notice of proposed assessment, an alleged violator has an opportunity to speak with the agency informally and present evidence on the alleged violator's behalf before the FAA issues an order of assessment.

The third commenter raised the issue of stale complaint, arguing that the NTSB's 6-month stale complaint rule for certificate actions should apply to civil penalty actions against pilots, flight engineers, mechanics and repairmen. This comment is moot because the NTSB has adopted a rule extending its 6-month stale complaint rule to civil penalty actions against pilots, flight engineers, mechanics and repairmen. 59 FR 59050, 59051–59052 (Nov. 24, 1994).

Discussion of the Rule

Interpretation of "Individual Acting as a Pilot, Flight Engineer, Mechanic, or Repairman"

In the NPRM, the FAA proposed an interpretation of the phrase "a person acting in the capacity of a pilot, flight engineer, mechanic or repairman." When Congress recodified the FAA's statute, it changed this phrase to "an individual acting as a pilot, flight engineer, mechanic or repairman". Congress intended no substantive change. The only comment directed at the definition outlined in the NPRM was the objection that the proposed definition would allow the FAA decisionmaker to review security screening violations involving pilots. As stated above, that objection is moot due to the transfer of aviation security functions to the Department of Homeland Security.

The FAA interprets the phrase "an individual acting as a pilot, flight engineer, mechanic, or repairman" to refer to an individual who has engaged in conduct that involves the exercise of the privileges and duties of these certificates, regardless of whether that individual holds a valid pilot, flight engineer, mechanic, or repairman certificate.

In adopting this interpretation, the FAA considered whether an individual must hold a relevant certificate to obtain NTSB review under 49 U.S.C. 46301(d)(5). The FAA concluded that holding one of these certificates is not determinative because the phrase "acting as" describes the alleged violator in terms of the activities he or she performs, not the alleged violator's legal status. Therefore, it is the nature of the activity involved in the violation that determines whether the case falls within the scope of 49 U.S.C. 46301(d)(5).

Furthermore, if the Congress had intended to limit NTSB review of civil penalty actions to those against certificate holders, it would have drafted section 46301(d)(5)(A) differently. For example, section 46301(a)(5) distinguishes between civil penalty liability of an "individual" and of an "airman serving as an airman." The Congress' failure to use more specific language is evidence of its intent that "individual acting as a pilot, flight engineer, mechanic, or repairman" be given a noticeably broader construction than "holder."

The term "acting" may include the failure to act. For example, acting as a pilot, flight engineer, mechanic, or repairman includes failing to surrender a pilot, flight engineer, mechanic, or repairman certificate when it has been revoked, as required by 14 CFR 61.19(f), 63.15(c), or 65.15(c). As this example shows, the privileges and duties under the FAA's regulations extend beyond actually flying an aircraft or performing maintenance on an aircraft. Therefore, the NTSB also reviews these cases.

In the NPRM, the FAA proposed that "* * * any civil penalty action for violations by a person acting in the capacity of a flight instructor would be heard under the NTSB procedures." (59 FR 40193.) Even though the FAA specifically welcomed comments on the interpretation of "person acting in the capacity of a pilot * * *," the FAA received no comments on the flight instructor aspect of the interpretation. On further review, the statement in the NPRM would be, in some instances, inconsistent with the proposition that "* * * [i]t is the nature of the activity that triggers the applicability of" NTSB review. For example, a flight instructor usually is not exercising the privileges of a pilot certificate when the flight instructor gives ground training or executes or maintains pilot records. (*See* 14 CFR part 61, subpart H.) In addition, 49 U.S.C. 46301(d) does not refer to "acting as flight instructor." Therefore, NTSB review in cases involving a flight instructor certificate will arise only when the violation involves his or her exercise of pilot privileges.

An inspection authorization differs from a flight instructor certificate in that it is more like a rating on a mechanic certificate than a separate certificate. Both the NTSB and its predecessor, the Civil Aeronautics Board, have recognized the inspection authorization as a rating on the mechanic certificate. *Administrator* v. *Luster*, NTSB Order No. EA–3974, pp. 3–4 (Aug. 24, 1993); *Gene Rawdon*, 31 CAB 1167, 1168 (Sep. 9, 1960). The NTSB therefore reviews civil penalty actions involving an inspection authorization not because one must hold a mechanic certificate to obtain an inspection authorization, but because exercising the privileges and duties of the inspection authorization results in one exercising the privileges and duties of the mechanic certificate.

The mere fact that an individual holds a pilot, flight engineer, mechanic, or repairman certificate is not sufficient to vest jurisdiction in the NTSB to review a case. If an alleged violator is not exercising the privileges associated with one of these certificates in connection with the alleged violation, then the case will be reviewed by the FAA decisionmaker under section 46301(d)(7) even though the alleged violator happens to hold one or more of these certificates. For example, the FAA decisionmaker would review a case involving a passenger who interferes with a cabin or flight crewmember even if the passenger holds a pilot certificate because the passenger's conduct did not involve the exercise of the privileges of the passenger's pilot certificate.

Procedures

New 14 CFR 13.18 implements the statutory requirements for initiating cases that the NTSB reviews. Section 46301(d)(5)(A) of the FAA's statute provides that the Administrator may issue an order imposing a civil penalty against an individual acting as a pilot, flight engineer, mechanic, or repairman only after (1) advising the individual of the charges or any reason relied on by the FAA for the proposed action, and (2) providing the individual with an opportunity to answer the charges. Once the Administrator has issued an order, section 46301(d)(5)(B) authorizes the individual against whom it was issued to appeal the order to the NTSB. In addition, section 46301(d)(5)(D) provides that filing an appeal to the NTSB stays the Administrator's order. These procedural requirements are substantially similar to the procedural requirements set forth in 49 U.S.C. 44709(c) through (e) of the FAA's statute for non-emergency certificate actions.

In preparing the final rule, we have reorganized the subsections of new § 13.18 to reflect as closely as possible the actual step-by-step processing of a civil penalty action.

Applicability

New 14 CFR 13.18(a)(1) states the statutory authority for administratively assessing a civil penalty against an individual acting as a pilot, flight engineer, mechanic, or repairman. Under 49 U.S.C. 46301(d)(5)(B), the

NTSB reviews cases falling within the scope of 14 CFR 13.18. Section 13.18(a)(2) states when a United States district court has exclusive jurisdiction of a civil penalty action against a pilot, flight engineer, mechanic, or repairman.

Definitions and Delegations

The FAA did not receive any comments on proposed § 13.18 (b) and (d), which contained definitions and delegations of authority, respectively. With some minor changes to paragraph (d) to improve clarity, including separating the delegations into numbered subparagraphs, these sections are adopted as § 13.18(b) and (c), respectively.

Notice and Informal Process

Under new § 13.18(d), the FAA initiates a civil penalty action against an individual acting as a pilot, flight engineer, mechanic, or repairman by issuing a notice of proposed assessment. The notice contains a statement of the charges and the amount of the proposed civil penalty. The notice also sets forth the procedures for responding to the notice. Subsections 13.18(d)(1)–(4) state the specific options for responding to the notice. The options are (1) submitting the amount of proposed civil penalty, (2) answering the charges in writing, (3) submitting a written request for an informal conference with an agency attorney and submitting relevant information or documents, or (4) requesting that an order be issued in accordance with the notice of proposed assessment so that the individual charged may appeal to the NTSB. The notice of proposed assessment and the opportunity to respond using informal procedures satisfy the statutory requirement in section 46301(d)(5)(A) of the FAA's statute to advise alleged violators of the charges and give them an opportunity to answer.

Order of Assessment

After the informal response procedures outlined above are completed, the FAA considers all information the alleged violator has supplied. If the parties have not agreed to resolve the case, the FAA will issue an order of assessment under new § 13.18(f). Before issuing the order of assessment, the FAA considers all the information available in the record at that point. The individual charged may then appeal the order of assessment to the NTSB, as provided in 14 CFR 13.18(g). These procedures satisfy the requirements of 49 U.S.C. 46301(d)(5)(B). As stated previously, once the individual charged has filed a notice of appeal with the NTSB, the case is subject to the NTSB's Rules of Practice in Air Safety Proceedings, located in 49 CFR part 821.

Under new § 13.18(e), the FAA may also issue an order of assessment if the individual charged does not respond to the notice of proposed assessment within 15 days. Furthermore, if the individual does not file a notice of appeal with the NTSB within the time provided by the NTSB's rules of practice, the order of assessment becomes final.

Appeal to the NTSB

Under 14 CFR 13.18(g), the alleged violator may file an appeal from an order of assessment with the NTSB. A timely appeal to the NTSB stays the effectiveness of the order of assessment until the NTSB issues a final decision in the matter, as required by 49 U.S.C. 46301(d)(5)(D).

Exhaustion of Administrative Remedies

Section 13.18(h) states the provision for judicial review of a final decision of the NTSB provided for in 49 U.S.C. 46301(d)(6). Appeal is to a United States court of appeals for the circuit in which the individual charged resides or has his or her principal place of business or to the United States Court of Appeals for the District of Columbia Circuit. Section 13.18(h) also specifies, based on 49 U.S.C. 46110(d), that the Administrator's order of assessment is not a final order for the purpose of judicial review unless it has first been appealed to the NTSB.

Compromise Orders

Section 46301(i)(1) of the FAA's statute authorizes the Secretary of Transportation to compromise the amount of a civil penalty. The Secretary has delegated this authority to the Administrator in 49 CFR 1.47. New § 13.18(i)(1) provides agency attorneys with the authority to compromise civil penalty assessment actions initiated under 49 U.S.C. 46301(d)(5) against an individual acting as a pilot, flight engineer, mechanic, or repairman with no finding of a violation. New § 13.18(i)(2) authorizes agency attorneys to compromise the amount of a civil penalty proposed or assessed in an order with a finding of a violation as well.

Existing § 13.16(l)(1), on which § 13.18(i) is modeled, does not specifically require the alleged violator either to pay the civil penalty or sign a promissory note before a compromise order is issued. As stated in the NPRM, the FAA has experienced problems with this approach. In some cases, when the FAA did not receive payment before it issued the compromise order, the alleged violator has subsequently failed to pay the civil penalty. Also, if the person has not signed a promissory note agreeing to the amount of the penalty and a payment schedule, a risk exists that the person will dispute whether the amount in the compromise order is the amount the parties agreed on, complicating collection procedures. Debt collection procedures often are time-consuming and costly, and may not result in recovery of the full amount of the debt.

To avoid these problems, the FAA proposed in the NPRM that it will not issue a compromise order under new § 13.18(i) unless the alleged violator has prepaid the civil penalty or has signed a promissory note providing for installment payments. The FAA did not receive any comments on this issue. We are therefore adopting these changes as proposed. The FAA also amends current § 13.16(l) to incorporate these changes; it is redesignated as § 13.16(n).

Payment of Civil Penalties

Under 14 CFR 13.18(j), the individual charged must pay the civil penalty assessed in an order of assessment within 30 days, unless the individual has filed a timely notice of appeal with the NTSB. In cases that have been appealed, § 13.18(j) further requires the individual charged to pay the civil penalty within 30 days after a final order of the Board or the Court of Appeals affirms the order of assessment in whole or in part.

Debt Collection

The NPRM included a provision, now located in new § 13.18(k), for collection of civil penalties. That proposed subsection was copied nearly verbatim from current 14 CFR 13.16(j). The provision was not discussed in the preamble to the NPRM. In reviewing the FAA's actual debt collection procedures, however, it appears that § 13.16(j), and therefore proposed § 13.18(i), do not reflect all methods the FAA may use to collect a delinquent debt. Following the enactment of the Debt Collection Act of 1996, the FAA generally transfers delinquent debts to the Department of the Treasury for collection. In addition, we have deleted reference to failure to pay within 60 days. The timeframe for payment after which a debt becomes delinquent is subject to change. In addition, an order of assessment, like an order assessing civil penalty, states when the debt imposed by the order may become delinquent and, if a delinquency notice is issued, it states what actions to recover the debt may be taken and

timeframe for taking them. Therefore, the FAA has determined that both current §§ 13.16(j) and 13.18(k) should be revised to reflect more generally the agency's practice to use all methods under the law to collect delinquent debts, which includes referring a case to the United States Attorney General for collection. Current § 13.16(j) is redesignated as § 13.16(l).

Changes to 14 CFR Part 13, Subpart G

The preamble to the NPRM proposed amending certain sections of the Rules of Practice in FAA Civil Penalty Actions. The FAA did not receive any comments on the proposed amendments. The FAA therefore adopts these amendments as proposed in the NPRM.

Civil Penalties Other Than Administrative Assessment

The FAA did not receive any comments on the proposed revision of the heading for 14 CFR 13.15. We are therefore adopting it as proposed.

Conforming Changes in the Final Rule That Were Not Proposed in the NPRM

Since the NPRM was issued, Congress has recodified the Federal transportation law, increased the amounts of civil penalties available for certain violations, provided a requirement for agencies to periodically adjust for inflation the amount of the minimum and maximum civil penalties for statutes the agencies enforce, and added provisions to the FAA's statute that include new authority to seek or administratively assess civil penalties. The FAA's Office of the Chief Counsel has also undergone certain organizational changes, including the creation of a new Deputy Chief Counsel for Operations position. We are conforming §§ 13.15, 13.16, and 13.18 to these changes. As discussed elsewhere, we are also adopting a new § 13.14, which among other things, lists in one place the statutory provisions for which the FAA has authority to seek or administratively assess civil penalties.

Civil Penalty Assessments Against Persons Other Than Individuals Acting as Pilots, Flight Engineers, Mechanics, and Repairmen

Applicability

Existing § 13.16(a) contains an obsolete list of the statutory provisions authorizing the FAA to assess civil penalties. In the NPRM, the FAA proposed to update the list to provide more information. Proposed § 13.16(a)(1) would have set forth a new list of the statutory provisions authorizing the FAA to assess civil penalties. Proposed § 13.16(a)(2) would have set forth the maximum amount of civil penalties that could be assessed. Because of recent changes in the FAA's governing statute and our adoption of regulations governing the periodic adjustment for inflation of civil monetary penalties, in compliance with 28 U.S.C. 2461 note, we have concluded that proposed § 13.16(a)(2) would be redundant. Accordingly, we are deleting proposed § 13.16(a)(2) from the final rule. Because we are adopting a new 14 CFR 13.14, discussed below, we are revising the remainder of § 13.16(a) to state that the FAA uses the procedures in § 13.16 when it assess a civil penalty against a person other than an individual acting as a pilot, flight engineer, mechanic or repairman for a violation cited in 49 U.S.C. 46301(d)(2) or 47531. We are adding a new paragraph (b) indicating when the United States district courts have exclusive jurisdiction. We are adding a new § 13.16(c) for violations of 49 U.S.C. chapter 51, the Federal hazardous materials transportation law. We are revising current § 13.16(d) to delete references to the statutes the FAA enforces and redesignating it as § 13.16(f). We are also redesignating the remaining paragraphs of current § 13.16 to accommodate the addition of new §§ 13.16(b) and 13.16(c). These actions are simply informational or editorial in nature. The agency has, therefore, determined that prior notice and opportunity for comment is unnecessary under section 553 of the Administrative Procedure Act.

Change to § 13.16(k). Judicial Review—Jurisdiction in Actions for Violations of the Federal Hazardous Materials Transportation Law

Under 49 U.S.C. 46110, exclusive jurisdiction for judicial review of final orders of the Administrator issued under the FAA's statute is in the United States courts of appeals. Current § 13.16(k) incorporates that statutory review provision.

Current § 13.16(k) makes no distinction between cases involving the FAA's governing statute and the Federal hazardous materials transportation law, 49 U.S.C. chapter 51, for purposes of judicial review. The Federal hazardous materials transportation law itself, however, is silent on the issue of judicial review. That statute's silence on the issue of judicial review results in judicial review in an appropriate United States district court under 5 U.S.C. 701 *et seq.* and 28 U.S.C. 1331. Section 702 of title 5, United States Code, states that "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action with the meaning of a relevant statute, is entitled to judicial review." Section 1331 of title 28, United States Code, states that "[t]he district courts shall have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States." Because we pursue hazardous materials violations under the Federal hazardous materials transportation law in 49 U.S.C. chapter 51, we are amending current § 13.16(k) to add a separate judicial review provision for such actions. We are also redesignating § 13.16(k) as § 13.16(m). Existing § 13.16(k) will become § 13.16(m)(1), and new § 13.16(m)(2) will state that judicial review of final agency orders under 49 U.S.C. chapter 51 is available in an appropriate district court of the United States, in accordance with 5 U.S.C. 701 *et seq.* and 28 U.S.C. 1331. Although this change was not included in the NPRM, the FAA finds good cause for not conducting notice-and-comment rulemaking on it based on the need to conform our rules to the law.

References to the FAA's Governing Statute and the Federal Hazardous Materials Transportation Law in §§ 13.15 and 13.16

The FAA published a final rule on December 28, 1995 (60 FR 67254), revising the authority citations for its regulations in Chapter I of Title 14 of the Code of Federal Regulations (14 CFR parts 1–199), including the authority citation for part 13. In adopting the revised authority citations, the FAA stated:

> In July 1994, the Federal Aviation Act of 1958 and numerous other pieces of legislation affecting transportation in general were recodified. The statutory material became "positive law" and was recodified at 49 U.S.C. 1101 *et seq.*
>
> The Federal Aviation Administration is amending the authority citations for its regulations in Chapter I of 14 CFR to reflect the recodification of its statutory authority. No substantive change was intended to any statutory authority by the recodification, and no substantive change is introduced to any regulation by this change.
>
> * * * * *
>
> Because of the editorial nature of this change, it has been determined that prior notice is unnecessary under the Administrative Procedure Act. * * *

In line with that revision to the authority citation to part 13, we are amending current §§ 13.15 and 13.16 to bring the statutory citations they contain into conformity with the recodification and the revised authority citation. The statutory citations in new § 13.18 also conform to the recodification and the revised authority citation. This action,

like the revision to the authority citations, is editorial in nature. The agency has, therefore, determined that prior notice and opportunity for comment is unnecessary under section 553 of the Administrative Procedure Act.

Changes in Position Titles in §§ 13.15, 13.16 and 13.18

The NPRM had proposed amending part 13 with respect to delegations of authority to reflect the reorganization of the former Regulations and Enforcement Division into two separate divisions. The proposed amendments are no longer necessary as the FAA published a final rule reflecting organizational changes and delegations of authority in various parts of the FAA's regulations on September 4, 1997 (62 FR 46864).

On March 3, 2004, however, the FAA published Notice 1100.290. Notice 1100.290 announces the realignment of functions and responsibilities within the Office of the Chief Counsel. Among other things, the new organizational structure created the position of Deputy Chief Counsel for Operations. Based on Notice 1100.290, we are revising §§ 13.15(b), (c)(1), (c)(3), 13.16(e)(1–4), and 13.18(d)(1–3) to replace references to the Deputy Chief Counsel with references to the Deputy Chief Counsel for Operations.

Other Changes

In preparing the final rule, we concluded that it would be helpful to list in one place those provisions of the statutes the FAA enforces, and rules, regulations, or orders issued under those statutes, for which civil penalties may be sought or administratively assessed. We also concluded that it would be helpful to include a statement indicating that the maximum amounts of civil penalties are subject to periodic adjustment for inflation under the formula established by Congress. Therefore, we are adopting a new section, 14 CFR 13.14. We have concluded that notice and comment are unnecessary because this new section does no more than list the applicable statutory provisions and states that Congress has established a formula for periodically adjusting the maximum amounts of civil penalties. That formula is implemented in 14 CFR part 13, subpart H.

Economic Assessment, Regulatory Flexibility Determination, International Trade Impact Assessment, and Unfunded Mandates Assessment

Proposed changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 directs that each Federal agency may propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (19 U.S.C. 2531–2533) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, this Trade Act requires agencies to consider international standards and, where appropriate, that they be the basis for U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $120.7 million or more annually, adjusted for inflation.

Regulatory Evaluation Summary

The FAA believes that the procedural changes adopted in this rule conform the existing procedural rules to amendments made in the FAA's statute, and clarify existing rules where necessary. The changes do not, in economic terms, alter the basic processes by which civil penalties are assessed within the agency. For this reason, a full Regulatory Evaluation is not warranted. This regulatory evaluation examines the potential costs and benefits of the amendments to part 13.

Benefits

The potential benefits of this rule include clarifying the rule and explaining in detail how portions of the Administrator's administrative civil penalty assessment authority are implemented. These changes will provide potentially affected aviation parties (*e.g.*, pilots, flight engineers, mechanics, and repairmen) with a better understanding of the civil penalty process.

Costs

The potential costs of the rule are zero because it consists only of procedural and clarifying changes to part 13. The procedural changes do no more than explain how the requirements of the Administrator's administrative civil penalty assessment authority under the FAA's statute and other statutes are implemented. The changes do not impose new economic requirements on potentially affected parties. The clarifying changes will enhance the public's comprehension of the civil penalty assessment process.

International Trade Impact Assessment

The rule represents procedural and clarifying changes only. These changes do not impose any costs on either U.S. or foreign operators. Therefore, a competitive trade disadvantage will not be incurred by U.S. operators abroad or foreign operators in the United States.

Regulatory Flexibility Determination

Under the Regulatory Flexibility Act of 1980, the FAA certifies that the rule will not have a significant economic impact, positive or negative, on a substantial number of small entities because the rule addresses procedures for initiating civil penalty actions against persons who have violated the statutes the FAA enforces, or rules, regulations, or orders issued under those statutes. Such changes do not impose any cost burdens or result in any cost savings.

Unfunded Mandates Assessment

The Unfunded Mandates Reform Act of 1995 (the Act) is intended, among other things to curb the practice of imposing unfunded Federal mandates on State, local, and tribal governments. Title II of the Act requires each Federal agency to prepare a written statement assessing the effects of any Federal Mandate in a proposed or final agency rule that may result in an expenditure of $100 million or more (adjusted annually for inflation) in any 1 year by State, local, and tribal governments, in the aggregate, or by the private sector. Such a mandate is deemed to be a "significant regulatory action." The FAA currently uses an inflation-adjusted value of $120.7 million in lieu of $100 million.

This final rule does not contain such a mandate. The requirements of Title II do not apply.

Federalism Implications

This amendment does 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. The respondents affected by the new procedures are private persons, not state governments. Therefore, under Executive Order 12612, preparation of a federalism assessment is not warranted.

Paperwork Reduction Act

This rule does not contain any information collection requests requiring approval of the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1980 (Pub. L. 96–511). There are no requirements for information collection associated with this rule.

Conclusion

For the reasons discussed in the preamble, and based on the findings of the Regulatory Flexibility Determination and the International Trade Analysis, the FAA has determined that this regulation is not economically significant under Executive Order 12866. Although there has been significant public interest in the FAA's rules of practice in civil penalty assessment actions in the past, the FAA has determined that this regulation is a nonsignificant regulatory action under the Executive Order. This regulation is considered nonsignificant under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). In addition, the FAA certifies that this regulation 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. In view of the minimal economic impact of this final rule, a full regulatory evaluation is unnecessary.

List of Subjects in 14 CFR Part 13

Administrative practice and procedure, Air transportation, Hazardous materials transportation, Investigations, Law enforcement, Penalties.

The Amendments

■ Therefore, the Federal Aviation Administration amends part 13 of the Federal Aviation Regulations, as follows:

PART 13—INVESTIGATIVE AND ENFORCEMENT PROCEDURES

■ 1. Revise the authority citation for part 13 to read as follows:

Authority: 18 U.S.C. 6002; 28 U.S.C. 2461 (note); 49 U.S.C. 106(g), 5121–5124, 40113–40114, 44103–44106, 44702–44703, 44709–44710, 44713, 46101–46110, 46301–46316, 46318, 46501–46502, 46504–46507, 47106, 47111, 47122, 47306, 47531–47532; 49 CFR 1.47.

■ 2. Add § 13.14 to part 13 to read as follows:

§ 13.14 Civil penalties: General.

(a) Any person who violates chapter 401 (except sections 40103(a) and (d), 40105, 40116, and 40117), chapter 441 (except section 44109), section 44502(b) or (c), chapter 447 (except section 44717 and 44719–44723), chapter 451, 46301(b), 46302–46303, 46318, 46319, 47528–47530 of Title 49 of the United States Code, or any rule, regulation, or order issued thereunder, is subject to a civil penalty.

(b) Any person who violates any of the following statutory provisions, or any rule, regulation, or order issued thereunder, is subject to a civil penalty of not more than the amount specified in 49 U.S.C. chapter 463 for each violation:

(1) Chapter 401 (except sections 40103(a) and (d), 40105, 40116, and 40117);

(2) Chapter 441 (except section 44109);

(3) Section 44502(b) or (c);

(4) Chapter 447 (except sections 44717 and 44719–44723);

(5) Chapter 451;

(6) Sections 46301(b), 46302, 46303, 46318, or 46319; or

(7) Sections 47528 through 47530.

(c) Any person who knowingly commits an act in violation of 49 U.S.C. chapter 51 or a regulation prescribed or order issued under that chapter, is subject to a civil penalty under 49 U.S.C. 5123.

(d) The minimum and maximum amounts of civil penalties for violations of the statutory provisions specified in paragraphs (a) and (b) of this section, or rules, regulations, or orders issued thereunder, are periodically adjusted for inflation in accordance with the formula established in 28 U.S.C. 2461 note and implemented in 14 CFR part 13, subpart H.

■ 3. In § 13.15 revise the section heading, paragraphs (a), (b), (c) introductory text, (c)(1), (c)(3), and (c)(5), to read as follows:

§ 13.15 Civil penalties: Other than by administrative assessment.

(a) The FAA uses the procedures in this section when it seeks a civil penalty other than by the administrative assessment procedures in §§ 13.16 or 13.18.

(b) The authority of the Administrator, under 49 U.S.C. chapter 463, to seek a civil penalty for a violation cited in § 13.14(a), and the ability to refer cases to the United States Attorney General, or the delegate of the Attorney General, for prosecution of civil penalty actions sought by the Administrator is delegated to the Chief Counsel; the Deputy Chief Counsel for Operations; the Assistant Chief Counsel for Enforcement; the Assistant Chief Counsel, Europe, Africa, and Middle East Area Office; the Regional Counsel; the Aeronautical Center Counsel; and the Technical Center Counsel. This delegation applies to cases involving:

(1) An amount in controversy in excess of:

(i) $50,000, if the violation was committed by any person before December 12, 2003;

(ii) $400,000, if the violation was committed by a person other than an individual or small business concern on or after December 12, 2003;

(iii) $50,000, if the violation was committed by an individual or small business concern on or after December 12, 2003; or

(2) An in rem action, seizure of aircraft subject to lien, suit for injunctive relief, or for collection of an assessed civil penalty.

(c) The Administrator may compromise any civil penalty proposed under this section, before referral to the United States Attorney General, or the delegate of the Attorney General, for prosecution.

(1) The Administrator, through the Chief Counsel; the Deputy Chief Counsel for Operations; the Assistant Chief Counsel for Enforcement; the Assistant Chief Counsel, Europe, Africa, and Middle East Area Office; the Regional Counsel; the Aeronautical Center Counsel; or the Technical Center Counsel sends a civil penalty letter to the person charged with a violation cited in § 13.14(a). The civil penalty letter contains a statement of the charges, the applicable law, rule, regulation, or order, the amount of civil penalty that the Administrator will accept in full settlement of the action or an offer to compromise the civil penalty.

* * * * *

(3) If the person charged with the violation offers to compromise for a specific amount, that person must send to the agency attorney a certified check or money order for that amount, payable to the Federal Aviation Administration. The Chief Counsel; the Deputy Chief Counsel for Operations; the Assistant Chief Counsel for Enforcement; the Assistant Chief Counsel, Europe, Africa, and Middle East Area Office; the Regional Counsel; Aeronautical Center Counsel; or the Technical Center Counsel may accept the certified check or money order or may refuse and return the certified check or money order.

* * * * *

(5) If the parties cannot agree to compromise the civil penalty action or the offer to compromise is rejected and the certified check or money order submitted in compromise is returned, the Administrator may refer the civil penalty action to the United States Attorney General, or the delegate of the

Attorney General, to begin proceedings in a United States district court, pursuant to the authority in 49 U.S.C. 46305, to prosecute and collect the civil penalty.

* * * * *

■ 4. Amend § 13.16 as follows:
■ a. Revise the section heading and paragraph (a);
■ b. Redesignate paragraphs (j) through (l) as (l) through (n) and revise newly designated paragraphs (l), (m), and (n) introductory text, (n)(1) introductory text, and (n)(1)(i);
■ c. Redesignate paragraphs (e) through (i) as (g) through (k);
■ d. Redesignate paragraphs (c) and (d) as (e) and (f), and revise newly redesignated paragraph (e) and the first sentence of paragraph (f) introductory text;
■ e. Redesignate paragraph (b) as paragraph (d); and
■ f. Add paragraphs (b) and (c).
■ The revisions and additions read as follows:

§ 13.16 Civil penalties: Administrative assessment against a person other than an individual acting as a pilot, flight engineer, mechanic, or repairman. Administrative assessment against all persons for hazardous materials violations.

(a) The FAA uses these procedures when it assesses a civil penalty against a person other than an individual acting as a pilot, flight engineer, mechanic, or repairman for a violation cited in 49 U.S.C. 46301(d)(2) or 47531.

(b) *District court jurisdiction.* Notwithstanding the provisions of paragraph (a) of this section, the United States district courts have exclusive jurisdiction of any civil penalty action initiated by the FAA for violations described in those paragraphs, under 49 U.S.C. 46301(d)(4), if—

(1) The amount in controversy is more than $50,000 for a violation committed by any person before December 12, 2003;

(2) The amount in controversy is more than $400,000 for a violation committed by a person other than an individual or small business concern on or after December 12, 2003;

(3) The amount in controversy is more than $50,000 for a violation committed by an individual or a small business concern on or after December 12, 2003;

(4) The action is in rem or another action in rem based on the same violation has been brought;

(5) The action involves an aircraft subject to a lien that has been seized by the Government; or

(6) Another action has been brought for an injunction based on the same violation.

(c) *Hazardous materials violations.* The FAA may assess a civil penalty against any person who knowingly commits an act in violation of 49 U.S.C. chapter 51 or a regulation prescribed or order issued under that chapter, under 49 U.S.C. 5123 and 49 CFR 1.47(k). An order assessing a civil penalty for a violation under 49 U.S.C. chapter 51, or a rule, regulation, or order issued thereunder, is issued only after the following factors have been considered:

(1) The nature, circumstances, extent, and gravity of the violation;

(2) With respect to the violator, the degree of culpability, any history of prior violations, the ability to pay, and any effect on the ability to continue to do business; and

(3) Such other matters as justice may require.

* * * * *

(e) *Delegation of authority.* (1) The authority of the Administrator under 49 U.S.C. 46301(d), 47531, and 5123, and 49 CFR 1.47(k) to initiate and assess civil penalties for a violation of those statutes or a rule, regulation, or order issued thereunder, is delegated to the Deputy Chief Counsel for Operations; the Assistant Chief Counsel for Enforcement; the Assistant Chief Counsel, Europe, Africa, and Middle East Area Office; the Regional Counsel; the Aeronautical Center Counsel; and the Technical Center Counsel.

(2) The authority of the Administrator under 49 U.S.C. 5123, 49 CFR 1.47(k), 49 U.S.C. 46301(d), and 49 U.S.C. 46305 to refer cases to the Attorney General of the United States, or the delegate of the Attorney General, for collection of civil penalties is delegated to the Deputy Chief Counsel for Operations; the Assistant Chief Counsel for Enforcement; Assistant Chief Counsel, Europe, Africa, and Middle East Area Office; the Regional Counsel; the Aeronautical Center Counsel; and the Technical Center Counsel.

(3) The authority of the Administrator under 49 U.S.C. 46301(f) to compromise the amount of a civil penalty imposed is delegated to the Deputy Chief Counsel for Operations; the Assistant Chief Counsel for Enforcement; Assistant Chief Counsel, Europe, Africa, and Middle East Area Office; the Regional Counsel; the Aeronautical Center Counsel; and the Technical Center Counsel.

(4) The authority of the Administrator under 49 U.S.C. 5123(e) and (f) and 49 CFR 1.47(k) to compromise the amount of a civil penalty imposed is delegated to the Deputy Chief Counsel for Operations; the Assistant Chief Counsel for Enforcement; Assistant Chief Counsel, Europe, Africa, and Middle East Area Office; the Regional Counsel; the Aeronautical Center Counsel; and the Technical Center Counsel.

(f) *Notice of proposed civil penalty.* A civil penalty action is initiated by sending a notice of proposed civil penalty to the person charged with a violation or on the agent for service for the person under 49 U.S.C. 46103.

* * *

* * * * *

(l) *Collection of civil penalties.* If an individual does not pay a civil penalty imposed by an order assessing civil penalty or other final order, the Administrator may take action provided under the law to collect the penalty.

(m) *Exhaustion of administrative remedies and judicial review.* (1) *Cases under the FAA statute.* A party may petition for review only of a final decision and order of the FAA decisionmaker to the courts of appeals of the United States for the circuit in which the individual charged resides or has his or her principal place of business or the United States Court of Appeals for the District of Columbia Circuit, under 49 U.S.C. 46110, 46301(d)(6), and 46301(g). Neither an initial decision nor order issued by an administrative law judge that has not been appealed to the FAA decisionmaker, nor an order compromising a civil penalty action, may be appealed under those sections.

(2) *Cases under the Federal hazardous materials transportation law.* A party may seek judicial review only of a final decision and order of the FAA decisionmaker involving a violation of the Federal hazardous materials transportation law or a regulation or order issued thereunder to an appropriate district court of the United States, under 5 U.S.C. 703 and 704 and 28 U.S.C. 1331. Neither an initial decision or order issued by an administrative law judge that has not been appealed to the FAA decisionmaker, nor an order compromising a civil penalty action, may be appealed under these sections.

(n) *Compromise.* The FAA may compromise the amount of any civil penalty imposed under this section, under 49 U.S.C. 5123(e), 46301(f), 46302(b), 46303(b), or 46318 at any time before referring the action to the United States Attorney General, or the delegate of the Attorney General, for collection.

(1) An agency attorney may compromise any civil penalty action where a person charged with a violation agrees to pay a civil penalty and the FAA agrees not to make a finding of violation. Under such agreement, a

compromise order is issued following the payment of the agreed-on amount or the signing of a promissory note. The compromise order states the following:

(i) The person has paid a civil penalty or has signed a promissory note providing for installment payments.

* * * * *

■ 5. Add § 13.18 to Part 13 to read as follows:

§ 13.18 Civil penalties: Administrative assessment against an individual acting as a pilot, flight engineer, mechanic, or repairman.

(a) *General.* (1) This section applies to each action in which the FAA seeks to assess a civil penalty by administrative procedures against an individual acting as a pilot, flight engineer, mechanic, or repairman, under 49 U.S.C. 46301(d)(5), for a violation listed in 49 U.S.C. 46301(d)(2). This section does not apply to a civil penalty assessed for violation of 49 U.S.C. chapter 51, or a rule, regulation, or order issued thereunder.

(2) *District court jurisdiction.* Notwithstanding the provisions of paragraph (a)(1) of this section, the United States district courts have exclusive jurisdiction of any civil penalty action involving an individual acting as a pilot, flight engineer, mechanic, or repairman for violations described in that paragraph, under 49 U.S.C. 46301(d)(4), if:

(i) The amount in controversy is more than $50,000.

(ii) The action involves an aircraft subject to a lien that has been seized by the Government; or

(iii) Another action has been brought for an injunction based on the same violation.

(b) *Definitions.* As used in this part, the following definitions apply:

(1) *Flight engineer* means an individual who holds a flight engineer certificate issued under part 63 of this chapter.

(2) *Individual acting as a pilot, flight engineer, mechanic, or repairman* means an individual acting in such capacity, whether or not that individual holds the respective airman certificate issued by the FAA.

(3) *Mechanic* means an individual who holds a mechanic certificate issued under part 65 of this chapter.

(4) *Pilot* means an individual who holds a pilot certificate issued under part 61 of this chapter.

(5) *Repairman* means an individual who holds a repairman certificate issued under part 65 of this chapter.

(c) *Delegation of authority.* (1) The authority of the Administrator under 49 U.S.C. 46301(d)(5), to initiate and assess civil penalties is delegated to the Chief Counsel; the Deputy Chief Counsel for Operations; the Assistant Chief Counsel for Enforcement; Assistant Chief Counsel, Europe, Africa, and Middle East Area Office; the Regional Counsel; the Aeronautical Center Counsel; and the Technical Center Counsel.

(2) The authority of the Administrator to refer cases to the Attorney General of the United States, or the delegate of the Attorney General, for collection of civil penalties is delegated to the Chief Counsel; the Deputy Chief Counsel for Operations; the Assistant Chief Counsel for Enforcement; Assistant Chief Counsel, Europe, Africa, and Middle East Area Office; the Regional Counsel; the Aeronautical Center Counsel; and the Technical Center Counsel.

(3) The authority of the Administrator to compromise the amount of a civil penalty under 49 U.S.C. 46301(f) is delegated to the Chief Counsel; the Deputy Chief Counsel for Operations; the Assistant Chief Counsel for Enforcement; Assistant Chief Counsel, Europe, Africa, and Middle East Area Office; the Regional Counsel; the Aeronautical Center Counsel; and the Technical Center Counsel.

(d) *Notice of proposed assessment.* A civil penalty action is initiated by sending a notice of proposed assessment to the individual charged with a violation specified in paragraph (a) of this section. The notice of proposed assessment contains a statement of the charges and the amount of the proposed civil penalty. The individual charged with a violation may do the following:

(1) Submit the amount of the proposed civil penalty or an agreed-on amount, in which case either an order of assessment or a compromise order will be issued in that amount.

(2) Answer the charges in writing.

(3) Submit a written request for an informal conference to discuss the matter with an agency attorney and submit relevant information or documents.

(4) Request that an order be issued in accordance with the notice of proposed assessment so that the individual charged may appeal to the National Transportation Safety Board.

(e) *Failure to respond to notice of proposed assessment.* An order of assessment may be issued if the individual charged with a violation fails to respond to the notice of proposed assessment within 15 days after receipt of that notice.

(f) *Order of assessment.* An order of assessment, which assesses a civil penalty, may be issued for a violation described in paragraph (a) of this section after notice and an opportunity to answer any charges and be heard as to why such order should not be issued.

(g) *Appeal.* Any individual who receives an order of assessment issued under this section may appeal the order to the National Transportation Safety Board. The appeal stays the effectiveness of the Administrator's order.

(h) *Exhaustion of administrative remedies.* An individual substantially affected by an order of the NTSB or the Administrator may petition for review only of a final decision and order of the National Transportation Safety Board to a court of appeals of the United States for the circuit in which the individual charged resides or has his or her principal place of business or the United States Court of Appeals for the District of Columbia Circuit, under 49 U.S.C. 46110 and 46301(d)(6). Neither an order of assessment that has not been appealed to the National Transportation Board, nor an order compromising a civil penalty action, may be appealed under those sections.

(i) *Compromise.* The FAA may compromise any civil penalty action initiated under this section, in accordance with 49 U.S.C. 46301(f).

(1) An agency attorney may compromise any civil penalty action where an individual charged with a violation agrees to pay a civil penalty and the FAA agrees to make no finding of violation. Under such agreement, a compromise order is issued following the payment of the agreed-on amount or the signing of a promissory note. The compromise order states the following:

(i) The individual has paid a civil penalty or has signed a promissory note providing for installment payments;

(ii) The FAA makes no finding of violation; and

(iii) The compromise order will not be used as evidence of a prior violation in any subsequent civil penalty proceeding or certificate action proceeding.

(2) An agency attorney may compromise the amount of any civil penalty proposed or assessed in an order.

(j) *Payment.* (1) An individual must pay a civil penalty by:

(i) Sending a certified check or money order, payable to the Federal Aviation Administration, to the FAA office identified in the order of assessment, or

(ii) Making an electronic funds transfer according to the directions specified in the order of assessment.

(2) The civil penalty must be paid within 30 days after service of the order of assessment, unless an appeal is filed with the National Transportation Safety Board. The civil penalty must be paid within 30 days after a final order of the

Board or the Court of Appeals affirms the order of assessment in whole or in part.

(k) *Collection of civil penalties.* If an individual does not pay a civil penalty imposed by an order of assessment or other final order, the Administrator may take action provided under the law to collect the penalty.

■ 6. In § 13.201 remove paragraph (c) and revise paragraph (a) to read as follows:

§ 13.201 Applicability.

(a) This subpart applies to all civil penalty actions initiated under § 13.16 of this part in which a hearing has been requested.

* * * * *

■ 7. In § 13.233 revise paragraphs (b) introductory text, (1) and (3), and the first sentence of paragraph (j) introductory text to read as follows:

§ 13.233 Appeal from initial decision.

* * * * *

(b) *Issues on appeal.* In any appeal from a decision of an administrative law judge, the FAA decisionmaker considers only the following issues:

(1) Whether each finding of fact is supported by a preponderance of reliable, probative, and substantial evidence;

* * * * *

(3) Whether the administrative law judge committed any prejudicial errors that support the appeal.

* * * * *

(j) *FAA decisionmaker's decision on appeal.* The FAA decisionmaker will review the record, the briefs on appeal, and the oral argument, if any, when considering the issues on appeal. * * *

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Issued in Washington, DC, on September 19, 2004.

Marion C. Blakey,

Administrator.

[FR Doc. 04–22276 Filed 10–1–04; 8:45 am]

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Federal Register

Monday,
October 4, 2004

Part V

Federal Communications Commission

47 CFR Part 15, et al.
Second Periodic Review of the Commission's Rules and Policies Affecting the Conversion To Digital Television; Final Rule

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 15, 27, 73 and 90

[MB Docket No. 03–15; FCC 04–192]

Second Periodic Review of the Commission's Rules and Policies Affecting the Conversion To Digital Television

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Commission adopts final rules that resolve several issues important to the rapid conversion of the nation's broadcast television system from analog to digital television. The Order adopts a multi-step channel election and repacking process through which broadcast licensees and permittees ("licensees") will select their ultimate DTV channel inside the core. The Order also adopts deadlines for replication and maximization; provides for flash cut transition for satellite stations; eliminates simulcasting requirements; mandates broadcaster use of PSIP; clarifies rules concerning closed captioning and v-chip functionalities; amends interference protection rules; and permits limited use of distributed transmission systems.

DATES: Effective November 3, 2004 except for § 73.1201 which contains information collection requirements that are not effective until approved by the Office of Management and Budget. The FCC will publish a document in the **Federal Register** announcing the effective date for those sections. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register, as of November 3, 2004.

FOR FURTHER INFORMATION CONTACT: Evan Baranoff, *Evan.Baranoff@fcc.gov*, (202) 418–7142. For additional information concerning the Paperwork Reduction Act information collection requirements contained in this document, contact Leslie Smith, Federal Communications Commission, Room 1–A804, 445 12th Street, SW., Washington, DC 20554, or via the Internet to *Leslie.Smith@fcc.gov*.

SUPPLEMENTARY INFORMATION: This is a summary of the Federal Communications Commission's Report and Order FCC 04–192, adopted on August 4, 2004 and released on September 7, 2004. The full text of this document is available for inspection and copying during normal business hours in the FCC Reference Center, 445 12th Street, SW., Washington, DC 20554. The complete text may be purchased from the Commission's copy contractor, Qualex International, 445 12th Street, SW., Room CY–B402, Washington, DC 20554. The full text may also be downloaded at: www.fcc.gov. Alternative formats are available to persons with disabilities by contacting Brian Millin at (202) 418–7426 or TTY (202) 418–7365 or at *Brian.Millin@fcc.gov*.

Paperwork Reduction Act

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 will be invited to comment on the modified information collection requirements contained in this proceeding.

Summary of the Report and Order

1. With this *Report and Order* in our second periodic review, we resolve several issues important to the rapid conversion of the nation's broadcast television system from analog to digital television ("DTV"). The Commission conducts these periodic reviews of the progress of the digital conversion to make any adjustments necessary to our rules and policies to "ensure that the introduction of digital television and the recovery of spectrum at the end of the transition fully serves the public interest." In our first DTV periodic review, begun in March 2000, we addressed a number of issues important to the transition. In the *Notice of Proposed Rulemaking* (68 FR 7737, February 18, 2003) in this second periodic review, we revisited several issues addressed in the first periodic review and sought comment on additional issues that we consider necessary to resolve in order to ensure continued progress on the digital transition. We received numerous comments in response to our NPRM.

2. In this *Report and Order*, we adopt a multi-step channel election and repacking process through which broadcast licensees and permittees ("licensees") will select their ultimate DTV channel inside the core (*i.e.*, channels 2–51). The process will start in November 2004 with licensees filing certain pre-election certifications. In December 2004, licensees currently with an in-core channel (whether one or two) will make their channel elections in the first round of elections. Licensees currently with only out-of-core channels (*i.e.*, channels 52–69), as well as licensees electing to be treated like them, will file elections in the second round, expected in July 2005. Licensees without confirmed elections from the previous two rounds will file elections in the third round, expected in January 2006. In a public notice released August 3, 2004, the Media Bureau implemented a freeze on the filing of certain TV and DTV requests for allotment or service area changes to facilitate the channel election and repacking process. The freeze includes applications to swap channels, but will not apply to proposals for negotiated channel election arrangements submitted as part of the channel election process. The freeze is described in section IV. A., infra.

3. We adopt the following replication and maximization protection deadlines:

- July 1, 2005—Use-it-or-lose-it deadline for DTV licensees affiliated with the top-four networks (*i.e.*, ABC, CBS, Fox and NBC) in markets 1–100. Those licensees that receive a tentative DTV channel designation in the channel election process on their current digital channel must construct full, authorized facilities. Those licensees that receive a tentative DTV channel designation on a channel that is not their current DTV channel must serve at least 100 percent of the number of viewers served by the 1997 facility on which their replication coverage was based.
- July 1, 2006—Use-it-or-lose-it deadline for all other commercial DTV licensees as well as noncommercial DTV licensees. Those licensees that receive a tentative DTV channel designation in the channel election process on their current digital channel must construct full, authorized DTV facilities. Those licensees that receive a tentative DTV channel designation on a channel that is not their current DTV channel must serve at least 80 percent of the number of viewers served by the 1997 facility on which their replication coverage was based.

4. In evaluating service areas we will consider the population served within the geographic area reached by a station's service area as defined under § 73.622(d) of the Commission's rules less any portions of that area that receive interference from other stations. Stations failing to meet the replication/maximization requirements on their allotted DTV channels by our deadlines will lose interference protection to the unserved portions of their current DTV service areas, as well as to the equivalent unserved portion of their NTSC Grade B contours for stations using those channels for DTV service after the transition occurs. Those

stations wishing to maximize their service area must meet the above requirements in order to "carry over" their maximized service area to their in-core assignment with a priority over Class A stations. We adopt limited exceptions for certain stations with out-of-core DTV allotments and satellite stations, both of which may turn in their DTV allotments and "flash cut" to digital by the end of the transition without losing their replication/maximization rights. We do not adopt an intermediate signal requirement, but retain the 7 dB increase in the principal community signal coverage required by December 31, 2004, for commercial stations and December 31, 2005, for noncommercial stations.

5. In this *Report and Order,* we also eliminate, for the time being, the requirement that broadcasters air on their digital channel the programming aired on their analog channel ("simulcasting"). We retain, however, the minimum digital operating hours requirement currently tied to the simulcast rule. We permit satellite stations to surrender their paired DTV channels and flash cut to DTV by the end of the transition. We are also reviewing the issues raised in the comments concerning the need for point-of-sale labeling for digital and analog televisions. We are monitoring retailer and manufacturer efforts to improve information provided to consumers and will address this issue in a future item. We adopt Program and System Information Protocol ("PSIP") and mandate its use by broadcasters. We also adopt new rules and clarify existing rules to support the functioning of closed captioning and v-chip on digital televisions. We approve in principle the use of distributed transmission system ("DTS") technologies and defer to a separate "fast track" proceeding the development of rules for DTS operation and the examination of several policy issues related to its use.

6. Finally, we sought comment in the NPRM on how we should interpret certain portions of section 309(j)(14) of the Communications Act, which requires the Commission to reclaim the 6 MHz each broadcaster uses for transmission of analog television service by December 31, 2006, unless an extension is granted pursuant to the criteria established in section 309(j)(14)(B). Commenters made a number of suggestions regarding the interpretation of various aspects of section 309(j)(14)(B). We are continuing to review these comments and to consider the issues raised in the NPRM regarding section 309(j)(14) and plan to address these issues in the near future.

Background

7. In January 2001, we released the *First DTV Periodic Report and Order* in which we made a number of determinations to further the transition. Among other things, we established channel election and interference protection deadlines. We also imposed a principal community coverage requirement that is stronger than the DTV service contour requirement adopted as an initial obligation in the *Fifth Report and Order.* This new principal community coverage requirement, which becomes effective December 31, 2004, for commercial stations and December 31, 2005, for noncommercial stations, was intended to improve the availability of service in the community of license and to prevent undue migration of stations from their communities of license.

8. In the *First DTV Periodic MO&O,* we revised a number of the determinations made in the *First DTV Periodic Report and Order.* To address broadcasters' concerns that they could not meet certain requirements in the *First DTV Periodic Report and Order,* we decided to allow stations to construct initial DTV facilities designed to serve at least their communities of license, while still retaining for the time being DTV interference protection to provide full replication at a later date. We did not, however, alter our decision to require stations to increase their signal strengths within their communities of license beyond those adopted as an initial requirement in the *Fifth Report and Order.* This principal community coverage requirement will become effective December 31, 2004, for commercial stations and December 31, 2005, for noncommercial stations. We also determined that we would continue to provide DTV interference protection to the maximized service area specified in outstanding DTV construction permits for facilities in excess of those specified in the DTV Table of Allotments. Television broadcast licensees may seek to expand or shift (also referred to as "maximize") their DTV allotments by filing applications to increase power or change the site or height of their antenna in such a way that it increases their DTV service area in one or more directions beyond the area resulting from the station's DTV allotment parameters. The term maximization can be confusing in that it does not necessarily entail enlarging the station's service area. Rather, it might more accurately be characterized as alteration of a station's previously allotted contour. Given that the term maximization is commonly used, however, we will continue to use it here. We temporarily deferred the replication protection and channel election deadlines established in the *First DTV Periodic Report and Order.* We stated, however, that in the second DTV periodic review we would establish a firm date by which broadcasters must either replicate their NTSC coverage or lose DTV service protection of the unreplicated areas, and by which broadcasters with authorizations for maximized digital facilities must either provide service to the coverage area specified in their maximization authorizations or lose DTV service protection to the uncovered portions of those areas. We also stated that we would establish a deadline by which broadcasters with two in-core allotments must elect which channel they prefer to use at the end of the transition. We stated that these replication, maximization, and channel election deadlines may be earlier than, but will in no event be later than, the latest of either the end of 2006 or the date by which 85 percent of the television households in a licensee's market are capable of receiving the signals of digital broadcast stations.

The reduced build-out requirements adopted in the *First DTV Periodic MO&O* allowed broadcasters to save both on construction and operating costs. In addition, we allowed DTV stations subject to the May 1, 2002, or May 1, 2003, construction deadlines to operate initially at a reduced schedule by providing, at a minimum, a digital signal during prime time hours, consistent with their simulcast obligations. Commencing April 1, 2003, DTV licensees and permittees were required to simulcast 50 percent of the video programming of the analog channel on the DTV channel. NCE stations were granted a six-month waiver of the simulcasting requirement, but not the minimum hours of operation requirement. This requirement stepped up to a 75 percent simulcast requirement in April 2004, and was to increase to a 100 percent requirement in April 2005. 47 CFR 73.624(f). Stations that were subject to the earlier construction deadlines (top four network affiliates in the top 30 markets) remained subject to the previous rule—*i.e.*, they must operate their DTV station at any time that the analog station is operating. For broadcasters unable to complete even the minimum permitted facilities by the applicable deadline, however, we revised our rules to permit applicants to seek an extension of time to construct a digital television station based on financial hardship. To qualify

for an extension of time to construct a digital television facility under the financial hardship standard, the applicant must demonstrate that the cost of meeting the minimum build-out requirements exceeds the station's financial resources. The applicant must provide an itemized estimate of the costs of construction and a detailed explanation of why its financial condition precludes such expenditures.

9. By permitting stations to elect a more graduated approach to providing DTV service, we allowed stations to focus their energies initially on providing digital service to their core communities, with the expectation that they would increase operating hours and expand their coverage area as the transition progresses.

10. On January 27, 2003, we began this Second Periodic Review of the Commission's Rules and Policies Affecting the Conversion to Digital Television. Among other things, we sought comment on new channel election, replication, and maximization deadlines for broadcast television service. We also sought comment on a number of other issues concerning the protection that must be provided to incumbent analog and digital broadcasters in channels 52–69 (698–806 MHz, also referred to as the "700 MHz band") during the transition. The Second DTV Periodic NPRM raised a number of other issues, including: (1) Whether the Commission should retain, revise, or remove the requirement that licensees simulcast a certain percentage of their analog channel programming on their DTV channel; (2) whether the Commission needs to take steps to assist noncommercial television stations in the transition; (3) whether labeling requirements for TV-related consumer equipment would assist the transition and protect consumers; (4) whether and how the Commission should license multiple lower-powered transmitters, similar to cellular telephone systems, called distributed transmission systems; (5) whether broadcasters should be required to include Program System and Information Protocol ("PSIP") information within their digital signals to ensure the availability of certain functions; (6) whether the Commission should adopt digital V-chip and closed captioning requirements; and (7) what station identification requirements should apply to digital stations. In the Second DTV Periodic NPRM, we also invited commenters to update the records in the DTV Public Interest Form NPRM (MM Docket No. 00–168), Children's DTV Public Interest NPRM (MM Docket No. 00–167), and the public interest NOI (MM Docket No. 99–360), and directed that such comments be filed in those proceedings. We will address any comments on public interest issues filed in response to the Second DTV Periodic NPRM when we finalize the public interest proceedings in the near future.

Progress Report

11. The transition to digital television is a massive and complex undertaking, affecting virtually every segment of the television industry and every American who watches television. The spectrum that will be recovered at the end of the transition will bring tremendous benefits to consumers and the United States economy. Twenty-four megahertz of spectrum currently used for television broadcast channels 63, 64, 68, and 69 will be returned and used for first responders and other critically important public safety needs. The remaining 84 MHz in the 700 MHz band (currently television broadcast channels 59–62 and 65–66) have been or will be auctioned for use by new wireless services. The Commission has been continuously involved in the migration to digital television by, among other things, adopting a standard for digital broadcasting, creating a DTV Table of Allotments, awarding DTV licenses, establishing operating rules for the new service, and overseeing the physical build-out of digital broadcast stations.

Build-Out Status

12. In 1997, the Commission set dates for construction and operation of broadcasters' allotted digital broadcast facilities. Pursuant to the construction schedule set forth in § 73.624(d) of the Commission's rules, affiliates of the top four networks in the top ten television markets were required to complete construction of their digital facilities by May 1, 1999; top four network affiliates in markets 11–30 by November 1, 1999; all remaining commercial television stations by May 1, 2002; and all noncommercial television stations by May 1, 2003.

13. As of July 28, 2004, 1,658 television stations in all markets (representing approximately 96 percent of all stations) have been granted a DTV construction permit ("CP") or license. A total of 1,423 stations are now broadcasting a digital signal, 634 with licensed facilities or program test authority and 789 operating pursuant to special temporary authority ("STA") or experimental DTV authority.

14. In the top 30 television markets, all 119 network-affiliated television stations are on the air in digital, 110 with licensed DTV facilities or program test authority and nine with STAs. In markets 1–10, of the 40 network affiliates due to be on the air by May 1, 1999, all are providing digital service, 38 with licensed DTV facilities and two with STAs. Two stations that were licensed and on the air prior to September 11, 2001, went off the air due to the attack on the World Trade Center. WABC–DT and WNBC–DT are now back and operating at STA facilities, thereby completing the list of stations once on the air that have returned to operations In markets 11–30, all 79 network affiliate stations required to be on the air by November 1, 1999 are providing digital service. Seventy-two have constructed their licensed DTV facilities and seven are on the air with STAs.

15. Approximately 1,230 commercial television stations were due to commence digital broadcasts by May 1, 2002. As of July 28, 2004, 1,018 of these stations (83 percent) are broadcasting a digital signal. In addition, approximately 373 noncommercial educational television stations were required to commence digital operations by May 1, 2003. As of July 28, 2004, 286 (77 percent) of these stations are broadcasting a digital signal.

DTV Equipment Availability

16. In the NPRM, we asked several questions about the types and availability of DTV equipment on the market. We invited commenters to provide us with up-to-date information about the pace of DTV receiver sales and the price of such units as well as trends in consumer demand for digital equipment.

17. The Consumer Electronics Association ("CEA") reports that manufacturers offer more than 400 models of HDTV monitors and integrated sets, which is three times the number from 2000. It reports an 11 percent drop in HDTV monitor prices from March 2002 to March 2003, with a larger drop expected over the duration of 2003. The consumer electronics industry invested $15 billion in DTV products from 1998 through 2003. In addition, CEA reports that DTV products represented more than 10 percent of all television sales in 2002. In the first quarter of 2003, according to CEA, 766,000 DTV product units were sold, which was up 86 percent over the first quarter unit sales of 2002. CEA projected that manufacturers would sell 3.8 million DTV sets and displays in 2003.

18. According to the CEA's website, 4.1 million DTV products were sold in 2003 for about $6.1 billion, a 44 percent increase in dollar sales and a 56 percent increase in unit sales from 2002. More

than 640,000 digital television sets were sold in December 2003 alone. CEA predicts that 5.8 million digital sets will be sold in 2004, 8.3 million in 2005, 11.9 million in 2006 and 16.1 million in 2007. CEA defines DTV products as integrated sets and monitors displaying active vertical scanning lines of at least 480p and, in the case of integrated sets, receiving and decoding ATSC terrestrial digital transmissions.

Ongoing Commission Efforts To Encourage the DTV Transition

19. Since the First DTV Periodic Report and Order, we have taken a number of important steps to encourage the consumer adoption of digital television. On August 8, 2002, the Commission adopted the DTV Tuner Order requiring that all TV receivers manufactured or shipped in the U.S. with screen sizes 13 inches and above be capable of receiving DTV signals over the air no later than July 1, 2007. This requirement will be phased in beginning with the largest sets in 2004 to minimize the cost impact on consumers. Receivers with screen sizes 36 inches and above—50 percent of a responsible party's units must include DTV tuners effective July 1, 2004; 100 percent of such units must include DTV tuners effective July 1, 2005. Receivers with screen sizes 25 to 35 inches—50 percent of a responsible party's units must include DTV tuners effective July 1, 2005; 100 percent of such units must include DTV tuners effective July 1, 2006. Receivers with screen sizes 13 to 24 inches—100 percent of all such units must include DTV tuners effective July 1, 2007. TV Interface Devices, VCRs, and DVD players/recorders, etc. that receive broadcast television signals—100 percent of all such units must include DTV tuners effective July 1, 2007 The DTV tuner requirement was designed to facilitate the transition to digital television by promoting the availability of reception equipment, as well as to protect consumers by ensuring that their television sets go on working in the digital world just as they do today.

20. In addition to the Order mandating DTV tuners, in October 2003, the Commission released a Second Report and Order and Second Further Notice of Proposed Rulemaking regarding Commercial Availability of Navigation Devices and Compatibility Between Cable Systems and Consumer Electronics Equipment. This Plug and Play Order was another step forward in the transition to digital television. Under the specifications developed by the cable and consumer electronics industries and adopted in the Plug and Play Order, consumers will be able to plug their cable directly into their digital TV set without the need of a set-top box. The new rules will ease the transition to digital TV by promoting competition, convenience, and simplicity for consumers.

21. In addition, we adopted a redistribution control system, also known as the "broadcast flag," for digital broadcast television. The goal of the Broadcast Flag Order is to prevent the mass indiscriminate redistribution of digital broadcast television in order to foster the transition to digital TV and forestall potential harm to the viability of free, over-the-air broadcasting in the digital age. We found that the current lack of digital broadcast content protection could be a key impediment to the DTV transition's progress. Specifically, we found that the absence of such content protection could lead to reduced availability of high value content on broadcast television and thereby harm the viability of free over-the-air television and slow the DTV transition. Given our progress on this front, we expect that such programming will not be unreasonably withheld from over-the-air television.

Issue Analysis

Channel Election

22. In the DTV Sixth Memorandum Opinion and Order, we determined that, after the transition, DTV service would be limited to a "core spectrum" consisting of current television channels 2 through 51 (54–698 MHz). Although some licensees received DTV transition channels out of the core, and a few have both their NTSC and DTV channels outside the core, there will be sufficient spectrum to accommodate all DTV stations at the end of the transition. At this stage in the transition it is important for licensees with two in-core channels to indicate which one of their channels they prefer to use for digital broadcasting after the transition. In addition, we will require licensees with one in-core channel to make a decision about their in-core channel, and will require licensees involved in negotiated channel election arrangements with other licensees to inform us of these arrangements. This step is critical in determining what channels will be available for stations with two out-of-core channels and in clearing the out-of-core spectrum.

23. In the First DTV Periodic Report and Order, we established December 31, 2003, as the channel election deadline for commercial stations. Largely due to reports of difficulties some stations were facing in meeting our construction deadlines, we later decided that this date might be too early for some stations and suspended the channel election deadline, announcing that we would use this second periodic review to re-establish the date. We also stated in the First DTV Periodic Report and Order that we would resolve in a future DTV periodic review whether and when licensees with one or both of their channels out of the core will have the opportunity to make a channel election as well as the details and procedures for the election process. We stated that *in* all cases, including licensees with both channels in-core, we reserve the right to select the final channel of operation in order to minimize interference and maximize the efficiency of broadcast allotments in the public interest. In the Second DTV Periodic NPRM, we stated that our goal was to establish a channel election deadline that gives broadcasters with two in-core channels enough time to make an informed decision about which of their two core channels they preferred to use for digital broadcasting, while at the same time providing licensees with two out-of-core assignments the time to plan their moves to in-core channels before the end of the transition. We proposed that commercial and noncommercial broadcast licensees with two in-core assigned channels make their final channel election by May 1, 2005. As an alternative, we sought comment on whether establishing the same deadline(s) for channel election as for replication and maximization protection and allowing broadcasters more time to increase to full power before they determine which channel is preferable for digital broadcasting would be more effective in speeding the transition.

24. In this *Report and Order*, we are establishing firm deadlines for channel elections and a procedure and time frame for evaluating, processing and confirming the elections. These decisions are consistent with the majority of the comments received from a wide range of participants in this proceeding. Most of the commenters that address channel election support establishing a firm deadline for channel election.

25. We initially established December 31, 2003, as the channel election deadline for commercial stations, but suspended the date pending a date to be established in this Order. We now agree with the commenters, such as CEA and KM Companies, which state that the industry has had enough time to evaluate DTV operations. Circumstances are significantly different from the time we suspended the channel election deadline. At the time, less than 400 of the 1,688 full-power stations with

paired DTV channels commenced DTV operations; now more than 1,400 stations have done so. Stations that chose to begin service at lower power have had an opportunity to operate DTV facilities and to test for interference or other service problems. DTV stations have had significant on-air time to conduct the necessary tests and evaluate available data in order to make reasoned channel election decisions. 47 CFR 73.624(d) required construction to be completed more than two years ago for most commercial broadcasters, fourteen months ago for noncommercial broadcasters, and more than four years ago for top-four network affiliated broadcasters in the top markets.

26. We therefore conclude that stations are likely to understand the performance characteristics of the DTV transmission standard and to know which channel they prefer to operate on after the transition, and reject the option that the channel election deadline be tied to replication requirements or DTV tuner penetration rates. As discussed more fully below in section IV.J.2., infra, we are adopting the ATSC A/65B ("PSIP") standard and mandating its use by DTV stations. As part of PSIP, a broadcaster's "major channel number" is its NTSC channel number. This major channel number is the station's channel identity during and after the transition. Therefore, a station's channel election decision will have no effect on the assignment of its NTSC channel number as its "major channel number" in PSIP. Consequently, channel election decisions need not be based on considering stations' historic "branding" to consumers, but instead may be based more on the operating characteristics of a particular frequency and the service populations the stations would project for each channel.

27. We find that the multi-step approach offered by MSTV has merit, and we adopt its proposal with modifications. We agree with many of the goals set forth by MSTV. First, the channel election process should provide the best possible DTV service to the public. Second, the plan should move the DTV transition along without undue delay. Third, we seek to create an orderly channel election process that produces as much clarity and transparency as possible. Fourth, licensees should be afforded the best opportunity for informed choice when making their channel election decisions. Fifth, we seek to provide every eligible station with a channel for operation after the end of the transition. Sixth, we seek to recognize industry expectations by protecting existing service and respecting investments already made, to the extent feasible. Finally, the channel election process should take into account overall spectrum efficiency, even as we seek to ensure to the extent possible that the final channel allotments accommodate replicated and maximized service areas for those stations certifying their intent to serve such areas.

28. To enable us to complete the reallocations necessary to accommodate all stations with a channel in the core, we need to know each in-core licensee's channel preference as soon as possible. Therefore, we adopt December 2004, as the starting date for channel elections, by which time commercial and noncommercial broadcast licensees with an in-core channel must state their channel preference. As of this date, commercial and noncommercial broadcasters will have had ample time after their applicable digital construction deadlines to make their channel decisions. A December 2004, channel election deadline for in-core licensees will also provide out-of-core licensees time to plan for their move into the core. We recognize that this date is earlier than the election date proposed in the Second DTV Periodic NPRM. Given, however, our adoption of a multi-step channel election process as proposed by MSTV and other necessary election procedures, this deadline is necessary to arrive at a final election for all stations in a timely manner. The choice of this election deadline strikes an appropriate balance between the need for stations to have a sufficient amount of time in which to gain experience in DTV operation and allowing stations that will have to move—particularly from out-of-core to in-core—to plan for the DTV channel conversion.

Channel Election and Repacking Process/New Allotment Process

29. We adopt a multi-step channel election plan based in considerable part on the MSTV proposal, but which also incorporates certain modifications and refinements. Specifically, we adopt a seven-step channel election and repacking process as follows: (1) Step 1 addresses any preliminary matters to the channel election and repacking process, which includes requiring all licensees to certify their intent to replicate their allotted facilities or maximize their already-authorized facilities; (2) Step 2 is the first round of elections in which in-core licensees (*i.e.*, those with at least one in-core channel) will file their channel election forms; (3) Step 3 analyzes the interference conflicts arising out of the first round and gives licensees an opportunity to resolve them; (4) Step 4 is the second round of elections, at which point the remaining licensees—out-of-core only licensees who have not yet filed channel election forms and those now being treated like them—will make their elections; (5) Step 5 analyzes the interference conflicts arising out of the second round elections, at which time staff will seek to place as many licensees as possible on their election preferences; (6) Step 6 is the third and final round of elections, at which point licensees not yet placed will file a final election preference; and (7) Step 7 is a Notice of Proposed Rulemaking to propose a new DTV Table of Allotments.

a. Step 1: Pre-Channel Election Matters

30. Database clean up. We agree with MSTV that it is important for our database to provide a consistent starting point. To that end, we ask that licensees review the accuracy of their database technical information and contact staff as quickly as possible with any submitted corrections. Any proposed corrections to database information must be consistent with station authorizations, as reflected in the Commission's records. So that we may consider any proposed corrections to our database, licensees should contact staff by October 1, 2004, with any concerns. We note that it may not be possible to process and consider any proposed corrections to database information offered after this date. Database errors that are discovered after this date may be corrected at the discretion of Commission staff. To ensure that licensees timely review their database information, we will require them to certify that they have reviewed their database information on file with the Commission and that it is accurate to the best of their knowledge. Licensees will make this certification using the Pre-Election Certification Form, which must be filed by November 2004. The Pre-Election Certification Form will also include licensees' certifications of their intent to replicate or maximize. While MSTV proposes a one-year period devoted to "database clean up," we do not believe such an extended period is necessary. Moreover, we do not believe that there is a need for a formal process to invite licensees to submit information to "clean up the database" because we expect that licensees have informed us of any discrepancies as they arose. We note that MSTV has notified its members about the need to make sure their database information is accurate, and invited them to contact the Commission and MSTV concerning questions about database inaccuracies or discrepancies. MSTV also asked its

members to share this notice with other stations. As a result of this letter dated June 1, 2004, the Commission has received three letters from licensees. We remind licensees that they have an ongoing obligation to ensure the accuracy of their database information and to apprise us of any discrepancies between their authorized facilities and their operations.

31. Filing freeze. On August 3, 2004, the Media Bureau imposed a freeze on the filing of certain TV and DTV requests for allotment or service area changes to facilitate the channel election and repacking process. Included in the freeze are: (i) Petitions for rulemaking to change DTV channels within the DTV Table of Allotments, (ii) petitions for rulemaking to establish a new DTV channel allotment, (iii) petitions for rulemaking to swap in-core DTV and NTSC channels; Notwithstanding the freeze, negotiated channel election arrangements may be sought during the election process. (iv) applications to change DTV channel allotments among two or more licensees; (v) petitions for rulemaking by licensees/permittees to change NTSC channels or communities of license; (vi) applications to maximize DTV or analog TV facilities; and (vii) certain Class A station applications. Notwithstanding this freeze, licensees are not prevented from filing modification applications that would resolve international coordination issues. We do this to alleviate a burden on those licensees who are actively working to resolve their international coordination issues, or when a broadcast station seeks a new tower site due to the events of September 11, 2001. In addition, the Media Bureau will consider requests for waiver of the freeze on a case-by-case basis. Such a filing freeze is necessary to provide a stable baseline for developing a final DTV Table of Allotments. The freeze is discussed more fully in section IV.A.2., infra.

32. Table of station assignment and service information. As a preliminary matter to the channel election process, the Media Bureau will issue a table of station assignment and service information ("table of station information") for use by TV station licensees and other interested parties so they may determine and evaluate the DTV service populations to be used by the Commission to process stations' channel elections and create the new DTV table of allotments. In developing the table of station information, the Commission will generally use the DTV and NTSC station locations and facilities authorized by license or construction permit (CP). Where station records include both a construction permit and license, we will use the construction permit given that the changes permitted in the construction permit reflect the station's facilities for the future, as of October 1, 2004, a month before TV station licensees will be asked to file their Pre-Election Certification Forms. The Pre-Election Certification Form will require all broadcast licensees and permittees to certify to (1) the accuracy of their database information on file with the Commission, which will be reflected by the table; and (2) their intent to replicate or maximize pursuant to their existing authority, as will be defined by the table. We will issue this table of station information prior to the filing of the Pre-Election Certification Forms. (We note that the Media Bureau imposed a freeze on the filing of certain TV and DTV requests for allotment or service area changes in anticipation of generating this table of station information.) The data provided in the table of station information will be based on the technical information on file in the Commission database. Licensees should review the table of station information before making their pre-election certifications. We will update the table of station information to reflect service areas based on certifications to build to replication or maximization facilities and any other changes to station facilities prior to the first round election date.

33. Station service evaluations based on currently authorized operations. As noted above, we will use current authorized station operations to determine and evaluate the DTV service populations in processing channel elections and creating the new DTV table of allotments. We believe that basing station service evaluations on current authorized station operations will more accurately reflect the current viewer access to station services than the parameters specified for the initial DTV Table of Allotments in 1997, and will at the same time preserve the service areas of those stations that constructed and are operating in accordance with the DTV buildout schedules. Consistent with MSTV ex parte submissions and discussions, we will define new interference as interference beyond that caused by NTSC and DTV operations, as described by the table of station information, in evaluating new interference to post-transition TV operations.

34. On this basis, stations that operate, or plan to operate as authorized by a CP, in accordance with the facilities specified in the initial DTV Table of Allotments will have the same service as that contemplated in the DTV Second MO&O, less any changes in interference received from new stations or from stations that changed their operations. Stations that have departed from their initial DTV allotment facilities (including location and/or channel changes) or maximized (or in a few cases reduced) their operations through such modifications and new stations, will have service as authorized in those changes or new authorizations, again less interference from other stations. Stations granted a DTV channel change are generally authorized facilities that they requested if such operations do not cause new interference to other stations that exceed the *de minimis* interference standards of § 73.623(c)(2) of the rules, 47 CFR 73.623(c)(2). In some cases the new channel allotment facilities cover more area than the stations were authorized on their initial DTV channel allotment, while in other cases the stations cover less area. In the case of stations whose applications for maximization of DTV facilities are delayed in processing due to international negotiations, we will consider the service that would be provided based on those applications pending the resolution of those coordination issues and authorizations of specific facilities. All analyses of service and reduction of service due to interference will be based on population only. We will use population data from the year 2000 census in determining the populations served by stations and the impact of interference on stations' service. In this regard, the more up-to-date population data from the year 2000 census will provide a more accurate indication of the station service and impacts of interference on that service than the older year 1990 population data used in computing the service data for the initial DTV Table of Allotments.

35. Border coordination. We agree with commenters that it is important to resolve international coordination issues as quickly as possible. To that end, we have reduced the number of coordination conflicts from several hundred to fewer than 50. We cannot, however, delay the implementation of our channel election and repacking process pending resolution of every outstanding case of Canadian or Mexican coordination. Parties with pending applications that are being delayed due to coordination issues are advised that while we will make every effort in negotiating on their behalf, we can provide no assurance that such issues will be resolved favorably. In nearly all of the remaining cases, the licensee can build a checklist facility.

Only a few stations cannot build checklist facilities because of border coordination issues. This list includes: WPXJ–DT, Batavia, NY (allotted DTV 53); WNYO–DT, Buffalo, NY (allotted DTV 34); and KAJB–DT, Calipatria, CA (allotted DTV 50). In some cases, additional coordination actions will be needed to provide in-core channel assignments. If an election would require international coordination, then that channel may be elected at authorized replicated and maximized facilities, subject to the outcome of the international coordination. We recognize that maximization may cause coordination issues and that successful coordination may require reduction to replication facilities We encourage stations in markets or regions that require coordination to work together to identify in-core channels that are feasible. Such arrangements among stations will be accepted as part of the channel election process and will be accorded great weight in determining final assignments. The Commission will continue to work with licensees to resolve remaining international coordination issues as part of the process of developing new DTV allotments and will consider a station's border coordination efforts when prioritizing channel assignments. Border coordination issues are discussed more fully below in section IV.A.3., *infra*.

36. We are aware of some stations with a DTV channel outside of the core and an analog channel inside the core for which, according to the stations, the analog channel is not available for digital transmission because of international coordination issues with Canada. These stations should indicate this fact on their channel election form and attach a brief explanation of why their in-core channel is not available for digital use under the U.S.—Canada Letter of Understanding, which governs modifications of the initial DTV table of allotments within 400 km of the U.S./Canadian border. Stations with an out-of-core DTV channel and an in-core analog channel that is not available for digital transmission because of international coordination issues will be treated like stations with two out-of-core channels.

Certifications for replication and maximization. We adopt a requirement, that stations that intend to fully replicate or maximize certify this commitment to the Commission by November 2004, subject to sanctions if the station fails to meet its commitment. In the Pre-Election Certification Form, licensees will certify their intent to build-out their allotted "replication" facilities or already-authorized "maximization" facilities. Licensees are reminded that false certifications may result in fines and loss of license. Moreover, where stations do not build-out to their certified facilities, we will limit their station's interference protection to the service population within the noise-limited contour predicted from the station's operating facilities, as of the certification date. (In other words, a licensee's failure to replicate or maximize to the extent it certified will result in the loss of interference protection to those service areas not replicated or maximized.) Licensees will be required to replicate and maximize by the replication/maximization deadline (*i.e.*, July 1, 2005, for affiliates of the top-four networks in markets 1–100; and July 1, 2006, for all other stations). Further, licensees may only certify to maximize pursuant to their existing authority to do so. Channel elections will be evaluated at this stage based on the coverage that is predicted from the certified authorized maximization or certified replication facilities. We anticipate that many licensees will have an opportunity to enlarge their final DTV allotment coverage after the final table has been adopted, pursuant to the rules for changes and applications established then. In developing rules for resolving or avoiding conflicts between stations requesting such coverage enlargements, we will consider giving priority to stations that can demonstrate that they had built-out their full authorized DTV facilities and had been unable to maximize on their transition DTV channel.

37. Such certifications must be filed with the Commission in advance of the channel election date so that all licensees will be able to consider the commitments of other licensees in their channel elections. To provide sufficient time for this information to be useful, we will require that such certifications be filed in November 2004. Stations that do not submit certification forms by this date will be presumed not to intend to replicate or maximize, and such decision will be taken into account in determining final channel assignments. More specifically, in establishing the authorized facilities and service area for a station not certifying to fully replicate or maximize, we will provide for the station to serve the same geographic area served by its existing DTV facilities, operating as of the certification date. Certifications must be filed electronically and will be made accessible to the public.

38. Election Forms. All broadcast licensees participating in the channel election process are required to file a pre-election certification form and a channel election form. Stations that do not timely submit a pre-election certification form will be presumed both (i) to agree that their database technical information on file with the Commission is accurate and complete, and (ii) not to intend to replicate or maximize, and such decision will be taken into account in determining final channel assignments. Stations that do not timely submit a channel election form will be assigned a post-transition DTV channel by the Commission prior to the end of the channel election process. Appendices E and F to this Report and Order illustrate the forms to be used in the channel election and repacking process. We have developed the following six forms: (1) Pre-Election Certification Form; (2) First Round Election Form; (3) First Round Conflict Decision Form; (4) Second Round Election Form; (5) Second Round Conflict Decision Form; and (6) Third Round Election Form. These forms, which are adopted by this Report and Order, must be filed electronically and will be made accessible to the public on the Commission's database.

b. Step 2: First Round of Elections; Election Forms Filed

39. We set December 2004 as the date for the first round of channel elections. Although we proposed in the NPRM an election date of May 1, 2005, we believe that the broadcasters making first round elections are able to make an informed statement of their final channel preference at this time. Moreover, given that we will be adopting a multi-step and multi-round approach that will occur over the course of several months, we find that we must begin the process as soon as possible in order to effectuate a timely transition.

40. In this first round, licensees with in-core channels (*i.e.*, licensees with two in-core channels and licensees with one in-core channel) will make their channel elections by filing a First Round Election Form. The First Round Election Form will provide up to three options for in-core licensees: (1) Elect one of its currently assigned in-core channels; (2) elect a negotiated channel pursuant to an agreement with another licensee(s); or, (3) if (i) a one-in-core licensee, or (ii) a two-in-core licensee with two low VHF channels (*i.e.*, channels 2–6), then such a licensee may choose to make no election in the first round and instead elect to participate in the second round of elections. Licensees in this round may not elect a channel that is not assigned to them, unless rights to that channel are being sought through a

proposed negotiated channel election arrangement. Licensees that have negotiated channel election arrangements with other licensees must obtain Commission approval for the proposed channel changes in the arrangement in order for their election of a negotiated channel to be considered valid. Upon completion of the first round and subsequent interference conflict analysis, each licensee electing an in-core channel will receive an informal tentative channel designation, to the extent possible. Licensees with two in-core channels (including those with two low VHF channels (*i.e.*, channels 2–6). We will permit two in-core low VHF licensees to release both of their channels in the first round and agree to be treated as two out-of-core licensees and participate in the second round of elections. Licensees that choose to elect, and which receive a tentative channel designation for, their in-core low VHF channel will have an opportunity to make an alternate election in the third round) will make the first channel elections, choosing between their two in-core channels. Licensees with only one in-core channel will be required to elect whether to keep their in-core channel, or turn it in and be treated like a licensee with two out-of-core channels. We believe that, by this time, one in-core licensees should know whether they intend to keep their in-core channel. This will further increase the number of channels available for future selection. Moreover, we are including in this one in-core licensee category those licensees with only one channel (*i.e.*, in-core singletons).

41. Negotiated Channel Election Arrangements. As an alternative to the channel election process, licensees may negotiate channel election arrangements with other stations. Such negotiated arrangements are subject to Commission approval, including particular consideration of the effect on the channel election rights of, and interference impact on, any licensee not a party to the negotiated channel election agreement. "Channel swapping" is an existing practice with beneficial results for the marketplace and consumers, and these channel election arrangements are similar in nature to them. We do not anticipate that channel election arrangements are likely to have anti-competitive effects. We will, however, review them for such effects. All licensees involved in a negotiated channel election arrangement must file a channel election form. Licensees will be asked to indicate their negotiated channel elections on their channel election forms. To select the channel they would use for digital operations after the transition if the negotiated channel election arrangement is approved, as well as the channel they would elect if the negotiated arrangement is not approved. Stations involved in the negotiated channel election arrangement must satisfy our DTV interference rules with regard to their relationship to other stations not involved in the negotiated arrangement. Evidence of a signed negotiated channel election arrangement and technical engineering information demonstrating compliance with § 73.623(g) of the Commission's rules must be submitted to the Commission to enable us to consider negotiated channel election arrangement requests. In order to demonstrate the validity of their negotiated channel election arrangements, licensees will be required to provide the name(s) and call sign(s) of the other licensees involved in the arrangement. Licensees may, upon request, be required to provide a copy of the negotiated channel election agreement and/or engineering information to the Commission. The Commission may contact proponents of these arrangements, as may be necessary. We will review all agreements to assure compliance with the public interest and will not approve agreements proposing the acceptance of significant levels of interference or loss of service.

42. Election of DTV in-core channel. We conclude that if a two in-core licensee elects its DTV channel, then its NTSC channel will be released. By "release," we mean that the licensee relinquishes its post-transition rights to this channel and that the channel now becomes available for future selection by another licensee. The DTV channel will be "locked in." By "locked in," we mean that the channel assignment is confirmed. However, the amount of interference the station is subjected to may increase to some extent in the Final Table in an effort to provide all licensees with an in-core DTV channel that replicates their analog service, to the extent the station has certified intent to so replicate. In other words, even though channels may be "locked in," licensees may be required at the end of the allotment process to accept interference resulting from establishment of DTV stations at full replication facilities to accommodate all stations with a channel in the DTV core spectrum. This system of "locking in" channels can be viewed as making an informal tentative channel designation to that licensee. While informal tentative channel designations in themselves cannot confer legal rights to licensees, they do come with a heavy presumption that these informal designations will be the channel assignments proposed in the new DTV Table of Allotments. (*i.e.*, channel will be protected. By "protected," we mean that a subsequent election may not cause an interference conflict to a "locked in" channel to the extent the "locked in" station's coverage is certified, except against interference that may result from establishment of DTV stations at the end of the allotment process at full replication facilities to accommodate all stations with a channel in the DTV core spectrum. An interference conflict would occur where interference exists any greater than existing interference plus no more than 0.1 percent additional reduction in service population. For purposes of this process, we will use this 0.1 percent interference protection standard proposed by MSTV. We agree with MSTV that "protect" in this context should mean that a subsequent election may not cause interference any greater than existing interference plus no more than 0.1 percent additional reduction in service population.) To the extent certified against future elections, except against interference that may result from establishment of DTV stations at full replication facilities to accommodate all stations currently allotted an out-of-core DTV channel with a channel in the DTV core spectrum). We recognize that a station that ends up keeping its in-core DTV channel as its final allotment might not have to incur any additional construction expenses. In contrast, a station that ends up operating in digital on its analog allotment would need to incur expenses to change its DTV operation to another channel. To allow stations to minimize the cost of this phase of the DTV transition whenever possible, we will afford the highest priority in the allotment process to maintaining existing DTV allotments selected on the channel election forms.

43. Election of NTSC in-core channel. If a two in-core licensee elects its NTSC channel, then Commission staff will determine whether and to what extent DTV operations on this channel would cause new interference to the service populations of other DTV stations. For purposes of this analysis, DTV service populations will be those resulting from the allotted "replication" facilities or authorized "maximization" facilities, as certified. This interference conflict analysis will take place in Step 3, when we intend to resolve, to the extent possible, the interference conflicts

resulting from the first round of elections.

44. We do not expect there to be widespread difficulties in fitting replicated DTV service into paired NTSC channels, as paired DTV channels were initially designed to be the best approximation of the NTSC Grade B contours. However, the interference relationships between DTV to DTV and NTSC to DTV operations are such that a DTV station would have a 1 dB greater interference impact on another co-channel DTV station than a NTSC station and an 8 dB greater impact on adjacent channel DTV station than an NTSC station, assuming the same coverage and locations for all stations. Thus, it is likely that in some cases DTV operation on an associated NTSC channel could result in new interference. In such cases, it may be possible to resolve the new interference by reducing the DTV station's operating facilities. We would allow stations to make such adjustments to address such conflicts. For those stations electing their NTSC channel for their eventual in-core DTV channel, we will attempt to accommodate the broadcasters' authorized maximized facilities into the NTSC "destination" channels. As discussed in section IV.B., *infra*, except for stations with out-of-core DTV channel allotments, stations failing to serve their authorized maximized service area by our replication/maximization deadlines will lose interference protection to any unserved areas. In addition, the Community Broadcast Protection Act of 1999 provides an interference protection priority to Class A TV stations with respect to certain maximized DTV facilities. Specifically, Class A stations are entitled to a protection priority with respect to those maximized DTV facilities, including technically necessary adjustments to those facilities, for which an applicant had not filed an application for maximization nor a notice of its intent to seek such maximization by December 31, 1999, or, if a notice of intent was timely filed, did not also file a *bona fide* application for maximization by May 1, 2000. 47 U.S.C. 336(f)(1)(D). *See also,* 47 CFR 73.623(c)(5). Thus, DTV broadcasters that did not meet these statutory filing deadlines are not entitled to carry over to their NTSC channels maximized DTV facilities that would conflict with a Class A TV station. *See* Class A Order, 15 FCC Rcd at 6379, para. 60. However, if a broadcaster's maximized DTV service area cannot be carried over to an NTSC channel or another DTV channel as part of a channel swap arrangement or it is not otherwise willing to reduce its operations, we may find it necessary to base its use of the new channel on its replication facilities or to assign the broadcaster another channel in the market that can accommodate its maximized facilities as part of the process of generating a new Table.

45. Elections by one in-core licensees. Licensees with only one in-core channel (including singletons Singletons' or "single-channel licensees" refers to those licensees that do not have a second or "paired" channel to convert to DTV. In 1998, in the "Service Reconsideration Order," the Commission decided to afford new NTSC permittees, whose applications were not granted on or before April 3, 1997, and who were therefore not eligible for an initial DTV paired license, the choice to immediately construct either an analog or a digital station on the channel they were granted. Pursuant to this policy, the Commission specified that these new NTSC permittees, which we now sometimes refer to as "singletons" or "single-channel licensees," would not be awarded a second channel to convert to DTV, but could, instead, convert on their single 6 MHz channel. It was further decided that if they choose initially to build an analog station, they may request Commission authorization to convert to DTV at any point during the transition, up to the end of that period), including those with low VHF channels (2–6), must elect to either (1) keep their in-core channel or (2) release their in-core channel in favor of being treated like a licensee with two out-of-core channels. MSTV proposed that we assume that such stations would decide to remain on their in-core channels; however, we find that it is more efficient to determine which in-core channels are unacceptable to these stations so that those channels can become available for future elections and to ensure that those stations are given an opportunity to identify a workable channel.

46. We expect that in most cases stations with only one in-core channel, where the channel is a DTV channel, will choose to remain on that channel. In such cases, that channel will be "locked-in," as defined above. If the one in-core licensee chooses not to elect its in-core DTV channel, then that channel will be released, and the licensee will be treated as a two out-of-core licensee. In being treated like a two out-of-core licensee, the licensee will be required to file a new election form in the second round of elections. Licensees with only one in-core channel (including singletons), where the in-core channel is the NTSC channel, must elect to either (1) keep their in-core NTSC channel or (2) release their in-core NTSC channel in favor of being treated like a two out-of-core licensee. If a one in-core licensee elects its NTSC, then Commission staff will determine (in Step 3's "interference conflict analysis") whether and to what extent this NTSC channel would cause new interference to the service populations of DTV stations. In light of their status, in-core NTSC channels of one in-core licensees will be afforded a high priority in permitting their conversion to a DTV channel.

47. Later opportunity to change elections of low VHF channels and channels subject to international coordination. Licensees electing, and receiving a tentative channel designation for, a low VHF channel or a channel subject to a pending international coordination issue will be permitted to seek an alternate tentative channel designation in the third round of elections. See discussion in section IV.A.1.f., infra.

48. No first round election for two out-of-core licensees. Licensees with two out-of-core channels will not make an election in the first round. Requiring two out-of-core licensees to elect at this time would be premature and unnecessarily limit the channel choices available to these licensees. We disagree with MSTV that it would be beneficial for two out-of-core licensees to make elections in the first round a month after the two in-core licensees have elected. We note, for example, that under MSTV's plan two out-of-core licensees would not know at this time whether a two in-core licensee selecting its NTSC channel in the first round would ultimately obtain that election. This situation would not be resolved until Step 3, through interference conflict analysis MSTV would have two out-of-core licensees protect both channels of two-in-core licensees electing their NTSC channel, effectively denying two out-of-core licensees' the ability to select certain otherwise available channels. Accordingly, as will be discussed below, two out-of-core licensees will make their elections in the second round, at which point two in-core and one in-core licensees may already have a channel "locked in" (as defined above) and have released an in-core channel, making that in-core channel available for future selection.

a. Step 3: First Round Interference Conflict Analysis and Tentative Designations;

Conflict Forms Filed

49. The interference conflict analysis contemplated in our Step 3, which we expect to complete by February 2005, will determine whether and to what extent an elected in-core NTSC channel would cause interference to an existing or proposed in-core DTV channel. Using objective computer analysis, we will identify and communicate interference conflicts arising from the first round. We agree with MSTV that knowing what channels are available for selection in the second round is important in order to provide second round electors with an informed choice among all channels remaining after completion of the first round. Accordingly, through the interference conflict analysis process, we will set tentative channel designations for in-core licensees with channels that have been elected in the first round and "locked in."

50. Specifically, through our first round interference conflict analysis, Commission staff will determine whether and to what extent an elected in-core NTSC channel causes an interference conflict to: (1) An in-core DTV channel that was elected in the first round; (2) an in-core DTV channel of any licensee that elected its NTSC channel in the first round that still may need to revert to its DTV channel; or (3) another elected in-core NTSC channel in the first round. We note that the nature of the interference conflict differs with respect to an elected NTSC channel of a one-in-core station, which enjoys a special status, as opposed to an elected NTSC channel of a two-in-core station, which has the option to change its election to its currently assigned DTV channel.

51. Upon completion of our first round interference conflict analysis, the Media Bureau will issue a letter to each licensee determined to cause an interference conflict(s). Licensees with interference conflicts will have 60 days from the date of this conflict notification letter in which to file their First Round Conflict Decision Forms, indicating how they intend to resolve their interference conflict. These First Round Conflict Decision Forms, which we expect to be filed in April 2005, will provide licensees with the opportunity to decide whether to maintain their in-core NTSC election, change their election to their in-core DTV channel, or, if a one-in-core licensee, elect to participate in the second round. Two in-core licensees may not release both in-core channels to participate in the second round of elections, except for the case of two in-core low VHF channels. We note that two in-core licensees already have the advantage of having an in-core DTV channel. Licensees can maintain their in-core NTSC election if they resolve their interference conflict by (1) agreeing to accept interference and reduce facilities; In choosing this option, licensees would have to agree to accept interference or reduce facilities, as necessary. Licensees must certify that they will resolve their interference conflict(s), and will be required to demonstrate such by submitting technical engineering data. and/or (2) negotiating an agreement (*i.e.*, conflict resolution agreement) with the licensee(s) with which they are in conflict. In choosing this option, licensees would have to negotiate a settlement with the licensee(s) with which they are in conflict. Licensees must certify that they will resolve their interference conflict(s), and will be required to demonstrate such by submitting evidence of a negotiated conflict resolution agreement and supplying engineering information, as may be necessary. Licensees' submissions must evidence compliance with 47 CFR 73.623(g).

52. Licensees currently allotted an out-of-core DTV channel will be afforded the opportunity for full replication facilities on an in-core DTV channel, unless they choose to accept less. The licensee may agree to accept interference as long as it is still able to serve all of its community of license. If the conflict is thus resolved, the licensee's currently assigned in-core DTV channel is released. After receipt of the First Round Conflict Decision Forms, we will announce any additional channel elections that have been "locked in" as tentative channel designations. Based on this information, second round electors will be able to determine which channels will be available for selection in the second round of elections.

53. An interference conflict exists when it is determined that more than tolerable new interference exists (*i.e.*, in this context, 0.1 percent in addition to existing interference). If it is determined that no interference conflict exists (meaning in this context that the elected in-core NTSC station adequately protects stations in each of the three categories noted above, to the extent required), then the licensee's elected NTSC channel will be "locked in" and its DTV channel will be released, if applicable. If it is determined that an interference conflict does exist, and would therefore prevent granting the in-core NTSC channel election with the certified coverage, then the licensee must decide whether to reduce its facilities to eliminate the interference, Licensees electing to reduce their facilities will be required to submit data demonstrating specifying how they will eliminate the interference conflict. or change its election to its DTV channel, or be treated as a two out-of-core licensee if its paired DTV channel is out of core. The licensee will indicate its decision by filing a conflict decision form. The licensee may agree to reduce its facilities to eliminate interference as long as it is still able to serve all of its community of license. With regard to stations with an allotted out-of-core DTV channel electing to operate a DTV station on their in-core NTSC channel, we will permit the 0.1 percent additional interference limit to be exceeded on a limited basis in order to afford these stations an improved opportunity to select their NTSC channel. Such allowance is justified because these single channel licensees have only one in-core channel to select and may need this additional accommodation. We are concerned, however, that such operations not cause substantial interference to existing DTV service (*e.g.* interfering within the area in which service replication is already being achieved by an operating station). Although we do not expect such instances will be widespread, where we find it appropriate to do so, we may ask a station seeking DTV operation on its in-core NTSC channel to operate at a power level that would avoid large amounts of interference to existing DTV operations, even if this would preclude that station from operating with full replication facilities. Licensees should be aware that the burden is on them to ensure that the channel they elect can serve their community of license. Consequently, should it be determined when proposing a final DTV Table of Allotments that a licensee's election does not cover its community of license, we will void that election and place the licensee on a more appropriate channel.

54. The interference conflict analysis performed in the first round is illustrated through the following examples. In the case of a two-in-core licensee whose election of its in-core NTSC channel causes an interference conflict which prevents granting the in-core NTSC channel with the certified coverage, the licensee will file a conflict decision form indicating whether it will accept its in-core NTSC channel with interference and reduced facilities or if it will revert to its DTV channel. The channel selected at this time would be "locked in" and the other channel

would be released. In the case of a licensee with only one in-core NTSC channel (including singletons) that elected its in-core NTSC channel and an interference conflict was found that would prevent granting coverage to extent certified, the licensee will file a conflict decision form indicating whether it wishes to accept its in-core NTSC channel with interference or if it wishes to be treated as a two out-of-core licensee and file an election in the second round (see Step 4). Licensees are cautioned that it is possible that they may obtain a less preferable tentative channel designation than had they decided to keep their in-core NTSC channel election with interference and reduced facilities. We note that these licensees may include their reduced-facilities NTSC channel on their list of second round election preferences. There would be, however, no guarantee that their discarded in-core channel would be awarded back to them should their higher second round election preferences not be available to them.

d. Step 4: Second Round Election Forms Filed

55. In our second round of elections, which we expect to occur July 2005, licensees with two out-of-core channels and those now treated like them, This category includes those first round electors that indicated in their conflict decision forms that they wanted to be treated as two out-of-core licensees, rather than accept their in-core NTSC channel with interference and reduced facilities. Also included in this category are licensees that do not have an in-core channel (*e.g.*, an out-of-core singleton). will be required to file a Second Round Election Form.

56. Two out-of-core licensees. In their Second Round Election Form, two out-of-core licensees may submit one channel election preference (two out-of-core licensees may negotiate channel election arrangements with other licensees) or may request that the Commission determine a "best available" channel (*i.e.*, one that minimizes new interference to all protected channels) for them at full replication facilities. Two out-of-core licensees wishing to ensure receipt of a tentative channel designation in the second round should consider making a Commission-determined "best available" channel their election preference. Thus, licensees that request that the Commission determine a "best available" channel for them at full replication facilities will be placed by Commission staff in this round. Second round electors may also submit one contingent channel preference which would be available for selection only if the licensee rescinds its original second round election as part of a negotiated conflict resolution or settlement agreement with another licensee. We do this in an effort to encourage licensees to resolve conflicting channel preferences through settlement negotiations. Licensees may also request that the Commission determine a "best available" channel for their contingent preference.

e. Step 5: Second Round Interference Conflict Analysis and Tentative Designations

57. We recognize that there may be a sizable number of election preferences filed in the second round and that licensees may list conflicting channel preferences. Second round electors may also be asked to accept a channel with interference and reduced facilities because of an interference conflict with a protected channel. In anticipation of these issues, our second round interference conflict analysis, which we expect to complete by September 2005, offers a process of identifying and resolving such interference conflicts. We will evaluate election preferences for interference conflicts (as defined above), and "lock in" second round election preferences as tentative channel designations, to the extent possible. We will accommodate the election preference of each licensee to the extent possible, but cannot guarantee that licensees will receive their selected channel. The Second Round Conflict Form will provide second round electors with the opportunity to decide whether the interference and reduced facilities to which they would have to agree to obtain their channel preference would be acceptable to maintain their election preference. Second round electors unwilling to accept its election preference with interference and reduced facilities or that otherwise cannot resolve their interference conflict may participate in the third round of elections. We believe that in many cases of conflicting second round channel preferences, licensees will be able to reach settlement agreements, thereby avoiding the necessity of having the Commission resolve their conflict after the third round of elections.

58. Upon completion of our second round interference conflict analysis, the Media Bureau will notify each licensee that is determined to cause an interference conflict(s). Licensees will have 60 days from the date of this conflict notification letter in which to file their Second Round Conflict Decision Forms, indicating how they intend to resolve their interference conflict. These Second Round Conflict Decision Forms, which we expect to be filed in November 2005, will provide licensees with the opportunity to decide whether to maintain their second round channel elections or instead participate in the third round. Licensees have several options available to them: Licensees can maintain their second round channel election if they resolve their interference conflict by (1) agreeing to accept interference and reduce facilities; Licensees must certify that they will resolve their interference conflict(s), and will be required to demonstrate such by submitting technical data. and/or (2) negotiating an agreement (*i.e.*, conflict resolution agreement) with the licensee(s) with which they are in conflict. Licensees must certify that they will resolve their interference conflict(s), and will be required to demonstrate such by submitting evidence of a negotiated conflict resolution agreement and supplying engineering information, as may be necessary Licensees can decide to change their election to their contingent second round channel by entering into a negotiated channel election arrangement with another licensee whereby they surrender rights to their original channel preference to that licensee. Licensees may use their contingent channel election only in the context of a negotiated settlement with another licensee, and may not use their contingent channel election at all if such use would result in an interference conflict. Finally, licensees can decide that they are not willing to accept their election preference with interference and reduced facilities or that they cannot otherwise negotiate a resolution to their interference conflict and elect to participate in the third round of elections. We believe that in many cases of conflicting second round channel preferences, licensees will be able to reach settlement agreements, thereby avoiding the necessity of having the Commission resolve their conflict after the third round of elections. We note that where more than one station elects the same channel and those stations cannot negotiate a settlement agreement, the subject channel will become unavailable for selection in the second round and licensees will have the opportunity to select that channel in the third round. The Commission will resolve third round conflicts pursuant to certain criteria After receipt of the Second Round Conflict Decision Forms, we will announce any additional channel elections that have been "locked in" as tentative channel designations. Upon completion of the

second interference conflict analysis and tentative channel designations, we expect that only a small number of licensees will remain with no channel "locked in." These licensees will be afforded an opportunity to file one additional election preference in the third and final round of elections. Based on this information, third round electors will be able to determine which channels are available to them for selection.

f. Step 6: Third and Final Round of Elections

59. We will hold a third round of elections, expected to occur in January 2006, to find channels for licensees that were not "locked in" at tentative channel designations in the previous two rounds. This third round provides a subsequent round for two out-of-core licensees whose election preferences could not be accommodated in their initial round of elections. We agree with MSTV that these licensees, as well as any other licensees that remain unplaced at this time, should be afforded the opportunity to make one additional channel election preference. These licensees will file a Third Round Election Form Election preferences made in this round must protect all "locked in" channels. Participants in the Third Round may elect from available channels and may file negotiated channel election arrangements. If a licensee is not able to specify a preferred channel on which it can operate satisfactorily without conflicting with a protected channel, it may ask the Commission to specify a channel for its use at full replication facilities. In such cases, the Commission will select a channel that minimizes new interference among all affected stations.

60. In this third round, we will also permit licensees with a low VHF channel or a channel subject to international coordination issues to seek an alternate tentative channel designation. Although the data are incomplete at this time, we are persuaded that low VHF licensees should be afforded an additional opportunity to find a channel that may better serve the public. For this reason, we will also permit two in-core low VHF licensees to release both of their channels after the first round so that they may be treated as two out-of-core licensee and participate in the second round of elections. MSTV proposed an additional election round for licensees who found their prior election unacceptable and contemplated that licensees which had to choose between two low VHF channels would be among those possibly dissatisfied licensees. Specifically, to the extent a preferred channel is available in this final election round, we will allow such licensees to elect a different channel for their final DTV operations, notwithstanding that they have an elected and "locked in" channel. These licensees may also request that the Commission determine a "best available" channel for them at full replication facilities. We note that it may not be possible to accommodate these preferences. Moreover, it is possible that the low VHF channel may be the best available channel for the licensee. No other licensees with an elected (and "locked in") channel will be permitted to participate in this third and final round of elections.

61. Conflicts among third round preferences. In deciding among third round election preferences, we will determine on a case-by-case basis what channel best replicates a station's service area while minimizing new interference to other stations. If, for example, the channel elected conflicts with a DTV channel tentatively designated for post-transition use by another station, the Commission will resolve the conflict by determining the best available channel for the licensee, as described herein. This analysis includes considerations of service to the public "including service to local communities Considering licensees" ability to reach and provide coverage to local communities is consistent with the Commission's statutory obligation to ensure that broadcasters are responsive to the needs and interests of local communities. "and overall spectrum efficiency. We will also consider in our analysis those factors enumerated by MSTV: (1) Whether the station was an early adopter of DTV technology (*i.e.*, the length of time the station has been operating on DTV); (2) the impact on the public's access to DTV services (*i.e.*, the population served by the station's digital signal and the percentage of replication population covered); (3) whether one or both of the station's channels is/are in the low VHF band (which might weigh in favor of that station receiving priority); (4) whether coordination with or interference to or from Canada or Mexico is a problem; (5) the existence of any zoning, environmental or other such issues; and (6) any other factors that may be relevant at the time.

g. Step 7: New DTV Table of Allotments and Authorizations Proposed and Adopted Through Rulemaking Process

62. After completion of our channel election and repacking process, expected by August 2006, we will issue a Notice of Proposed Rule Making to propose a New DTV Table of Allotments. In creating the new DTV allotments proposals, we will provide all eligible stations with channels for DTV operations after the transition. In developing the new allotments, we will attempt to accommodate the preferences of broadcasters to the extent possible. To clarify as requested by Cox Broadcasting, the process will account for interference agreements among stations under § 73.623(g) of the Commission's rules and will generally preserve the protection afforded by those agreements. Our proposed Table will be based on the tentative channel designations established through our channel election process, as well as on our evaluation of overall spectrum efficiency and providing the best service to the public, including service to local communities. In the NPRM, we will seek comment on our proposed new DTV Table of Allotments.

63. Only Commission licensees and permittees will participate in the channel election process. Applicants for new stations and petitioners for new allotments will not make elections. We note that there are remaining applications that have been pending since before 1997 to obtain approximately 50 new NTSC stations. These applications will be dismissed if found to be inconsistent with the current protection requirements. In developing the post-transition DTV table, we will generally protect those NTSC allotments with pending new station applications that have "cut-off" status (do not face an additional opportunity for filing of mutually exclusive applications). This is consistent with the protection that must be afforded by DTV applications pursuant to § 73.623(h)(2) of the rules. An exception to this protection is that we will not protect the existing channel allotment where the applications are associated with a rule making petition that requests another channel (but may protect the new channel proposed in the rule making petition in accordance with the discussion that follows). For mutually-exclusive groups of applications where there is a settlement, or the tentative selectee is known, we will consider the facilities proposed by the prevailing applicant in the settlement group or the tentative selectee. We will continue to process these protected applications to grant of an NTSC construction permit and note that these will be new single-channel stations, allowed to choose between NTSC and DTV operation during the transition, but required to become DTV

at the end of the transition. At the conclusion of the channel election and repacking process, remaining unprotected new station applications will be evaluated and may be accommodated with a post-transition DTV allotment or dismissed when we issue the NPRM proposing the new DTV Table of Allotments.

64. Pursuant to opportunities the Commission provided, some of the pre-1997 NTSC applicants have continued to pursue a new station authorization by filing rule making petitions requesting a different NTSC channel or a DTV channel. In addition, some petitions have been filed seeking DTV channel allotments for new stations. These pending NTSC and DTV rule making proposals will be dismissed if found to be inconsistent with the current protection requirements. Each rule making request, including those associated with applications and those seeking new DTV allotments, falls into one of three groups: (1) Pending petitions for rulemaking; (2) outstanding rule makings (Notice of Proposed Rule Making issued); or (3) completed rule makings that now have pending applications for a construction permit. We will attempt to protect allotments and proposed allotments in the second and third groups where we have already adopted a Notice of Proposed Rule Making or a Report and Order to establish a channel allotment. Protection of these rule making proceedings is consistent with the requirements placed on DTV applications by § 73.623(h)(2) of the rules. However, we advise these petitioners that there may be a few cases where we must modify, restrict or eliminate their requested allotment in order to accommodate all eligible broadcasters with a post-transition DTV allotment. Remaining rule making petitions will be evaluated at the conclusion of the channel election and repacking process and may be accommodated with a post-transition DTV allotment or dismissed when we issue the NPRM proposing the new DTV Table of Allotments.

Freeze of Procedures To Change Allotments

65. A stable database is not only crucial to the channel election process, but is vital to the completion of the technically difficult task of developing a new DTV Table of Allotments. To make the channel election process and the creation of the new DTV Table of Allotments as manageable as possible, the Media Bureau has temporarily suspended certain procedures for altering DTV and analog TV service areas and channels until after the new DTV Table of Allotments is complete. We will continue to process rulemakings in which a Notice of Proposed Rule Making has been issued prior to the adoption of this Order. Additionally, the Media Bureau staff is directed to dismiss all pending petitions to change the NTSC Table of Allotments in which a Notice of Proposed Rule Making has not been issued prior to the adoption of this Order. We note that the Media Bureau staff previously dismissed or denied a number of petitions for new or changed NTSC allotments on various grounds, thereby declining to issue a Notice of Proposed Rule Making for these petitions. Several petitioners have sought reconsideration or review of these actions. In view of our decision to dismiss all pending petitions for new NTSC allotments which have not been subject to the notice process, all pending petitions for reconsideration or review of NTSC allotment requests that have not advanced to the notice stage are hereby dismissed. Pursuant to the freeze, the Media Bureau we will not accept for filing, until further notice, the following:

- Petitions for rulemaking to change DTV channels within the DTV Table of Allotments.
- Petitions for rulemaking for new DTV allotment proceedings.
- Petitions for rulemaking to swap in-core DTV and NTSC channels. In the NPRM, we sought comment on whether we should allow stations to use an application process to make these swaps. We proposed to require that parties meet the spacing requirements for amending the analog Table of Allotments pursuant to 47 CFR 73.610 and to allow parties to use Longley-Rice analysis to demonstrate that an analog TV station protects DTV stations and for amending the DTV Table of Allotments pursuant to 47 CFR 73.623. We invited comment on these proposals and on how the Commission should address any loss of analog service or cable carriage or other public interest issues that may arise in connection with analog/DTV channel swap proposals. *Second DTV Periodic NPRM,* 18 FCC Rcd at 1288, para. 28. Currently, two or more DTV licensees/permittees are allowed to request a swap of their DTV channel allotments by filing modification applications for each station. Few commenters address this issue on the record. Fewer state that they support channel swaps by application. *See* CEA Comments at 16; Thomas Smith Comments at 4. *See also* NYS–OFT Comments at 12–13; NPSTC Reply at 3–4 (supporting easing Taboo restrictions on early DTV/In-core analog swaps); MSTV/NAB Comments at 7; Paxson Reply at 10; Sinclair Comments at 8. For the reasons stated above, we have determined that we will freeze all NTSC/DTV channel swaps upon adoption of this Order. We therefore do not reach the issue of streamlining the NTSC/DTV channel swap process.
- Applications to change DTV channel allotments among two or more licensees. 47 CFR 73.622(c)(1), 73.623. Stations hoping to participate in negotiated channel election arrangements, discussed supra, must notify the Commission in the channel election form. If these arrangements are approved, the participants will be notified.
- Petitions for rulemaking by licensees/permittees to change NTSC channels or communities of license.
- Television modification applications that would increase a station's DTV service area in channels 2–51 in one or more directions beyond the combined area resulting from the station's parameters as defined in the following: (1) The DTV Table of Allotments; (2) Commission authorizations (license and/or construction permit); and (3) applications on file with the Commission prior to release of this Order; and television modification applications that would increase a station's analog service area in channels 2–51 in one or more directions beyond the combined area resulting from the station's parameters as defined in the following: (1) Commission authorizations (license and/or construction permit) and (2) applications on file with the Commission prior to release of this Order. We froze maximization applications for channels 52–59 on June 18, 2002. Public Notice, 17 FCC Rcd 11290 (2002). We froze maximization applications for channels 60–69 on January 24, 2003. Public Notice, 18 FCC Rcd 627 (2003). We will continue to process applications on file as of the date this Order is adopted. The Media Bureau may consider, on a case by case basis and consistent with the public interest, amendments to those applications to, for example, resolve interference with other stations or pending applications or resolve mutual exclusivity with other pending applications.
- Class A station displacement applications and applications for coverage changes that would serve any area that is not already served by that Class A station's authorized facilities. As an exception to this freeze, on-air Class A stations demonstrating that they

face imminent disruption of service may request an STA to continue operations. Displacement applications filed by out-of-core LPTV stations that have been deemed Class A-eligible requesting a move to an in-core channel where Class A authority could be granted will not be acted on during this freeze, but for such stations, immediate non-Class A LPTV displacement relief may be requested through an STA.

66. Notwithstanding the freeze, licensees will not be prevented from filing modification applications when the application would help resolve international coordination issues or when a broadcast station seeks a new tower site due to the events of September 11, 2001. In addition, the Media Bureau will consider, on a case-by-case basis, requests for waiver of the freeze when the modification application is necessary or otherwise in the public interest for technical or other reasons, such as when zoning restrictions preclude tower construction at a particular site or when unforeseen events, such as extreme weather events or other extraordinary circumstances, require relocation to a new tower site.

Border Interference Issues

67. There are approximately 43 stations with DTV applications awaiting international coordination. As of August 4, 2004, there are 32 pending DTV applications/rule making proposals requiring Canadian approval and 11 pending DTV applications/rule-making proposals requiring Mexican approval. (These numbers do not reflect those applications which have failed the coordination process or which require further action by the applicant.) We recognize that certain issues may remain to be completed in connection with the Canadian approval process for these stations. We will still require, however, broadcasters to make timely channel elections. As noted above, broadcasters with an out-of-core DTV channel and an in-core analog channel that is not available for digital use under the LOU should indicate this fact on their channel election form. Like any one in-core licensee, these licensees may release their in-core channel and participate in the second round of elections; however, we will also afford licensees a later opportunity in the third round to elect another channel in the event their elected channel remains subject to, or was in the interim adversely affected by, international coordination. Those broadcasters remaining on their DTV allotments that do not have applications to maximize should not have unusual difficulties in the approval process. With respect to post-transition DTV replication of stations' current analog service, we must coordinate DTV use of NTSC channels in border areas. We will conduct this coordination in the course of the new allotment rulemaking. We will resolve any remaining international coordination issues as part of the process of developing new DTV allotments.

Replication and Maximization

68. In the creation of the DTV Table of Allotments, each DTV channel allotment was chosen to allow DTV service thereon to best match the Grade B service contour of the NTSC station with which it was paired. We took this approach to ensure that broadcasters have the ability to reach the audiences that they have been serving with the NTSC analog transmission system and that viewers continue to have access to the stations that they are accustomed to receiving over the air. Although we have declined to make full signal replication mandatory, we continue to believe that most DTV broadcasters eventually will replicate their NTSC coverage with DTV service. As an incentive to replicate, we stated that DTV licensees must either be on the air replicating their April 1997 NTSC Grade B service area as of the replication deadline or lose interference protection to the unreplicated portion of this service area outside the noise-limited signal contour. We stated that other full or low-power stations would then have the opportunity to expand their service areas to serve the viewers made available as a result of a DTV station's failure to fully replicate. We also stated in the First DTV Periodic MO&O that we would treat stations seeking to maximize their service areas in a similar manner. First DTV Periodic MO&O, 16 FCC Rcd at 20606, paras. 29–30. By maximizing, stations make power and antenna height increases above the values allotted in the DTV Table, and site changes that extend the service area of DTV facilities beyond the NTSC replication facilities. Class A Order, 15 FCC Rcd at 6377, para. 52. Congress has recognized the importance of preserving the right of DTV stations to maximize and has established specific measures to protect coverage areas defined in maximization applications. In the Community Broadcasters Protection Act of 1999, Congress protected applications for maximization against new Class A stations. To be entitled to protection by low power television stations applying for primary Class A status, DTV stations were required to have filed an application for maximization or a notice of intent to seek maximization by December 31, 1999, and to have filed a bona fide application for maximization by May 1, 2000. We have emphasized DTV service maximization in the digital transition as a means by which stations may increase their DTV signal coverage and provide DTV service competitively within their respective markets. Sixth Report and Order, 12 FCC Rcd at 14605, para. 30. The Media Bureau froze maximization applications in the 698–746 MHz band (channels 52–59 or the "Lower 700 MHz band") to assist participants in Auction No. 44 to determine the areas potentially available in the band for the provision of service by auction winners before the channels are cleared. Public Notice, 17 FCC Rcd 11,290 (2002). The Media Bureau later froze maximization applications in the 746–806 MHz spectrum band (channels 60–69 or the "Upper 700MHz band") to protect Guard Band and Public Safety entities from shifts or expansion in existing broadcast service, and to facilitate the eventual clearing of this spectrum and the auction of the commercial portions of the spectrum.

69. In the First DTV Periodic MO&O, our goal in temporarily deferring the replication protection deadline established in the First DTV Periodic Report and Order was to permit stations to elect a more gradual build-out of their DTV facilities, and thereby increase the number of stations capable of commencing digital service to at least their core communities by the May 2002 and May 2003 construction deadlines. We also gave DTV licensees seeking to maximize facilities, including analog UHF licensees, the same flexibility to implement graduated construction plans as analog VHF licensees.

70. We stated in the First DTV Periodic MO&O that we would establish in this second DTV periodic review a date by which broadcasters must either replicate their NTSC coverage or lose DTV service protection to the unreplicated areas, and by which broadcasters with authorizations for maximized digital facilities must either provide service to the associated coverage area or lose DTV service protection to the uncovered portions of those areas. For DTV channels within the core spectrum, we proposed in the NPRM to set new replication and maximization protection dates: July 1, 2005, for affiliates of the top-four networks (*i.e.*, ABC, CBS, Fox and NBC) in markets 1–100; and July 1, 2006, for all other commercial DTV licensees as well as noncommercial DTV licensees. We sought comment on these dates, stating our goal to allow stations sufficient time to provide full replication and maximization service while also ensuring that stations

continue to progress toward an all-digital broadcast service. We requested comment on whether we should adopt the same or different replication and maximization interference protection deadlines for stations operating in the 700 MHz band. We also sought comment on the disposition of construction permits or applications for replication or maximization pending after the deadline.

71. We take seriously our mandate to speed the transition and to ensure that the spectrum is used efficiently. At the same time, we have attempted to accomplish these objectives without imposing undue cost and delay on broadcasters. After careful consideration of the comments, we will adopt the following use-it-or-lose-it replication and maximization deadlines:

- July 1, 2005—Use-it-or-lose-it deadline for DTV licensees affiliated with the top-four networks (*i.e.*, ABC, CBS, Fox and NBC) in markets 1–100. Those licensees that receive a tentative DTV channel designation in the channel election process on their current digital channel must construct full, authorized facilities. Those licensees that receive a tentative DTV channel designation on a channel that is not their current DTV channel must serve at least 100 percent of the number of viewers served by the 1997 facility on which their replication coverage was based. The number of viewers served by a station's 1997 facility on which its replication is based will be determined using population data from the year 2000 census. Thus, the population that will be reported as served by a station's 1997 facility on the table of station information that we plan to issue soon will generally be different (in most cases larger) than the population reported as served by that facility.
- July 1, 2006—Use-it-or-lose-it deadline for all other commercial DTV licensees as well as noncommercial DTV licensees. Those licensees that receive a tentative DTV channel designation in the channel election process on their current digital channel must construct full, authorized DTV facilities. Those licensees that receive a tentative DTV channel designation on a channel that is not their current DTV channel must serve at least 80 percent of the number of viewers served by the 1997 facility on which their replication coverage was based.

72. We adopt these deadlines for the following reasons. First, we believe that the time has come to ensure that consumers have access to a full range of digital programming services from their local broadcast stations. We note that, even according to MSTV's own study, approximately 40 percent of stations operating pursuant to STAs are reaching less than 70 percent of their analog population with a digital signal. The unserved households are more likely to be in outlying or rural areas, since the minimum STA coverage requirement is that a station's DTV signal covers its actual community of license. Those consumers, like all consumers, reasonably expect that when they buy a digital television set they will be able to receive the same broadcast stations in digital that they receive in analog.

73. Second, our temporary deferral of the replication and maximization deadlines in 2001 recognized that, given the existing marketplace conditions, some broadcasters, particularly those in smaller markets, needed to take a more graduated build-out approach. In particular, we recognized the existing reality of modest DTV receiver penetration, which affected the financial decisions of broadcasters and those who fund them. The outlook for DTV receivers has changed dramatically since 2001. In August 2002, the Commission adopted a DTV tuner mandate. Beginning on July 1, 2004, television receivers shipped in the U.S. must include digital broadcast tuners on a phased-in basis; by July 2007, all television receivers 13 inches and above must include a digital broadcast tuner. In addition, in September 2003, the Commission adopted rules to permit the manufacture of cable-ready "plug-and-play" sets for one-way digital programming. By Commission mandate, each of these sets will also include an over-the-air digital tuner. Between these mandates and the overall increasing pace of the DTV transition, we expect that the penetration of digital televisions with off-air reception capability will dramatically increase in the coming years. Indeed, in testimony before Congress in June 2004, the Consumer Electronics Association ("CEA") forecast that more than 85 million American homes will have DTV tuners by 2010. This emerging reality should alleviate the concerns of commenters stating that they do not wish to provide service in advance of widespread DTV set penetration. Therefore, we do not believe it is appropriate to further postpone replication and maximization deadlines.

74. Third, we do not believe a replication/maximization deadline will impose an undue burden on broadcasters. Approximately 45 percent of broadcasters currently on the air have built licensed facilities and are operating at full power. Many of these full-power stations are located in smaller markets and/or are non-commercial. Not only did they incur higher build-out costs than a station building today, but they have been incurring higher power costs to operate at full power. It would be inequitable to permit broadcasters operating at lower power—who have already accrued significant benefits from the Commission's STA policy—to continue to require the full-power broadcasters continue to shoulder a heavier load throughout the transition.

75. Fourth, we do not believe that the build-out deadlines will result in undue "stranded investment." As an initial matter, we are not requiring stations to replicate or maximize. The "use-it-or-lose-it" deadline simply means that after a reasonable build-out period has passed, if a station fails to provide a signal to serve certain viewers, another entity should have the opportunity to do so. After a reasonable build-out period, we believe that the objectives of providing service to the public and spectrum efficiency militate against further protection of the unserved areas. In addition, we have made a significant accommodation for those broadcasters moving to a new DTV channel at the end of the transition: The top-four network affiliates in the top 100 markets need only provide service to the same number of viewers as their replicated service area in order to preserve their right to maximize/replicate on their ultimate DTV channel; the remaining stations need only serve 80 percent of the number of viewers in their replicated service area to preserve their right to maximize/replicate on their ultimate DTV channel. If, as MSTV asserts, a significant amount of power (and hence, expense) is needed to "push" a UHF television signal out the last few miles beyond the station's "line of sight" or "radio horizon," this should help address the concern. Moreover, we have made a special accommodation, described below, for many of the broadcasters for whom there would certainly be stranded investment—those with a DTV allotment outside of the core. We also note, according to Harris Corporation, that much of the investment in building out will not be stranded even if a station ultimately moves to another channel because some of the equipment can be re-used. Depending on the station's power level and whether it ultimately moves to an in-core VHF or UHF channel, the "stranded" investment caused by an intermediate power increase on the existing DTV channel could range from $345,000 for a higher power station (out of a total investment of $1,355,000 to $1,975,000) to $505,000 for a lower

power station (out of a total investment of $1,145,000 to $1,720,000). Finally, for those broadcasters with an in-core DTV allotment that may want to consider moving elsewhere at the end of the transition, whatever additional costs there are can be factored into that decision just like the sunk costs of the initial STA facility. In any event, these broadcasters would be in no worse position than the hundreds of broadcasters that have already built out to full power and may face a similar choice.

76. Fifth, as with other aspects of the transition such as the initial construction deadlines, we recognize the particular needs of smaller market and non-commercial broadcasters by setting earlier deadlines for the larger market, commercial broadcasters expected to lead the transition. In addition, we are adopting a waiver process for stations that truly cannot afford to build out to these minimum requirements, or that cannot build out for other reasons beyond their control.

77. Stations on any channel that have received construction permits with construction deadlines that extend beyond these replication/maximization interference protection dates must meet their replication/maximization requirements at the expiration date specified by their construction permit. In the First DTV Periodic MO&O, the Commission established a process whereby certain commercial stations and all noncommercial educational stations operating pursuant to a DTV STA would receive automatic DTV CP extensions until a future "use or lose" date. 16 FCC Rcd at 20608, para. 36. In the Second DTV Periodic NPRM, we sought comment on new replication and maximization protection dates and on the disposition of construction permits or applications for replication or maximization pending at the time of the deadline. In conjunction with the replication and maximization protection dates adopted herein, we clarify that we will also apply the DTV CP extension policy to all stations operating with a licensed DTV facility. Therefore, all properly authorized operating DTV stations with authorized CPs to make changes to their licensed facilities, including the network affiliate stations in the top 30 markets, will have their CPs extended until the replication/maximization interference protection deadlines established in this order. We believe this change is appropriate in order to provide consistency in the treatment of stations with outstanding CPs that have already received a DTV license and those with an outstanding CP operating pursuant to a DTV STA. They must build facilities that meet the minimum requirements by that date or lose interference protection.

78. A station that fails to meet the above replication/maximization requirements will lose interference protection to the unused portion of the associated area as of the applicable interference protection deadline, as described more fully in section IV.D., infra. As a practical matter, nearly every station that has fully replicated its analog coverage will have maximized its DTV coverage by reaching at least some small areas beyond the analog Grade B contour. Where a station has maximized its DTV coverage by a coverage shift that leaves some of its replication coverage area unserved, then the station's protection will shift to its maximized coverage area and it will lose interference protection to the unserved replication area. In addition, a station failing to meet the above deadlines will lose the ability to "carry over" its interference protection to its unserved DTV service area on its post-transition channel (*e.g.*, on its in-core NTSC channel), as determined in the channel election process described above. Analog service will remain protected throughout the transition, but DTV service to the former analog area will not be protected after the transition unless replication deadlines are met. Some stations may currently have licenses or construction permits to serve areas smaller than the service area allotted to them in the DTV table of allotments. Unless broadcasters in this situation construct facilities to serve these unserved areas within the DTV allotment prior to the replication/maximization interference protection deadline, they risk not being able to expand later to regain that service area. Thus, for example, if a station subject to the July 1, 2006 deadline builds out only to 60 percent of its replicated service population by that date, it will lose interference protection on its digital allotment beyond that 60 percent service area, and, if it seeks to move to its NTSC allotment at the end of the transition, it will not retain the ability to carry over interference protection beyond the 60 percent service area.

79. By contrast, a station that meets its applicable build-out requirements will retain interference protection to its authorized service area on its DTV channel if it remains on that channel, as well as the ability to "carry over" its interference protection for its authorized DTV service area if it moves to a different DTV channel post-transition. This decision modifies our decisions in the Class A Order and Class A Recon. Class A Order, 15 FCC Rcd at 6379–80, para. 58; Class A Recon., 16 FCC Rcd 8269–70, para. 67. In the Class A Order, in the context of relative interference protection priorities of Class A and DTV stations, we stated that "[t]o preserve their ability to maximize * * * within the core, we will require stations * * * to * * * maximize their DTV service area on their * * * DTV channel. These stations must have filed a notice of intent to maximize and must file an application to maximize within the deadlines mandated by the CBPA. [W]e will allow these stations to carry over to their in-core [NTSC] channel the maximized digital service area achieved on the [DTV] channel, to the extent that the [NTSC] channel facilities for maintaining the maximized service area provide required interference protection to other DTV stations." Class A Order, 15 FCC Rcd at 6379–80, para. 58. Under today's decision, stations need only meet our replication/maximization build-out deadlines to preserve their ability to maximize on their ultimate DTV channel. Similarly, stations electing to forfeit their current DTV channel and "flash-cut" to digital on their analog channel under the options described below for stations with out-of-core DTV allotments and satellite stations, will be entitled to interference protection as if they met the applicable replication/maximization build-out deadlines. However, a station moving to a different DTV channel at the end of the transition will lose interference protection during the transition to any unserved areas on its current DTV channel as of the applicable deadlines, notwithstanding the fact that it meets the minimum build-out requirements. For example, assume a broadcaster subject to the July 1, 2006 deadline will be changing DTV channels at the end of the transition and meets the 80 percent build-out requirement by serving 90 percent of its replicated service population by July 1, 2006. Assume further that it was authorized to build maximized facilities, serving 120 percent of its replicated service population. At the end of the transition, it will be entitled to "carry over" its full maximization service area, to the extent possible under our rules. However, during the transition, the station will lose interference protection on its existing DTV channel for those areas within its maximized service area that are unserved as of the deadline (*i.e.*, those areas containing 90 percent–120 percent of its service population).

80. For those stations that are unable to provide the required service by our replication/maximization protection deadlines because of severe financial

constraints or circumstances beyond a station's control, we will establish a limited waiver process and grant extensions of the applicable replication or maximization interference protection deadline on a six-month basis if good cause is shown. Broadcasters seeking a waiver on the basis of financial hardship must make a showing similar to that required to obtain a waiver of the DTV construction deadlines on financial hardship grounds. As with any request for waiver of our rules, a request for an extension of the applicable deadline will be granted only upon a showing of good cause and where grant of the extension will serve the public interest.

Single Channel Broadcasters

81. KM Companies requests that we specifically address the treatment of single channel broadcasters with respect to the interference protection deadline. As discussed elsewhere, single channel broadcasters will participate in the channel election process. Analysis of their channel elections will be based on their authorized facilities (construction permit for stations that have both a license and a construction permit). Whether their single-channel authority is analog or digital, a broadcaster that has not constructed or is not operating the appropriate facilities on which its election analysis is based will lose protection of the unserved area as of the applicable interference protection deadline (except in cases where the DTV allotment coverage is based on a construction permit that expires after the deadline, in which case they will keep their protection as long as the construction permit remains valid).

Early Surrender of DTV Out-of-Core Channels ("Flash Cut")

82. The Second DTV Periodic NPRM asked if we should establish earlier replication and/or maximization interference protection deadline(s) for out-of-core broadcasters (*i.e.*, in the 700 MHz band) than broadcasters operating on channels within the core in order to allow new services to be provided in portions of replication areas that a DTV licensee may never plan to serve in this spectrum.

83. The Commission permits broadcasters with NTSC stations in the Upper 700 MHz (60–69) or the Lower 700 MHz (52–59) to enter into voluntary band clearing arrangements consistent with the Commission's existing band-clearing rules and Section 6 of the Auction Reform Act of 2002. Auction Reform Act of 2002, Pubic Law 107–195, 116 Stat. 715 ("Auction Reform Act") section 6(a), 47 U.S.C. 337 note. Section 6 of the Auction Reform Act restricts the Commission from waiving certain broadcast interference standards and the minimum spacing requirements for certain proposals to relocate Channel 52–69 analog operations to a Channel 2–51 DTV allotment, if such waiver "will result in any degradation in or loss of service, or an increased level of interference to any television household except as the Commission's rules would otherwise expressly permit, exclusive of any waivers previously granted." Id. These restrictions do not, however, apply to proposals to move Channel 63, 64, 68, or 69 analog operations to in-core DTV allotments "in order to make such frequencies available for public safety purposes." Id., Section 6(b). In furtherance of the significant public interest in rapid band clearing, and in recognition of the fact that all out-of-core DTV facilities will have to move at the end of the transition, we will permit stations with an in-core NTSC channel paired with an out-of-core DTV channel, as well as stations with two out-of-core channels, to surrender their out-of-core DTV channels and operate in analog on their analog channels. We will also permit single-channel DTV stations out of the core, upon Commission approval, to elect not to construct DTV facilities and instead to give up their assigned DTV channel in the 700 MHz band in return for a DTV channel inside the core. We will assign these broadcasters an in-core DTV channel when we generate a revised DTV Table of Allotments Stations have up to their initial channel election deadline to inform the Commission that they will use this option. We delegate the authority to grant these requests to the Media Bureau. Upon approval from the Commission, these stations will then surrender their out-of-core digital channel and be treated as single channel stations, allowed to "flash cut" to digital on their in-core channel no later than the end of the transition in the stations' markets. These stations will retain their ability to replicate and/or maximize on their NTSC allotment as if they met the applicable replication/maximization build-out requirement. The station will then be responsible for meeting any DTV service obligations (*e.g.* hours of operation, and replication/maximization requirements), applicable to other like broadcasters on the date it commences DTV operations. Because of the greater potential for wasted expenditures in DTV facilities built in the 700 MHz band (since there will not be an opportunity to remain in that band after the transition), and given the potential for earlier use of this spectrum by public safety and other 700 MHz licensees, we will presume that granting such a request will be in the public interest if the station demonstrates that it is assigned a DTV channel out of the core and that grant of the request would not result in the loss of a DTV channel affiliated with one of the four largest national television networks (ABC, CBS, NBC, or Fox). We have consistently relied on affiliates of the four largest national television networks to achieve the necessary milestones throughout the DTV transition. These stations also must remain on the air in order to fulfill Congress' directive that stations "licensed to or affiliated with one of the four largest national television networks" must be "broadcasting a digital television service signal" in order for the transition to occur. We conclude that the presumption we establish is consistent with Congress' objectives for this spectrum, should generally increase the attractiveness of the spectrum to potential 700 MHz licensees, and will not unduly delay the expeditious transition to DTV.

84. This presumption, however, is neither conclusive nor dispositive. We will also consider whether special circumstances raised by the resulting loss of digital broadcast service would be sufficient to rebut the presumption. We find that the surrender of DTV channels of these out-of-core stations will generally not create a loss of particular programming to viewers during the transition because, as presented in Paxson's comments, the stations will continue analog operations until switching to DTV by the end of the transition Also, for requests that do not meet the presumption, we would consider all the relevant public interest factors regarding opportunities for provision of wireless and public safety services, acceleration of the DTV transition, and the loss of broadcast service in deciding whether or not to approve the request.

85. Stations that have been denied an extension of the construction requirements and admonished because they failed to demonstrate that they are meeting the necessary criteria for an extension and have not come into compliance are not eligible to surrender their out-of-core DTV channel. On April 16, 2003, the Commission released an Order establishing remedial measures to be followed when a television station fails to meet its DTV construction deadline and fails to adequately justify an extension of its DTV construction deadline. Under the three-step graduated sanction process we will first deny the request for an unqualified extension and admonish the station for its failure to comply with its DTV

construction obligation. The station will then have six months to complete its construction, subject to reporting requirements and possible additional sanctions in the interim. Under the second step, if the station has not come into compliance with the DTV construction requirement within the six-month period, then, absent extraordinary and compelling circumstances, we will issue a Notice of Apparent Liability for forfeiture to the licensee and require that the station report every 30 days on its proposed construction milestones and its efforts to meet those milestones. Under the third and final step, if the station has continued to fail in its efforts to come into compliance with the DTV construction requirement within the second six-month period of time (*i.e.*, one year from the date of the formal admonition), then, absent extraordinary and compelling circumstances, we will consider its construction permit for its DTV facilities to have expired and we will take whatever steps necessary to rescind the station's DTV authorization.

Satellite Stations

86. In the Second DTV Periodic NPRM we sought comment on whether the public interest would be served by allowing television satellite stations to turn in their digital authorization and "flash-cut" to DTV transmission at the end of the transition period. TV satellite stations are full power terrestrial broadcast stations authorized under part 73 of the Commission's rules to retransmit all or part of the programming of a parent station that is typically commonly owned. Eligible satellite stations were assigned a paired DTV channel in the current DTV Table of Allotments. The Commission first authorized TV satellite operations in small or sparsely populated areas, which were deemed to have economic bases insufficient to support stand-alone, full-service operations. The Commission later authorized satellite stations in larger markets when the applicant demonstrated that the proposed satellite could not operate as a stand-alone, full-service station. The Commission has also allowed a full-service station to convert to satellite operation upon a showing that the community no longer has a sufficient economic base to support a full-service operation.

87. On October 16, 2003, the Commission deferred the digital construction deadlines for 30 satellite stations that had requested a third extension of time to construct. The Commission noted that the issue of whether to permit satellites to turn in their digital authorization and "flash cut" to DTV transmission at the end of the transition period is under consideration in this proceeding.

88. To ensure that the channel election process described herein proceeds smoothly and that the channels being surrendered by satellite licensees are included, we will require all satellite stations to participate in the channel election process. We will permit satellite stations to surrender one of their paired channels (the one not elected on their channel-election form for use after the transition) and flash cut from analog to digital transmission by the end of the transition period. Satellite stations that choose to flash cut must make the flash cut decision and notify the Commission by their initial channel election deadline. Satellite stations choosing the flash cut option will be required to surrender one of their two broadcast channels. Except as provided below (for stations with out-of-core analog and in-core DTV channels), satellite stations that choose not to flash cut and instead choose to retain both an analog and a digital channel during the transition period must comply with the applicable digital construction deadlines, including any extension granted by the Commission. As noted above, a satellite station that surrenders one of its channels under the "flash-cut" option will be treated as if it met the applicable replication/maximization build-out requirements.

89. Satellite stations with an analog channel outside the core and that are electing their current in-core DTV channels for post-transition DTV service will not be required to surrender a channel at this time. To do so would require these stations to give up their DTV channels unnecessarily or to build DTV facilities now, unlike other satellite stations which, under the flash cut policy announced herein, may elect to wait to build their digital facilities until closer to the end of the transition period. In this instance, we believe the benefits of this approach outweigh our interest in rapid clearing of the out-of-core television spectrum. Satellite stations with an out-of-core analog channel and an in-core digital channel may retain their out-of-core channel for continued analog service until the end of the transition or until they decide to build and transmit only in digital, whichever is earlier.

90. Stations electing to return their DTV channel to the Commission will retain interference protection to the areas defined in existing DTV replication or maximization applications on file with the Commission until the end of the transition when the station must commence digital transmissions. This interference protection will apply to the digital service area of the channel on which the station flash cuts to digital to the extent that the station replicates and maximizes at the time of the flash cut and to the extent consistent with our DTV interference protection rules. To ensure that satellite stations that have already constructed digital facilities or that do so before the end of the transition are not disadvantaged, we will also permit these stations to retain replication and maximization interference protection for their digital stations until the end of the transition in their market. Similarly, to provide satellite stations that have constructed digital facilities additional flexibility during the transition while maintaining an basic level of service to the public, we will also permit satellite stations that choose to construct separate digital facilities to operate only during prime time hours (at a minimum) until the end of the transition.

91. We believe that this approach will best ensure that satellite stations complete the conversion to digital format and continue to provide broadcast programming to viewers in their communities. We agree with LeSEA, Media General, and MSTV/NAB that many satellite stations may not be financially capable of operating both an analog and a digital facility concurrently. As these commenters point out, satellite stations provide programming to communities that cannot support operation of these stations on a full-service basis. Indeed, Media General and LeSEA state that their satellite stations continually operate at a loss and that, absent some relief from the requirement of constructing and operating dual facilities during the transition, they may be forced to turn in their satellite licenses and cease all operations. Unlike full-service stations, satellite stations have chosen to forego or relinquish full-service status and instead retransmit the programming of a parent station because full-service operation of the satellite facility is not economically viable. We believe that the unique status of and circumstances faced by satellite stations warrant special treatment of these stations during the transition.

92. We do not believe that granting this special relief to satellite stations will unduly hinder the overall transition to digital television. Some of the affected viewers may have access to other digital signals. According to a study of its satellite stations. Moreover, the alternative to the flash-cut option we are adopting today, that of requiring

satellites to operate dual facilities during the transition, could result in the cessation of all service, either analog or digital, by some satellite stations. The approach we adopt today will ensure that satellite stations provide digital service by the end of the transition and will help preserve television service in the historically underserved communities in which most satellite stations operate.

Disposal of Construction Permits and Applications for Replication/Maximization

93. In the NPRM, we asked for comment on how the Commission should dispose of a station's construction permit or application for replication or maximization facilities if the station fails to construct and operate facilities that fully replicate its NTSC service or provide signal coverage over an authorized maximized service area by the interference protection deadlines established in this proceeding. We stated that our inclination was to restrict any station that has failed to fully replicate or construct its authorized maximization facilities by the applicable deadline from filing an application to expand coverage for a certain period of time in order to allow other existing or new stations, including Class A eligible LPTV stations on out-of-core channels, to apply to use this spectrum.

94. We will dismiss any applications and cancel any construction permits for facilities in excess of those in actual operation by a station as of the applicable interference protection date. We will require broadcasters to file applications for licenses to cover their actual facilities served as of the interference protection deadline. We have given broadcasters ample opportunities over the past years to expand their service areas, and advance warning that if they elect not to provide their viewers with DTV the Commission may ensure the area is served in other ways. Therefore, we will permit existing DTV stations seeking to expand their coverage area and Class A eligible stations on out-of-core channels to apply for unused spectrum within the core. LPTV stations may also apply for secondary operation on unused spectrum. We will describe the procedures for filling in those unserved areas in a future public notice or as part of the periodic review process. Broadcasters failing to meet our replication or maximization deadlines will be permitted to reapply for authorization to provide service to those areas, but their applications will be subject to conflicting applications. This will allow other existing stations, including Class A eligible LPTV stations on out-of-core channels, the opportunity to apply to use this spectrum. The process for resolving conflicting applications will be announced in another public notice or proceeding.

Pending DTV Construction Permit Applications

95. Approximately 65 commercial and noncommercial television licensees have not yet been granted an initial DTV CP. Almost all of these licensees have filed an application for a digital CP, but grant of these applications has been delayed for a variety of reasons, including delays in international coordination with Canada and Mexico and unresolved interference issues. To date, these applicants have not been required to construct DTV facilities pending action on their outstanding DTV applications. To ensure that all licensees that have been allotted digital spectrum begin to provide digital service, we proposed in the Second DTV Periodic NPRM to require that all television licensees that have filed an application for a digital CP with the Commission that has not yet been granted commence digital service pursuant to special temporary authority ("STA") within one year from adoption of the Report and Order in this proceeding.

96. It is crucial at this stage of the transition that all licensees with DTV CP applications that have not yet been granted begin to construct digital facilities. We will therefore adopt a proposal similar to that advanced in the NPRM. Rather than requiring licensees with pending DTV CP applications to construct at least the minimum initial facilities required to serve their communities of license within a year from the adoption of this Report and Order, as we proposed, we will instead require such licensees, within the same time frame, to construct and operate "checklist" facilities that conform with the parameters of the DTV Table of Allotments and other key processing requirements. "Checklist" facilities have power and antenna height equal to or less than those specified in the DTV Table of Allotments and are located within a specified minimum distance from the reference coordinates specified in the DTV Table of Allotments. Because these facilities comply with the interference requirements specified in the rules, no further consideration of interference is required. In addition, because the DTV Table has been coordinated with Canada and Mexico, "checklist" facilities generally do not require further international coordination. This approach best advances our goal of ensuring continued progress in the transition by requiring that all licensees begin to provide DTV service. "Checklist" applications are routinely processed by the Commission staff within three days of filing, and most do not require international coordination. Thus, this procedure is the most expeditious means of awarding DTV construction permits to those licensees who do not yet have them.

97. Many licensees with pending DTV CP applications are facing delays beyond their control. Some are awaiting international coordination of pending applications or resolution of interference issues. Other licensees have applied for new DTV allotments either to replace an initial out-of-core allotment with one in the core or to otherwise improve their potential DTV service. Although the Commission will continue to work with applicants to resolve outstanding issues and to process pending applications for digital facilities as expeditiously as possible, we nonetheless agree with those commenters who argue that it is critical at this stage in the transition that all licensees begin working toward construction of DTV facilities.

98. We will allow licensees with pending DTV CP applications that file checklist applications to continue to pursue their non-checklist applications now on file. Thus, while these applicants will receive a construction permit for a checklist facility and will be required to construct such facilities within one year from adoption of the Report and Order in this proceeding, we will permit these applicants to continue to attempt to resolve the issues delaying approval of their non-checklist application currently on file with the Commission. If the non-checklist application is approved before construction of the checklist facility is complete, the permittee may request that the Commission substitute the non-checklist CP for the checklist CP. The Commission will consider requests for waiver of the one year construction deadline, on a case-by-case basis, using the criteria for extension of DTV construction deadlines. Grounds for an extension must relate to the checklist facility, not the pending non-checklist application.

Intermediate Signal Level

99. In the First DTV Periodic MO&O, we allowed stations to commence digital operations by constructing and operating facilities that at least provide the required level of digital signal strength to their communities of license. We predicted that the "requirement that

broadcasters serve their community of license will ensure that, for most stations, the majority of their analog service populations will receive initial digital service." We also decided to retain our enhanced principal community signal strength standard, which requires a 7dB increase in community of license coverage that must be met by December 31, 2004, for commercial stations and December 31, 2005, for noncommercial stations. In the First DTV Periodic Report and Order, we imposed a principal community coverage requirement that is stronger than the DTV service contour requirement that we adopted as an initial obligation in the Fifth Report and Order. The purpose of our revised requirement was to improve the availability and reliability of DTV service in the community of license and provide an extra measure of protection from interference to DTV service in the community. The NPRM asked if significant numbers of consumers are not being served by stations operating under low-power STAs, and, if so, what actions the Commission should take. We asked whether we should establish a deadline by which stations must provide DTV service within the entire area of their analog "city-grade" coverage contour or their Grade A coverage. We also asked whether the 7dB increase in community of license coverage will likely ensure that the majority of viewers are served without an additional coverage requirement.

100. We conclude that we will not impose an intermediate signal level requirement. With the community of license signal strength increases set for 2004 and 2005, we expect that more of broadcasters' service areas will be covered as these dates approach. Increasing power is one way of increasing the signal strength within an area, such as the community of license. A 7 dB increase in a station's power will result in a 7 dB increase in signal strength. A power increase will also increase the station's service area. Increasing antenna height is another way to increase a station's signal strength and service area. Nonetheless, we will closely monitor reports from consumers and other parties regarding broadcasters operating at insufficiently low power levels and will act on these reports should a pattern of abuse of our signal level requirements become evident. We may also, on our own initiative, conduct signal strength tests to ensure that broadcasters are operating at power levels that are consistent with the Commission's requirements.

Interference Protection of Analog and Digital Television Service in TV Channels 51–69

Definition of "Actual" Parameters

101. The Second DTV Periodic NPRM sought comment on an issue raised in the Public Safety Spectrum Report and Order. The NPRM explained that §§ 90.545(c) and 27.60(b) of the Commission's rules describe alternative methods for a wireless applicant or licensee in the 700 MHz band to move closer to an analog TV or DTV antenna while still complying with the interference protection requirements in the rules. Pursuant to one of these alternatives, the applicant or licensee may submit an engineering study that considers the "actual," rather than "hypothetical," parameters of the analog TV or DTV station and that demonstrates that the station's actual coverage area is smaller than its hypothetical operating parameters—because the station is operating, for example, with lower power than that presumed in the hypothetical parameters or because intervening terrain or other factors reduce the station's coverage area—thereby permitting land mobile stations and these broadcast facilities to be more closely spaced. Reference to the Grade B contour of a "hypothetical" station permits an applicant or licensee to determine if there is any need to submit additional engineering studies or if there is not even a hypothetical station within the relevant area. If there is a hypothetical station, then the applicant or licensee must demonstrate how it would protect the actual (including authorized or applied for) parameters. The Public Safety Order allowed applicants to submit engineering studies showing how they propose to meet the appropriate desired to undesired ("D/U") signal strength ratio at the existing TV station's "authorized or applied for" Grade B service contour or equivalent contour for DTV stations instead of providing the protection built into the distance spacing table, which is based on a standard TV station's hypothetical Grade B contour. In the Second DTV Periodic NPRM, we tentatively concluded that §§ 90.545(c)(1)(ii) and 27.60(b)(1)(iii) of our rules should be amended to make clear that the interference protection specified in those provisions should be afforded to authorized and/or applied for NTSC and DTV facilities, including the facilities specified on the broadcast station's license or construction permit or both when a station has both a license and a construction permit. We sought comment on this tentative conclusion, as well as alternatives.

102. As proposed, we will amend §§ 90.545(c)(1)(ii) and 27.60(b)(1)(iii) to make clear that the interference protection specified in those provisions will be afforded to authorized and/or applied for NTSC and DTV facilities, including the facilities specified on the broadcast station's license or construction permit or both when a station has both a license and a construction permit. In the TV and DTV broadcasting services, applicants file separately for a construction permit and a license to operate a facility when construction is completed. Licensees may also file applications for construction permits to modify their stations' facilities. When applications are granted, the facilities are authorized by a construction permit or license. While some public safety and other entities in the 700 MHz band assert that protecting authorized and/or applied for NTSC and DTV facilities is unnecessary, this protection is necessary to permit broadcasters to increase their service to reach their replication and maximization levels without risk of interference from new services. Permitting stations to achieve replication and maximization coverage serves the transition to DTV by increasing the population with access to digital signals. In addition, as discussed in section IV.B., supra, replication on out-of-core DTV channels is necessary to preserve broadcasters' opportunity to carry over their DTV service areas to their eventual in-core channels. As asserted by Sinclair, protecting less than the full replicated or maximized facilities could create loss of service to wireless or public safety providers when DTV stations increase to replicated or maximized facilities. Our existing band-clearing policies and newly introduced "flash cut" policy discussed in section IV.B.2, supra, should alleviate some of the 700 MHz entities' concerns by more rapidly freeing up additional spectrum in channels 52–69. New operations in the 700 MHz band will essentially need to provide the interference protection specified in §§ 90.545(c)(1)(ii) and 27.60(b)(1)(iii) for authorized or applied for but un-built facilities only until the July 1, 2005, and July 1, 2006, replication/maximization interference protection dates. In limited circumstances we will grant interference protection beyond the replication/maximization dates for stations granted construction extension waivers. As discussed above, if a broadcaster is not serving its fully authorized replication or maximization facilities on the

applicable interference protection deadline, we will require the broadcaster to obtain a license to cover its existing facility and will only protect that existing facility going forward.

Applications for New Analog TV or DTV Facilities

103. As we stated in the *Second DTV Periodic NPRM*, the Commission has determined it will not authorize new DTV facilities in channels 60–69. The Commission has also determined that it will not authorize additional new analog full-service television stations on channels 60–69, and that it would dismiss any application or allotment petition for a new analog facility that was not satisfactorily amended to specify a channel below channel 60 by the established deadline (referred to herein as the "July 15, 2000 filing window"). Thus, there will be no new analog TV or DTV entrants in the 746–806 MHz band, other than those acquired through auction, which wireless and other new service providers must protect.

104. In the Lower 700 MHz Band Report and Order, we dismissed pending petitions for new NTSC channel allotments in the band comprising channels 52–59, stating that adding new analog TV allotments or stations at this stage of the transition would be inconsistent with the DTV transition process. With respect to pending applications for construction permits for new analog TV stations in this band, we provided a 45-day opportunity (referred to herein as the "March 8, 2002 filing window") for applicants to request a change in their applications to either (1) provide analog or digital service in the core television spectrum, *i.e.*, channels 2–51, or (2) provide digital service in the 698–740 MHz band, *i.e.*, channels 52–58. Any applications or rulemaking proposals and later associated applications filed by pending applicants during this 45-day window must be protected by wireless and other entities. Because of the adjacent channel interference that new stations on channel 59 could cause to new licensees in the adjacent Upper 700 MHz band, we concluded that we will no longer accept or grant any application for a new analog TV or DTV station on channel 59 nor permit an existing DTV station to modify its channel to channel 59. We required parties with outstanding applications specifying channel 59 to request another channel within 45 days after release of the Lower 700 MHz Band Report and Order.

105. In the Second DTV Periodic NPRM we indicated that digital service in the Lower 700 MHz band could be proposed after the auction of channels in that band by a station with an existing DTV allotment on a channel outside the 52–58 band seeking to move to a channel inside this band or by a DTV station inside this band seeking to move to another channel inside the band. As we indicated in section IV. A. 2, supra, we have determined herein that, in order to facilitate the channel election process, we will no longer accept, as of the date of adoption of this Report and Order, applications for DTV channel changes and swaps. Thus, there will be no new analog or DTV entrants in the 698–740 MHz band other than those acquired through auction.

106. A few requests for DTV channels in the 52–58 band were filed during the July 15, 2000, and March 8, 2002, filing windows. The Commission has completed processing all but one of these petitions for rulemaking. While these parties may continue to pursue construction of their proposed facilities within the 52–58 band, we will permit these parties, upon Commission approval, to elect not to construct these facilities and instead to give up their assigned DTV channel in the 52–58 band in return for a DTV channel inside the core. We will assign these broadcasters an in-core DTV channel when we generate a revised DTV Table of Allotments.

Channel 51

107. In the Second DTV Periodic NPRM, we sought comment on the interference protection that should be afforded by wireless entities and other new service providers to future analog TV and DTV facilities on channel 51 that are authorized or requested after the auction of the spectrum comprising channel 52. Channel 51 will remain allocated to broadcast use as part of the core television spectrum (channels 2–51), and is available for use by existing and new analog TV and DTV stations. However, as we stated in the Second DTV Periodic NPRM, because channel 51 is adjacent to channel 52 we are concerned about possible interference between new wireless and other licensees on channel 52 and operations on channel 51. In the Lower 700 MHz Report and Order, we declined to adopt a guard band or other specialized mechanism to protect DTV operations on channel 51, and stated that we would instead rely on interference protection criteria to ensure that new licensees adequately protect core channel TV and DTV operations. We noted that the adjacent channel protection for TV and DTV stations on channels 52–69 is no different from the protection for those stations in the core spectrum; only the duration of that protection differs. Because DTV stations on channels 52–69 will eventually relocate to the core TV spectrum, the broadcast interference protection standards on channels 52–69 will no longer apply after the transition. By contrast, the need for protection of broadcast operations on core TV channel 51 will continue indefinitely. In light of our concern about possible adjacent channel interference, we sought comment on whether we should provide the same level of adjacent channel protection to future analog and digital broadcast facilities on channel 51 as is currently provided by wireless or other operators to incumbent analog and digital stations on this channel and, if so, how we can accomplish such protection without unduly restricting use of the channel 52 spectrum.

108. We will accord the same level of adjacent channel protection to both incumbent and future analog and digital broadcast facilities on channel 51. Thus, wireless and other operators on channel 52 must provide the interference protection prescribed in the Lower 700 MHz Report and Order to all broadcasters on channel 51, including any that may commence operation after the auction of the adjacent channels in the 52–58 band. We agree with MSTV/NAB that stations on channel 51 should receive the same level of protection as other stations on in-core channels, including protection from wireless and other new service providers. We disagree with Flarion that any interference protection the Commission adopts for channel 51 should be reciprocal. Channel 51 is part of the core channels reserved for broadcast use, and we do not believe use of channel 51 for broadcast purposes should be restricted in order to protect operations on channel 52, even if those operations predate the commencement of operations on channel 51. We also decline to adopt Flarion's proposal that the Commission reduce or eliminate the required desired/undesired signal strength ratio for "distantly adjacent" wireless channels. This proposal to revisit the wireless to TV and DTV protection criteria established in the 700 MHz proceedings is beyond the scope of this proceeding. The Commission's rules do permit wireless and other operators in the 52–58 band to negotiate agreements with broadcasters and other operators to accept any interference that may be caused by operations on distantly adjacent frequencies. Licensees proposing new operations in the 700 MHz bands on a frequency "distantly adjacent" to an existing

operation could also file a request for waiver of the interference requirements.

Simulcasting

109. In the *DTV Fifth Report and Order*, we adopted rules requiring DTV licensees to simulcast 50 percent of the video programming of their analog channel on their DTV channel by April 1, 2003. This requirement increased to a 75 percent simulcasting requirement on April 1, 2004, and increases to a 100 percent requirement on April 1, 2005. The simulcasting requirement was intended to ensure that consumers enjoy continuity of free over-the-air video programming service when analog spectrum is reclaimed at the end of the transition. The Commission has stated that it may be difficult to terminate analog broadcast service if broadcasters show programs on their analog channels that are not available on their digital channels.

110. In the Second DTV Periodic NPRM, the Commission sought comment on whether we should retain, revise, or remove the simulcasting requirement in 47 CFR 73.624(f), how to define simulcasting, and whether the existing dates for implementation of the simulcasting requirements are appropriate. We asked in the Second DTV Periodic NPRM whether the ultimate requirement of 100 percent simulcasting other than at the very end of the transition creates a disincentive for broadcasters to innovate. We also asked whether a requirement to simulcast is necessary or whether broadcasters have a market-based incentive to simulcast and are currently simulcasting 100 percent of their analog programming on their digital channel. In addition, we sought comment on whether something less than a 100 percent simulcasting requirement would be sufficient to protect analog viewers while allowing for innovation on the DTV channels.

111. In an Order adopted April 28, 2003, the Media Bureau granted noncommercial educational television stations a six-month waiver of the DTV simulcasting requirements, until November 1, 2003. The Bureau noted that, in light of the burden faced by NCE stations in complying with both the construction and simulcasting requirements at once, and in light of our pending re-evaluation of our simulcasting requirements, good cause existed to grant NCE stations a six-month waiver of the simulcasting requirements in § 73.624(f) of the Commission's rules. We also stated that we would consider requests for waiver extensions from NCE stations on their individual merits if the Commission had not yet acted on the simulcasting issues raised in the Second DTV Periodic NPRM by November 1, 2003. The Media Bureau has granted several additional requests for waiver of the DTV simulcasting requirements to give stations additional time to acquire and install the facilities necessary to meet the simulcasting requirement or to permit stations to experiment with innovative uses of the digital channel.

112. We believe that, at this point in the transition, mandating a requirement that the programming aired on the analog channel be simulcast on the digital channel is not necessary to advance transition progress. Simulcasting has been the general practice of broadcasters as the transition has progressed. Thus, broadcasters are not now treating their digital channel as a separate, unique program stream. We also agree with HDNet, Belo, and Disney/ABC that the availability of high-quality innovative digital content is critical to the advancement of the transition. There is evidence in the record that the simulcasting rule may impede the distribution of high definition programming to broadcasters. We are concerned that broadcasters not be impeded in developing, obtaining, or airing high definition and other innovative programming that could spur consumer demand for DTV.

113. Accordingly, we will eliminate, for the time being, the requirement that broadcasters air on their digital channel the programming aired on their analog channel. We expect broadcasters to use this increased flexibility to provide innovative, value-added programming to consumers; if this expectation proves misplaced, we will take appropriate action. However, as we continue to monitor the progress of the transition in future DTV periodic reviews, we will continue to consider whether re-imposition of a simulcasting requirement is advisable. Our concern is to ensure that, as the end of the transition nears, significant numbers of viewers will not be denied access to desirable programming aired only on analog channels. We believe that eliminating rather than reducing the simulcasting requirement is appropriate at this point in the transition. There is no evidence of the need for any simulcasting requirement at this time. While we recognize that, as NCTA argues, viewers could lose access to programs at the end of the transition if programs available on analog channels are not available on digital channels, we believe we can address this concern if the need arises closer to the end of the transition. Because we are eliminating the simulcasting requirement, we do not address herein the issue of how to define simulcasting in the context of the digital transition.

114. Minimum hours of operation of digital stations. In the DTV Fifth Report and Order, we required DTV licensees and permittees to transmit at least one DTV signal at any time the licensee or permittee transmits an analog signal. In the First DTV Periodic MO&O, the Commission revised this requirement to allow stations subject to the May 1, 2002, or May 1, 2003, digital construction deadlines to operate initially at a reduced schedule by providing, at a minimum, a digital signal during prime time hours, consistent with their simulcasting obligations. The top-four network affiliates in the top 30 television markets are required to operate their DTV stations whenever their analog stations are operating. The reduced digital operating schedule tied to the simulcasting requirements applies only to commercial stations in the top 30 markets not affiliated with a top-four network, commercial stations in markets below the top 30, and noncommercial stations. The minimum operating hours for these digital stations effectively increases as the simulcasting obligations are phased in. For example, beginning April 1, 2003, DTV stations that were required to be on the air by May 1, 2002, are required to provide a simulcast digital signal at least 50 percent of the time they transmit an analog signal and, under the requirements of § 73.624(b)(1) of the Commission's rules, are also required to air a digital video program signal during prime time. Along with the simulcasting requirements, the minimum hours requirements step up to a 75 percent requirement in April 2004, and a 100 percent requirement in April 2005. Stations that were subject to the earlier DTV construction deadlines (May 1, 1999 for top-four network affiliates in the top 10 television markets and November 1, 1999 for all remaining top-four network affiliates in the top 30 television markets) are subject to our original rule requiring that they operate their DTV station at any time that the analog station is operating.

115. We proposed in the Second DTV Periodic NPRM that, if we eliminate or reduce the simulcasting requirements in § 73.624(f), we amend § 73.624(b)(1) of our rules in order to retain the same phased-in minimum DTV operating hours for smaller and smaller-market stations that were tied to the simulcasting requirements. A number of commenters argue that the Commission should postpone the date by which smaller-market stations have to expand

operating hours. For example, MSTV/NAB argues that the Commission should maintain the DTV operating hours minimum at 75 percent for smaller and smaller-market broadcasters until the end of the transition, at which time a full-time operating requirement would begin. MSTV/NAB points out that, at 75 percent, a station on the air in analog full time would provide digital service 18 hours a day, leaving only the station's least demanded hours of operation, such as the overnight hours, without DTV service.

116. As we proposed in the NPRM, we will retain the same minimum DTV operating hours for smaller and smaller-market stations as were in effect under the simulcasting requirements. Thus, DTV stations subject to the May 1, 2002, or May 1, 2003, construction deadlines will continue to be subject to the requirement, effective April 1, 2004, that they air a digital signal for an amount of time equivalent to 75 percent of the amount of time they provide an analog signal. Effective April 1, 2003 and until the requirement increased on April 1, 2004, these stations were required to air a digital signal for 50 percent of the time they provided an analog signal The digital signal must be aired during prime time hours. The minimum digital operation requirement will increase to 100 percent on April 1, 2005 (requiring the airing of a digital signal for an amount of time equivalent to at least 100 percent of the amount of time the station airs an analog signal). We herein amend § 73.624 of our rules to retain the minimum operating hours requirements while deleting the simulcasting requirements.

117. We disagree with Paxson that the minimum operating hours requirement should be delayed pending the Commission's decision in the must-carry proceeding. As we indicated in denying Paxson's earlier request for a one-year waiver of the April 1, 2003 operating hours requirement, we do not believe that the increase in the hours of digital programming offered to viewers needs to await finalization of the Commission's separate proceeding regarding mandatory carriage of analog and digital signals during the transition.

118. We also disagree with the other commenters who support a delay in the increase in the minimum operating hours of DTV stations. Increasing the operating hours of digital stations subject to the May 1, 2002, and May 1, 2003, digital construction deadlines will help further the transition by helping to drive DTV set penetration and encouraging content producers and advertisers to invest in DTV. These stations have been on notice since the November 2001 adoption of the phased-in simulcasting requirement in the First DTV Periodic MO&O that their DTV operating hours must be stepped-up on April 1, 2004, and April 1, 2005. Postponing the required, gradual increase in the digital operating hours of these stations would be inconsistent with the ultimate goal of this proceeding of moving to an all digital television service.

119. Finally, MSTV/NAB suggests that the Commission permit DTV stations coming on the air later than the April 1, 2003, and April 1, 2004, minimum operating hour deadlines (*i.e.*, stations that have been granted an extension of time to complete construction of their DTV facilities and stations that have not yet been granted a DTV construction permit) to ramp up their hours of operation gradually. In the Second DTV Periodic NPRM, we stated that stations that have been granted an extension of time to construct beyond the simulcast deadlines must comply with the minimum digital operating requirements in effect at the time the station commences digital operations. We continue to believe that this approach is appropriate. We disagree with MSTV/NAB that these stations should be entitled to postpone increasing their digital hours of operation while other similar sized stations are required to provide more digital service.

Noncommercial Educational Television Stations

120. Noncommercial television broadcasters were scheduled to complete construction of their digital stations and commence digital service by May 1, 2003. Of the 373 noncommercial television stations, 84 were on the air either on time or ahead of this construction deadline and approximately 214 requested extensions of the deadline. The Commission has granted all of these extension requests. Other NCE stations have construction permits that have not yet expired or have filed construction permit applications with the Commission that have been processed and are awaiting additional information or international coordination, or are mutually exclusive. We invited comment in the Second DTV Periodic NPRM on what steps, if any, the Commission should take to assist noncommercial stations in the transition to DTV. In particular, we sought comment on whether the financial hardship standard for grant of an extension of time to construct a digital television station should be applied differently to noncommercial licensees.

121. As we have acknowledged before, noncommercial stations face unique financial difficulties in constructing digital facilities. According to Public Television, 24 percent of the public television stations seeking an extension of the May 1, 2003, construction deadline cited funding difficulties as a motivating reason for the extension request. For those stations facing funding shortfalls we have and will continue to consider the unique funding needs of noncommercial educational broadcasters in assessing a station's request for an extension of time to construct a DTV facility. As the unique circumstances of noncommercial stations are being considered under our current extension criteria, we do not believe it is necessary at this time to revise those criteria for noncommercial stations or to change the way we are applying the current criteria to this group.

122. According to Public Television, NCE stations cite non-financial impediments to construction more frequently than financial impediments as the cause for delay in completing their DTV facilities. However, there is no evidence that noncommercial licensees face unique non-financial obstacles to completing construction. Thus, we also do not believe it is necessary at this time to revise our criteria for evaluating non-financial grounds for an extension for noncommercial licensees to assist this group to complete the digital transition. We will continue to monitor the progress of noncommercial educational television stations in their conversion to digital transmissions, however, and will continue to assess whether further steps are needed to assist these stations in accomplishing the conversion.

DTV Transmission Standard and PSIP

Update of the DTV Transmission Standard

123. In the DTV Tuner Order, we revised our rules to specify that the August 7, 2001, version of the ATSC] DTV standard A/53B should be used in place of the September 16, 1995, version originally adopted. We revised § 73.682(d) of the rules to specify ATSC Doc. A/53B (ATSC Digital Television Standard, 7 Aug. 01), except for § 5.1.2 ("Compression format constraints") of Annex A ("Video Systems Characteristics") and the phrase "see Table 3" in Section 5.1.1 Table 2 and Section 5.1.2 Table 4). We also acknowledged the likelihood that there will be further improvements made to the DTV standard over time, and stated our intention to consider incorporation

into our rules of proposed changes that reflect the kind of broad industry consensus developed through ATSC's standards-making procedures. In the NPRM, we sought comment on whether our rules should be further changed to reflect any revisions to the ATSC DTV standard A/53B since the August 7, 2001, version.

124. We find that it is desirable and appropriate to update our DTV rules to recognize Amendment 1 (May 23, 2002) to ATSC DTV Standard A/53B (August 7, 2001). We decline to mandate that broadcasters use the AFD when the active video portion picture does not completely fill the coded picture. The revisions in the new version of the ATSC DTV Standard were developed through careful consideration and deliberation within the technical committees of ATSC and thus reflect a consensus agreement based on the input of parties from various segments of the industry. While broadcasters will have the option to use AFD, if a station includes AFD data it must follow the ATSC DTV standard. As more consumers acquire widescreen aspect ratio sets, the problem of "postage stamp video" will become more prevalent if not addressed by broadcasters. Broadcasters should have every incentive to make their programming attractive to viewers and to avoid disenfranchising those viewers as they begin to adopt DTV.

125. We will update our DTV rules to recognize Amendment 2, as released by the ATSC on May 19, 2003. Updating the rules to reflect improvements in the standard will benefit both the public and broadcasters by allowing broadcasters to make technical improvements in their service that will enhance the quality of DTV services they provide. Accordingly, we are revising § 73.682(d) of the rules to specify ATSC Doc A/53B (ATSC Digital Television Standard, 7 Aug 01), Revision B with Amendment 1 and Amendment 2. We also continue to encourage further improvements to the DTV standards. Although it will be necessary to conduct additional rule making activity to incorporate such changes in the rules, we nonetheless will endeavor to pursue such rule making as quickly as possible, either through our periodic review of the DTV transition or through separate proceedings as may be appropriate.

126. The ATSC also adopted Amendment 2 to A/53B, which revises the transport section of the ATSC Digital Television Standard, Annex C, to update normative references to avoid conflicts, and to establish a common methodology for carriage of private data in the ATSC Transport Stream. The amendment defines the ATSC Private Information Descriptor for the carriage of private descriptor-based data, and it also clarifies rules for use of the MPEG–2 Registration Descriptor mechanism for management of private data in the digital multiplex. To be consistent with the current version of the ATSC A/52 Digital Audio Compression Standard, Amendment 2 revises the way audio language is signaled in the ATSC system and specifies the use of ISO–639 language encoding to identify written and spoken languages. Amendment 2 also specifies some requirements that had been implemented in transmission and receiving equipment but not properly specified in A/53B. These included the requirement that each service with an audio component must include at least one "complete main" audio service and the requirement that the video Elementary Stream component be identified with MPEG–2 stream-type value 2. Upon final approval of the ATSC membership, ATSC suggests that the Commission incorporate Amendment 2 to A/53B into its rules.

PSIP

127. In the DTV Tuner Order, we stated that we would seek comment on whether the Commission should adopt the ATSC Program System and Information Protocol ("PSIP") standard into our rules as part of the DTV periodic review process. We stated that in the interim we will continue to support and encourage the voluntary use of the PSIP specification by broadcasters and cable operators and its inclusion in consumer electronics equipment. Section 73.682(d) of our rules includes a reference to the ATSC PSIP Standard as a document that licensees may consult for guidance PSIP is data that is transmitted along with a station's DTV signal that tells DTV receivers information about the station and what is being broadcast. PSIP provides a method for DTV receivers to identify a DTV station and to determine how a receiver can tune to it. PSIP identifies both the DTV channel and the associated NTSC channel and enables DTV receivers to associate the two channels, thereby making it easy for viewers to tune to the DTV station even if they do not know the channel number. Linkages between analog and DTV channels are managed through the DTV "Transport Stream Identifier" and analog "Transmission Signal ID" (Both, "TSID"). The Association for Maximum Service Television ("MSTV") has undertaken the task of maintaining a list of TSIDs. In addition to identifying the channel number, PSIP tells the receiver whether multiple program channels are being broadcast and, if so, how to find them. It also identifies whether the programs are closed captioned, and conveys available v-chip information, among other things. As will be discussed in sections J. 3 and K., infra, PSIP enables the proper functioning of v-chip and closed captioning. The Commission has recognized the utility that the ATSC PSIP Standard offers for both broadcasters and consumers. The channel mapping protocols contained in the PSIP identification stream could help resolve issues associated with digital channel positioning. In the NPRM, we sought comment on whether to require the use of PSIP and which aspects of PSIP should be adopted into our rules. We also sought comment on, among other things, whether and how broadcasters include PSIP information with their digital broadcast signals and also how consumer electronics equipment manufacturers build equipment to search for information in DTV signals.

128. We conclude that adoption of ATSC A/65B (PSIP) into our broadcast transmission standards will serve the public interest. As pointed out by commenters, during the development of PSIP, the ATSC carefully considered which elements of PSIP should be mandatory and which should be optional. Further, based its experience with the deployment of over 180 PSIP systems, Harris states that it is not aware of any difficulties that are experienced by either the broadcaster or the viewing consumer if the ATSC A/65B PSIP standard is properly implemented. We find the cost to broadcasters of implementing PSIP will be minor in comparison to the overall costs of converting to DTV and will provide many options to expand on the investments they have made to convert to DTV. Harris reports that based on its experience as a manufacturer of broadcast station PSIP equipment, it currently would cost a DTV broadcast station $29,900 for full implementation of PSIP, including all Program and System tables. Harris Comments at 9. We therefore require that broadcasters fully implement PSIP to the extent that ATSC A/65B requires. According to A/65, the PSIP mandatory tables are: Master Guide Table (MGT); Terrestrial Virtual Channel Table (TVCT); Event Information Tables (EIT–0 to EIT–3); System Time Table (STT); Rating Region Table (RRT). According to A/65, the RRT is not mandatory for the U.S. region (0x01). Transmission of the RRT is not necessary where the content

advisory ratings table is fixed, as is the case now in the U.S. If the ratings system were to change, however, or an addition to the ratings system were to be adopted, broadcasters would have to transmit a new RRT in order to transmit the new or additional ratings information. See section IV.J.3., infra, for discussion of the RRT. In order to give broadcasters adequate time to come into compliance, this requirement shall take effect 120 days after publication in the **Federal Register**. We expect broadcasters to populate the required tables and descriptors with the proper information to help receivers assemble functioning guides. All tables and descriptors that require one time setup should be set correctly, including TSID, Short Channel Name, Service Type, Modulation Mode, Source ID, and Service Location Descriptor. ATSC A/65B also requires that broadcasters send populated EITs covering at least a 12 hour period. These EITs should be populated with the correct information, so that the user knows what programs are on for this 12 hour period. Also, we expect that manufacturers will have every incentive to build equipment that looks to PSIP for its basic functionality, but we will revisit the issue if necessary. Standardized use of the data transmitted through PSIP will ensure that the full benefits and innovations of the new digital system will be available to the public. PSIP enables improvements to program guides, closed captioning, and use of v-chip, and enables channel number navigation using the familiar analog channel numbers to tune to new digital channel assignments.

129. Major/Minor Channel Numbers. In the NPRM, we noted that the ATSC PSIP standard attaches the assignment of "major channel number" values to a broadcaster's current NTSC RF channel number regardless of the actual RF channel used for DTV transmission, and sought comment on whether there was any need to modify this standard. For example, a broadcaster who operates an NTSC service on channel 4 and a DTV service on channel 27 would use the major channel 4. The PSIP "minor channel number" is used to identify programs and other services, which are a part of the DTV service. For example, channel 4.1 may be an HDTV program service and it may be multiplexed with an SDTV service, which is channel 4.2. According to ATSC, this allows a viewer to easily "surf" from, for example, 4.0 (NTSC) to 4.1 (HDTV) to 4.2 (SDTV). ATSC, MSTV/NAB, and others state that the major/minor channel number scheme established in ATSC A/65B will be useful. ATSC states that the PSIP Standard defines specific requirements for use of "major channel numbers" to provide viewers with a uniform methodology to access DTV services and to avoid conflict with duplicative numbers in a market. The major channel number also allows broadcasters to maintain their local brand identification. We see no reason to modify this standard. During the development of PSIP, ATSC recognized that in some situations broadcasters would need to deviate from the rule that the major channel number is the same as the broadcaster's NTSC channel number and created certain exceptions. Exceptions are, for example: (1) If a broadcaster without an NTSC broadcast license applies and receives a license for a digital broadcast channel, the major channel number should be the same as the DTV RF channel; (2) if a broadcaster owns or controls broadcast licenses for two or more different RF channels having overlapping service areas, a common major channel number for all services on all channels may be used; (3) if a broadcaster includes in its DTV service programming originating from a different licensed broadcaster, the major channel number of the original broadcast may be used as long as it is coordinated to avoid conflicts; and, (4) for a translated signal, the major/minor channel numbers shall remain the same as the original broadcast station unless the major channel conflicts with a broadcaster operating in the service area of the translator. In that case, the translator changes the major number to a non-conflicting number. We agree with ATSC and MSTV/NAB that these exceptions should provide broadcasters with the necessary flexibility to address most circumstances. To the extent broadcasters have a unique situation that is not provided for in PSIP, the Commission may grant exceptions on a case-by-case basis. The correct TSIDs must be used to ensure that receivers link the analog and digital channels properly. Accordingly, broadcasters are required to transmit the TSIDs assigned for their stations in their digital transmission. During the transition period while both analog and digital signals are broadcast, stations are required to transmit the NTSC TSID in line 21, field 2 in order for the receiver to locate the programs referenced in PSIP.

PSIP and DTV V-Chip

130. In the NPRM we asked if the Commission needs to do more to ensure that v-chip functionality is available in the digital world. While the Commission's rules require that digital television receivers have the capability to enable viewers to block the display of programs with a common rating, the technical standards to achieve this goal are not specified. We expressed concern that the lack of a specific requirement may lead to confusion among broadcasters and manufacturers with regard to where to place program rating information, resulting in the failure of the blocking functionality that the v-chip provides. Accordingly, we sought comment on whether the Commission should adopt the provisions of the ATSC A/65A standard that requires all digital television broadcasters to place v-chip rating information in the PSIP. We also asked whether it was necessary to require equipment manufacturers to develop equipment that accesses program rating information in the PSIP. Finally, we requested comment on a Petition for Rulemaking filed by CEA which sought to incorporate industry standard EIA/CEA—766 into the Commission's rules to facilitate v-chip functionality in digital receivers.

131. As an initial matter, we reiterate that this Order adopts the ATSC A/65 PSIP standard in its entirety. This Order also requires that broadcasters transmit all mandatory tables and descriptors of PSIP with their digital programming. Accordingly, the Event Information Tables ("EITs") defined within PSIP will contain any available Content Advisory Descriptors ("CADs") for broadcast programming. The PSIP requirements do not mandate broadcaster use of v-chip but rather require that broadcasters that choose to provide v-chip blocking information do so by following the PSIP protocols. For terrestrial broadcast, if parental advisory information is to be provided, the Content Advisory Descriptor is required in the EIT, which is an element of the PSIP Standard. This uniform transmission practice will ensure that various receiver manufacturers can more readily design products which will search for and react to program rating information on a consistent basis. Sharp Electronic Corporation states that numerous consumer electronics companies are currently designing and/or selling digital televisions that utilize the content advisory data as defined in the PSIP. While we believe that this is indeed the case, we are nonetheless adopting rules to require digital television receivers to look for the content advisory descriptors in the EITs. 47 U.S.C 330(c) instructs the Commission to oversee "the adoption of standards by industry for blocking technology," and to ensure that blocking capability continues to be available to consumers as technology advances.

132. The PSIP carries the Rating Region Table ("RRT"), which describes the content advisory rating system being used. Without the information in the RRT, the program rating icons (*e.g.*, TV–Y7 or PG–13) will be displayed, but the explanations of the icons will not. ATSC in their comment states that: "The PSIP Standard does provide the ability to extend or replace the content advisory system in the U.S. by assignment of a new, different rating region code. Receivers that are built compliant with CEA standards and recommended practices will support an additional new system with one or more independent categories, each with a series of levels definable by a new RRT." Some have expressed concern that the current ratings system is "hard-wired" into digital televisions, making modifications impossible on existing sets. We generally believe that the ability to modify the current content advisory system is beneficial. The suggestion by ATSC to use a different U.S. rating region code for any additional new rating system ensures that the older RRT remains intact for legacy digital receivers that have not been designed to process newer versions of the RRT. These legacy digital receivers could continue to be used and would not be rendered obsolete. At the same time, newer digital receivers would be able to recognize and respond to an additional rating system. Accordingly, to ensure the ability to modify the content advisory system, receivers must be able to process newer RRT version numbers or use new rating region codes as suggested by ATSC.

133. As requested by CEA, we are adopting by reference CEA–766 CEA–766 specifies the exact syntax to be used to define the U.S. and Canadian RRTs in accordance with A/65, as well as exact syntax to be used for the CADs that convey the rating information. U.S. and Canadian Rating Region Tables (RRT). We note that the adoption of the standard will not preclude manufacturers from incorporating additional blocking standards or techniques into receivers. Therefore, additional blocking techniques that are dependent only on inputs such as the date, time of day, or television channel, may be incorporated into television receivers as manufacturers see fit.

134. Additionally, we are adopting our proposal to apply v-chip rules to digital television receivers with displays in the 16:9 aspect ratio that are 7.8 inches or greater in height. Furthermore, we are requiring that v-chip technology be included in all digital television receivers with integrated 4:3 displays measuring at least 13 inches diagonally. Similar to our requirements for closed caption capabilities in digital television receivers, the rules will also be applicable to DTV tuners which are sold without an associated display device.

135. Finally, we are inclined to provide a transition period for manufacturers to begin producing compliant digital television receivers. We understand that the design cycle of a television receiver model is generally about 18 months. The Commission has previously taken into consideration receiver design cycles in proceedings that required the introduction of new television technology. We also understand that many manufacturers are currently relying on CEA 766 to comply with the Commission's v-chip requirements as applied to digital receivers. Our existing requirement that digital television receivers react in a similar manner as analog televisions when programmed to block specific rating categories ensures that digital receivers will continue to respond to v-chip information during the phase-in period. Therefore, we believe it is reasonable to provide an 18 month transition period. After the transition period, all digital television receivers will be required to provide v-chip functions following the regulations that we adopt in this proceeding.

PSIP and LPTV/TV Translators

136. We also requested comment on issues concerning the implications of PSIP on the operation of TV translator facilities. We requested comment on how the proper PSIP information is to be provided on TV translator rebroadcasts and who will be responsible for ensuring that that information is provided. We also requested comment regarding the costs of providing PSIP information on TV translators as well as any other concerns that translator operators might have in implementing PSIP on their DTV operations. We further note that a similar issue arises with cable service when a broadcast DTV signal or its associated analog signal is carried on a cable system on a channel that is different from its broadcast signal. PSIP in the context of cable carriage is a topic in a pending proceeding. We received comments from CEA, ATSC, Public Television, and Harris in response to our questions. In August 2003, the Commission initiated a proceeding to examine issues related to the authorization of digital translators and boosters. Because the record will be more specifically tailored to LPTV, translators, and boosters, we will address the implications of PSIP on those facilities in connection with the Digital LPTV proceeding.

DTV Closed Captioning

137. The Television Decoder Circuitry Act of 1990 requires generally that television receivers contain circuitry that is able to decode and display closed captioning. The Act also directs the Commission to take such action that it determines appropriate to ensure that closed captioning service continues to be available to consumers as new technology is developed. In accordance with the Act, in July, 2000, the Commission adopted regulations with regard to the functioning of digital television receivers and closed captioning services. The DTV Closed Captioning Order incorporated Section 9 of the EIA/CEA standard EIA–708–B with minor modifications into the Commission's rules. This industry standard provides guidelines for caption providers as well as encoder and decoder manufacturers to implement closed captioning services with digital television technology. The DTV Closed Captioning Order also amended § 79.1 of the Commission's regulations to require an increasing amount of digital programming to be captioned in a format that can be recovered and displayed by decoders meeting the EIA–708–B standard.

138. As part of Second DTV Periodic NPRM, the Commission sought comment on whether there was additional action that it should take to ensure the accessibility and functioning of closed captioning service for digital television. Several commenters asserted that some issues need to be clarified in order for closed captioning services to be consistently and effectively delivered. For example, NCAM contends that in some cases broadcasters may not be delivering true DTV caption data intended for digital television receivers. Instead, those broadcasters are delivering NTSC type data, intended for use when digital programming is down-converted for display on analog receivers. NCAM states that, without DTV captioning data, digital receivers may not be able to function in the manner in which the Commission intended. In fact, some of these receivers may not display any captions at all.

139. We note that the EIA–708 standard provides comprehensive instructions for the encoding, delivery, and display of closed caption information for digital television systems. The standard provides for a larger set of captioning characters than the analog captioning standard, EIA–608. However, EIA–708 also supports

transport of the analog EIA–608 captioning information for use when a digital broadcast is being viewed on an analog receiver through a DTV converter. The rules adopted in the DTV Closed Captioning Order were intended to require that the decoder circuitry in digital tuners respond primarily to any digitally formatted caption information. Accordingly, consumers who purchase DTV receivers will be confident that they will be able to take advantage of the new capabilities of captioning in the digital environment. Therefore, we hereby clarify that digital television receivers must first search for and respond to native EIA–708 closed caption information. Only if that information is not available in the DTV datastream should the receiver search for any available transcoded analog captioning data conforming to the EIA–608 standard. Furthermore, broadcasters should be aware that receivers will be searching for EIA–708 data in all digital broadcasts. If digital programming is to be captioned, it must contain EIA–708 data. This applies to all digital broadcast programming, regardless of whether the programming is delivered in standard definition or high definition.

140. In the DTV Closed Captioning Order, the Commission observed that viewers will be able to watch digital programming on existing analog displays by using a DTV converter. With regard to the broadcasters' responsibility to deliver closed caption data, the DTV Closed Captioning Order states that, "[I]n order for programming distributors to count captioned digital television programming toward their closed captioning requirements in 47 CFR Section 79.1, they must also transmit captions than can be decoded by the decoder in that analog set." Therefore, while all captions supplied with new digital programming should conform to the standards for "native" EIA–708 style captions as detailed in the standard, analog captions must also be provided if a broadcaster wishes to count the programming towards its quarterly captioning requirements.

141. In the Second DTV Periodic NPRM we noted that at the time the DTV Closed Captioning Order was adopted the Commission had not made broadcasters' adherence to the ATSC A/65 (PSIP) standard a requirement. We stated that the standard requires the caption service descriptor to be in the EITs and makes optional the presence of the caption service descriptor in the Program Mapping Table (PMT). EIA–708 standard requires the caption service descriptor to be in the PMT and, when present, in the EITs. We questioned whether a requirement for all digital television broadcasters to place the caption service descriptor in the EITs alone would eliminate situations in which digital television receivers that search for closed captioning information in the EITs are not able to find any captioning information although it is present in the PMT according to EIA–708. We believe that our decision to adopt the PSIP standard in its entirety along with the previous adoption of the EIA–708 results in the caption service descriptor being present in both EITs and in the PMTs. This proposal to require the caption service descriptor to be present in both places will ensure that legacy digital receivers that have been designed according to EIA–708 alone could continue to find the caption service descriptor in the PMT and would not be rendered obsolete.

DTV Labeling Requirements and Consumer Awareness

142. The *Second DTV Periodic NPRM* requested comment on the need for labeling requirements to provide consumers with information on the capabilities of digital television equipment at the point of sale. We noted that a General Accounting Office ("GAO") Report to Congress in 2002 found that at least 40 percent of the public was unfamiliar with the digital transition, and 68 percent of those surveyed did not know that when the transition ends, consumers with analog-only sets will be unable to continue receiving over-the-air broadcast television without use of an external digital tuner or converter. Only 14 percent of those surveyed by the GAO were "very familiar" with the difference between analog and digital televisions. GAO speculates that even this number may be high because consumers may be confusing current digital television services provided by cable or satellite with DTV. In addition, we sought comment on whether to require a disclosure label on analog-only sets or a digital conversion fact sheet to inform consumers that a converter or external DTV tuner will be needed to ensure reception of television broadcast signals after stations in the consumer's market complete conversion to digital-only broadcasting.

143. In the first DTV periodic review proceeding, we sought comment on whether we should require digital television equipment that cannot receive over-the-air digital broadcast signals to carry a label informing consumers of this limitation on the receivers' functionality. In the DTV Tuner Order, we observed that the reluctance of the public to buy digital receivers is the problem with reaching the 2007 target date for completing the transition. We required that all TV receivers with screen sizes greater than 13 inches manufactured in the U.S. after July 1, 2007 be capable of receiving DTV signals over-the-air. As DTV tuners reach the market, consumers will only buy them if they understand what they are and that the future utility of analog-only televisions is limited. We decided not to require in that proceeding that television receivers that cannot receive over-the-air digital broadcast signals carry a label informing consumers of this limitation but we resolved to monitor the marketplace and take steps as necessary to protect consumers' interests.

144. Accurate communication of the impending change from analog to digital transmission is a highly material disclosure for consumers contemplating the purchase of a television. Retailers sell analog-only televisions for over $500 without prominent disclosure that they will not receive television signals without additional equipment after the analog spectrum is returned. We believe, as retailers and manufacturers agree, that communicating product attributes and features spur sales. We agree with Thompson that it is important to use the same nomenclature and definitions industry-wide. CEA has developed uniform nomenclature that appears in its Consumer Guide to HDTV, but the labeling recommended has not been adopted by manufacturers and retailers on a widespread basis. For example, Best Buy offers "HD-Ready" televisions, which is not a term defined in CEA's consumer guide. Best Buy's website defines it as "Fully capable of high-definition display when connected to an optional HDTV source. Conventional analog TV reception is provided via a built-in NTSC tuner." The prices for such "HD-Ready" televisions range from $999.99 (Samsung) to $1999.99 (Toshiba). Recent ex parte filings indicate that the relevant industries, manufacturers and some retailers, are working on improved sales materials and clear, standard terminology and an increasing amount of information available for consumers who research on the Internet or in industry publications. However, much of the mass advertising and point of sale information remains confusing, inconsistent, and lacks explanation of the eventual limitations on analog-only equipment. For example, a sign or cling label displayed at point of sale could say: "Analog only—Not digital; will need separate converter box for over-air reception." We have been reluctant to

require specific labeling and expected that manufacturers and retailers would develop consistent, clear and uniform terminology to convey to consumers prior to purchase the features and limitations of television products, such as a chart of available features with "Yes" or "No" or checkmark indicated for each feature, including whether the equipment is analog-only and will require additional equipment to receive television signals after the transition. We are working with the parties and consumer organizations to develop materials and techniques for consumer education. Therefore, at this time, we will not determine whether it is necessary for the Commission to require labeling. We will reserve that determination for further consideration in the Second Report and Order in the Second DTV Periodic Review, which will address the interpretation of section 309(j)(14).

DTV Station Identification

145. Under our current rules, television stations are required to make station identification announcements at the beginning and end of each time of operation as well as hourly. 47 CFR 73.1201(a). Section 73.1705 ("Time of Operation") of the FCC's rules specifies whether commercial and noncommercial TV and radio stations may be licensed for unlimited time operation, share time operation, and/or specified hours operation (such as daytime-only). 47 CFR 73.1705. Official station identification may be made visually or aurally, and must consist of the station's call letters immediately followed by the community or communities specified in the station's license as the station's location. 47 CFR 73.1201(b). Digital television stations have been assigned the same call letters as their associated analog TV stations, except that the digital station is identified with the suffix "DT." Either or both the name of the licensee and the station's channel number may be inserted between the call letters and the station location, but no other insertion is permissible. Television satellite stations must include in their station identification announcements the number of the channel on which each station is operating. 47 CFR 73.1201(c)(3)(i).

146. We will adopt our proposal and require digital television stations to follow the same rules for station identification as analog television stations. Thus, digital stations will be required to make station identification announcements, either visually or aurally, at the beginning and end of each time of operation as well as hourly. As with analog stations, we will require that the identification consist of the station's call letters followed by the community or communities specified in the station's license as the station's location. Stations may insert between the call letters and the station's community of license the station's frequency, channel number, name of the licensee, and/or the name of the network, at their discretion. We will not adopt the proposal of WDLP to permit stations to omit the station's call letters in their identification. Each station's call letters are unique; thus, call letters serve as the clearest means of distinguishing among stations. As stations transition to digital format and provide multicast programming, thereby increasing the number of program streams potentially available to the public, clear identification of the station providing the programming viewers are watching becomes increasingly important, both for viewers and for stations themselves.

147. If a station chooses to include its channel number in its station identification, we will require that the station use the major (analog) channel number. As discussed above, we have decided to adopt the ATSC A/65B standard into our rules. One of the most important benefits of PSIP is that it defines specific requirements for use of "major" channel numbers to provide viewers with a uniform methodology to access DTV services and avoid conflict with duplicative numbers in a market. PSIP will allow viewers to see a broadcaster's major channel number regardless of the broadcaster's allocated digital broadcast channel. Thus, PSIP allows broadcasters to keep their existing channel number in the digital world, thereby assisting viewers who have come to identify these numbers with particular broadcasters and preserving the investment broadcasters have made in marketing these numbers. We believe that it is consistent with our adoption of the PSIP standard into our rules to require stations electing to identify themselves by channel number to use their major channel number, which is defined in the PSIP standard as the broadcaster's current NTSC RF (analog) channel number. Thus, a broadcaster who operates an NTSC service on channel "26" and a DTV service on channel "27" would use the major channel "26" in station identification announcements. We will permit stations that choose to multicast to include additional information in their station announcements identifying each program stream. Thus, a station with major channel number 26 might have channel 26.0 (NTSC program stream), channel 26.1 (HDTV) and 26.2 (SDTV). Stations may also provide information in the station announcement identifying the network affiliation of the program service (*e.g.*, "WXXX–DT, channel 26.1, YYY (community of license), your WB network channel").

148. For stations simulcasting their analog programming on the digital channel, we will permit station identification announcements to be made simultaneously for both stations as long as the identification includes both call signs (*e.g.*, "WXXX–TV and WXXX–DT") if it is intended to serve as the identification for both stations. Our rules currently allow co-owned AM/FM radio stations licensed to the same community simultaneously broadcasting the same programming on both stations to make joint station identification announcements for both stations. 47 CFR 73.1201(c)(2). If they chose to make simultaneous identifications for more than one channel, stations should ensure that these announcements are adequate to identify both program streams.

Distributed Transmission Technologies

149. In the Second DTV Periodic NPRM we sought comment on whether we should provide for DTV stations using distributed transmission technologies. A DTV distributed transmission system would employ multiple synchronized transmitters spread around a station's service area. Each transmitter would broadcast the station's DTV signal on the same channel, relying on the performance of "adaptive equalizer" circuitry in DTV receivers to cancel or combine the multiple signals plus any reflected signals to produce a single signal. Such distributed transmitters could be considered to be similar to analog TV booster stations, a secondary, low power service used to "fill in" holes in the parent station's coverage area, but DTV technology has the potential to enable this type of operation in a much more efficient manner. The Commission's Spectrum Policy Task Force has recommended that digital television broadcasters be permitted to operate single frequency low power distributed transmission systems within their present service areas. For analog TV boosters, in contrast, significant self-interference will occur unless there is substantial terrain blocking the arrival of multiple signals into the same area (for example, one signal from the primary analog station directly and one signal from a booster station).

150. In addition to the fundamental question of whether to allow distributed transmission technology, we sought comment on many related issues, such as whether such facilities should have primary or secondary regulatory status, whether we should limit the location of or area served by distributed transmitters, how interference to and from such transmitters should be calculated, and what power, antenna height, or other technical standards or limits should be imposed.

151. We agree with the generally supportive comments that the technology has potential benefits to the public and the reported testing to date is encouraging. Thus, in principle, we approve of the use of DTS technology. As suggested by MSTV/NAB, we will soon open a separate "fast track" proceeding to propose rules for DTS operation and to develop an adequate record on several technical and policy issues related to its use. In that proceeding, we will address the regulatory status of DTS facilities, limitations on where DTS facilities can provide service, and how DTS facilities are treated from the standpoint of interference they would be predicted to cause to other broadcast stations and interference they would receive from other stations. In addition, we will consider policy issues such as how to avoid situations where stations could fail to serve significant populations within their nominal coverage area and how stations employing DTS facilities should be evaluated with respect to meeting replication and maximization deadlines.

152. While that DTS proceeding is conducted, we will allow stations to request DTS operation on a case-by-case basis based on conservative parameters. Specifically, interim DTS operations will not be allowed if they would provide predicted service beyond a station's currently authorized area (including its replication area as well as any maximization area resulting from facilities granted by a construction permit or license). An interim DTS proposal will only be approved if it is designed to serve essentially all of its replication coverage area. An acceptable application during this interim period must show that all viewers within the station's replicated service area who are predicted to be served by their current analog transmitter would likewise be predicted to receive the minimum signal strength from at least one DTT transmitter. A station's desire to explore DTS operation will not be acceptable grounds for it requesting an extension of the replication and maximization interference protection deadline. Beyond these decisions, our staff will determine on a case-by-case basis the adequacy of other aspects of proposed operation (including permissible power, antenna height, and the acceptability of interference showings). We note that the record in this proceeding does not reflect current successful and practical operation of DTS technology. We will authorize additional experimentation and development work through our Special Temporary Authority (STA) process. Operation under such authority will be allowed to continue while we conduct the rule making proceeding. Depending upon the outcome of that proceeding, we may then convert the STAs to regular authorizations.

Procedural Matters

153. Accessibility Information. Accessible formats of this Report and Order (computer diskettes, large print, audio recording and Braille) are available to persons with disabilities by contacting Brian Millin, of the Consumer & Governmental Affairs Bureau, at (202) 418–7426, TTY (202) 418–7365, or at *bmillin@fcc.gov*.

154. Paperwork Reduction Act of 1995 Analysis. This Report and Order contains new or modified information collection(s) 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. The Commission is requesting OMB approval under the emergency processing provisions of the 1995 Act (5 CFR 1320.13) of the information collection requirements and forms contained in this Report and Order. OMB, the general public, and other Federal agencies are invited to comment on the new or modified information collection(s) contained in this proceeding.

155. Written comments by the public on the proposed information collection(s) are due 60 days from date of publication of this Report and Order in the **Federal Register**. Written comments must be submitted by the public, Office of Management and Budget and other interested parties on the proposed information collection(s) on or before 60 days from date of publication of this Report and Order in the **Federal Register**. In addition to filing comments with the Secretary, a copy of any comments on the information collection(s) contained herein should be submitted to Judith F. Herman, Federal Communications Commission, Room 1–A804, 445 12th Street, SW., Washington, DC 20554, or via the Internet to *Judith-B.Herman@fcc.gov*, and to Kristy L. LaLonde, OMB Desk Officer, Room 10234 NEOB, 725 17th Street, NW., Washington, DC 20503, or via the Internet to *Kristy L. LaLonde@omb.eop.gov*, or via fax at 202–395–5167.

156. Regulatory Flexibility Act. As required by the Regulatory Flexibility Act, the Commission has prepared a Final Regulatory Flexibility Analysis ("FRFA") relating to this Report and Order.

Final Regulatory Flexibility Analysis

157. As required by the Regulatory Flexibility Act of 1980, as amended ("RFA"), an Initial Regulatory Flexibility Analysis ("IRFA") was incorporated in the Notice of Proposed Rule Making ("NPRM"). The Commission sought written public comment on the proposals in the NPRM, including comment on the IRFA. One comment was received on the IRFA and is discussed below. This Final Regulatory Flexibility Analysis ("FRFA") conforms to the RFA.

158. Need for and Objectives of the Report and Order. The policies and rules set forth herein are required to ensure a smooth transition of the nation's television system from analog to digital format. In the Commission's DTV proceeding (MM Docket No. 87–268), the Commission stated its intention to hold periodic reviews of the progress of the digital conversion and to make any adjustments necessary to our rules and policies to "ensure that the introduction of digital television and the recovery of spectrum at the end of the transition fully serves the public interest." In this second periodic review, we revisit, as we indicated we would, several issues addressed in the first periodic review, and address a number of additional issues that we consider essential to resolve in order to ensure continued progress on the digital transition. The objective of this second periodic review is to make adjustments to our rules and policies to facilitate the introduction of digital television and the recovery of spectrum at the end of the transition.

159. Foremost among the steps taken in this item, the Report and Order establishes the timing and procedures necessary to establish a new Table of DTV Allotments that will determine the post-transition channels for all digital stations. Specifically, the item commences a three-round channel election process in the fall of 2004. Licensees are encouraged to ensure accuracy of database technical information on-file with the Commission before October 1, 2004. The Commission will issue a Table of

Station Information (based on licensees' on-file database information) so that station licensees will know the DTV service populations to be used in the channel election process. In November 2004, the channel election process begins with all stations certifying their database technical information; and certifying intent to replicate or maximize on their post-transition channel. In December 2004, round one begins and station licensees with two in-core (channels 2–51) channels elect the channel they prefer to retain for digital broadcasting, and licensees with one in-core and one out-of-core (channels 52–69) channel elect whether to use their in-core channel for post-transition digital operation. In round two, expected in July 2005, station licensees without a current in-core channel assignment elect a channel from those available after round one. In round three, expected in January 2006, station licensees not yet assigned a channel, or assigned channel 2 through 6, may elect a channel from those available after round two. Between each round, the Commission will announce which channels are protected, which are in conflict, and which are available. Station licensees with conflicts will decide whether to accept interference and remain on elected channels or move to the next election round. After round three, the Commission will resolve remaining conflicts based on relevant factors. Finally, the Commission will issue a Notice of Proposed Rulemaking, expected by August 2006, proposing and seeking comment on new DTV Table of Allotments.

160. To facilitate the election process, the Media Bureau has implemented a freeze on certain requests for allotment and service area changes by TV and DTV stations. Notwithstanding the freeze, stations with international coordination issues or other problems beyond their control may amend applications as necessary.

161. In addition, the Order finds that firm but fair replication and maximization dates are necessary to increase DTV service to the public and also to advance the clearing of spectrum in the Lower and Upper 700 MHz bands (comprising television channels 52–69). The Order establishes two replication and maximization deadlines. The first deadline is July 1, 2005 and it applies to the top four affiliates in the top 100 markets. If they will remain on their digital channel assignments after the transition, they must fully replicate and maximize by this date. If they will move to another channel post-transition, they must be serving by July 1, 2005 100% of the number of viewers served by the 1997 facility on which their replication was based. The second deadline, July 1, 2006, applies to all other stations. If they will remain on their current digital channel after the transition, they must fully replicate and maximize by this date. If they will move to another channel post-transition, they must be serving by July 2006 at least 80% of the number of viewers served by the 1997 facility on which their replication was based. Failure to replicate or maximize by these deadlines will result in loss of interference protection to the unserved areas. If they have met these deadlines, the item would allow stations that are going to move to a different channel after the transition to carry-over their authorized maximized area to their new channels.

162. The Order does not adopt an intermediate signal requirement, but retains the 7 dB increase required by December 31, 2004, for commercial stations and December 31, 2005, for noncommercial stations.

163. To provide additional flexibility and fairness for many of the stations that are currently out-of-core, the Order allows such stations to return out-of-core digital channels before the transition and "flash cut" to digital on their in-core channels without losing replication or maximization protection on their eventual in-core channel assignments.

164. In addition to resolving the channel election, replication and maximization issues, the item encourages creative and value-added programming on digital channels by removing the requirement that licensees simulcast their analog video programming on their digital channel, while retaining the requirements for minimum hours of operation. This "simulcast requirement" could be reinstituted near the end of the transition if warranted.

165. In addition, the Report and Order permits satellite stations to "flash-cut" from analog to digital at the end of the transition; clarifies the interference protection parameters of broadcast stations on channels 51–69; and requires stations to use Program and System Information Protocol ("PSIP"), which will facilitate digital operations and features, including channel numbering, v-chip, and closed captioning, and will establish technical requirements that will permit the TV ratings system to be modified in the future.

166. Finally, the Report and Order approves in principle the use of distributed transmission technologies for digital television service. Digital Transmission Systems ("DTS") would employ multiple synchronized transmitters spread around a station's service area, enabling broadcasters to fill gaps in service coverage. The item states the Commission will open a separate "fast track" proceeding to propose rules for DTS operation and to address related technical and policy issues. In the interim, the Order allows stations to request authorization for DTS operation on a case-by-case basis based on conservative parameters.

167. The Report and Order defers action on whether to require point-of-sale labels describing TV equipment capabilities (such as, high definition, digital monitor only, or analog) and on the issue of how the Commission should interpret the Section of the Communications Act that sets December 31, 2006, as the deadline for return of analog spectrum and establishes criteria for extensions of that deadline. The Order states that the Commission plans to address these issues in the near future.

168. Summary of Significant Issues Raised by Public Comments in Response to the IRFA. The American Cable Association ("ACA") filed a comment in response to the IRFA in this proceeding. ACA states that the Commission's DTV transition regulations must accommodate the unique circumstances and higher cost structures of smaller cable systems. In particular, ACA asks that the Commission address the following issues: (1) The disproportionate cost of the DTV transition for smaller cable systems due to headend and set-top box costs; (2) the disproportionate burden of dual must-carry for smaller cable systems due to more limited channel capacity; (3) the unwillingness of some broadcasters to deliver an adequate quality DTV signal to outlying areas of their markets; and (4) the "continuing abuse" of retransmission consent of a handful of media conglomerates, which is constraining channel capacity, raising costs, and hampering small systems' ability to develop solutions to DTV carriage. ACA urges the Commission to consider alternatives to its rules that would minimize any significant economic impact on small entities, including exemption from coverage of the rule or parts thereof for small entities.

169. The issues raised by ACA regarding the impact of the transition on smaller cable systems are more pertinent to the Commission's pending must-carry proceeding than to this DTV periodic review. The rules and policies addressed herein apply primarily to broadcasters and equipment manufacturers, and relate only

indirectly to cable operators. A copy of ACA's comments have been associated with the file in the must-carry proceeding.

170. Although we decline to address the issues raised by ACA in this proceeding, we do adopt herein a number of policies that take into consideration the legitimate needs and interests of small businesses. For example, the item provides for a later replication and maximization interference protection deadline of July 1, 2006 for smaller stations (not affiliated with a top-four network) and those in smaller markets. Affiliates of the top-four networks (*i.e.*, ABC, CBS, Fox, and NBC) in markets 1–100 are given an earlier replication and maximization interference protection deadline of July 1, 2005. In addition, smaller stations and those in smaller markets that will move to another channel post-transition are permitted to serve only 80% (rather than 100%) of the number of viewers served by the 1997 replication coverage area by the July 2006 deadline to carry-over their authorized maximized service area to their new channel. To assist stations facing severe financial constraints or obstacles beyond a station's control that are specific to the DTV transition process, the item permits these stations to apply for a six-month waiver of the interference protection deadline.

171. The Report and Order also permits certain stations with an in-core NTSC channel paired with an out-of-core DTV channel, as well as stations with two out-of-core channels, to surrender their out-of-core DTV channel before the end of the transition and operate in analog on their in-core channel. The item also permits single-channel DTV stations out of the core, upon Commission approval, to elect not to construct DTV facilities and instead give up their out-of-core DTV channel in return for a DTV channel inside the core. Upon approval from the Commission, these stations will "flash-cut" to digital operations on their in-core channel no later than the end of the transition in the station's market. This "flash-cut" policy will assist stations with an out-of-core DTV channel that are concerned about the cost of constructing DTV facilities outside the core that cannot be operated after the transition. In addition, the Report and Order permits satellite stations to surrender one of their paired channels and flash cut from analog to digital transmissions by the end of the transition period. This flash-cut option should provide significant financial relief for satellite stations, many of which are small and all of which serve communities unable to support a full-service station.

172. Description and Estimate of the Number of Small Entities to Which the Proposed Rules Will Apply. The RFA directs the Commission to provide a description of and, where feasible, an estimate of the number of small entities that will be affected by the proposed rules. The RFA generally defines the term "small entity" as having the same meaning as the terms "small business," "small organization," and "small government entity." 5 U.S.C. 601(3) (incorporating by reference the definition of "small business concern" in 15 U.S.C. 632. Pursuant to the RFA, the statutory definition of a small business applies, "unless an agency, after consultation with the Office of Advocacy of the SBA and after opportunity for public comment, establishes one or more definitions of such the term which are appropriate to the activities of the agency and publishes such definition(s) in the **Federal Register**. In addition, the term "small business" has the same meaning as the term "small business concern" under the Small Business Act. 5 U.S.C. 601(3) (incorporating by reference the definition of "small business concern" in the Small Business Act, 15 U.S.C. 632. Pursuant to 5 U.S.C. 601(3), the statutory definition of a small business applies "unless an agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the **Federal Register**." 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"). 15 U.S.C. 632. Application of the statutory criteria of dominance in its field of operation, and independence are sometime difficult to apply in the context of broadcast television. Accordingly, the Commission's statistical account of television stations may be over-inclusive.

173. Television Broadcasting. The Small Business Administration defines a television broadcasting station that has no more than $12 million in annual receipts as a small business. Business concerns included in this industry are those "primarily engaged in broadcasting images together with sound." NAICS Code 515120. This category description continues, "These establishments operate television broadcasting studios and facilities for the programming and transmission of programs to the public. These establishments also produce or transmit visual programming to affiliated broadcast television stations, which in turn broadcast the programs to the public on a predetermined schedule. Programming may originate in their own studios, from an affiliated network, or from external sources." Separate census categories pertain to businesses primarily engaged in producing programming. See Motion Picture and Video Production, NAICS code 512110; Motion Picture and Video Distribution, NAICS Code 512120; Teleproduction and Other Post-Production Services, NAICS Code 512191; and Other Motion Picture and Video Industries, NAICS Code 512199. According to Commission staff review of the BIA Publications, Inc. Master Access Television Analyzer Database as of May 16, 2003, about 814 of the 1,220 commercial television stations in the United States have revenues of $12 million or less. We note, however, that, in assessing whether a business concern qualifies as small under the above definition, business (control) affiliations "Concerns are affiliates of each other when one concern controls or has the power to control the other or a third party or parties controls or has to power to control both." 13 CFR 121.103(a)(1). Must be included. Our estimate, therefore, likely overstates the number of small entities that might be affected by our action, because the revenue figure on which it is based does not include or aggregate revenues from affiliated companies. There are also 2,127 low power television stations (LPTV). Given the nature of this service, we will presume that all LPTV licensees qualify as small entities under the SBA definition.

174. In addition, an element of the definition of "small business" is that the entity not be dominant in its field of operation. We are unable at this time to define or quantify the criteria that would establish whether a specific television station is dominant in its field of operation. Accordingly, the estimate of small businesses to which rules may apply do not exclude any television station from the definition of a small business on this basis and are therefore over-inclusive to that extent. Also as noted, an additional element of the definition of "small business" is that the entity must be independently owned and operated. We note that it is difficult at times to assess these criteria in the context of media entities and our estimates of small businesses to which

they apply may be over-inclusive to this extent.

175. Cable and Other Program Distribution. The SBA has developed a small business size standard for cable and other program distribution services, which includes all such companies generating $12.5 million or less in revenue annually. This category includes, among others, cable operators, direct broadcast satellite ("DBS") services, home satellite dish ("HSD") services, multipoint distribution services ("MDS"), multichannel multipoint distribution service ("MMDS"), Instructional Television Fixed Service ("ITFS"), local multipoint distribution service ("LMDS"), satellite master antenna television ("SMATV") systems, and open video systems ("OVS"). According to the Census Bureau data, there are 1,311 total cable and other pay television service firms that operate throughout the year of which 1,180 have less than $10 million in revenue. Economics and Statistics Administration, Bureau of Census, U.S. Department of Commerce, 1997 Economic Census, Subject Series—Establishment and Firm Size, Information Sector 51, Table 4 at 50 (2000). The amount of $10 million was used to estimate the number of small business firms because the relevant Census categories stopped at $9,999,999 and began at $10,000,000. No category for $12.5 million existed. Thus, the number is as accurate as it is possible to calculate with the available information. We address below each service individually to provide a more precise estimate of small entities.

176. Cable Operators. The Commission has developed our own definition of a small cable system operator for the purposes of rate regulation. Under the Commission's rules, a "small cable company" is one serving fewer than 400,000 subscribers nationwide. 47 CFR 76.901(e). The Commission developed this definition based on its determinations that a small cable system operator is one with annual revenues of $100 million or less. Sixth Report and Order and Eleventh Order on Reconsideration, 10 FCC Rcd. 7393 (1995). We last estimated that there were 1,439 cable operators that qualified as small cable companies. Since then, some of those companies may have grown to serve over 400,000 subscribers, and others may have been involved in transactions that caused them to be combined with other cable operators. Consequently, we estimate that there are fewer than 1,439 small entity cable system operators that may be affected by the decisions and rules in this Report and Order.

177. The Communications Act, as amended, also contains a size standard for a small cable system operator, which is "a cable operator that, directly or through an affiliate, serves in the aggregate fewer than 1 percent of all subscribers in the United States and is not affiliated with any entity or entities whose gross annual revenues in the aggregate exceed $250,000,000." The Commission has determined that there are 68,500,000 subscribers in the United States. Therefore, an operator serving fewer than 685,000 subscribers shall be deemed a small operator if its annual revenues, when combined with the total annual revenues of all of its affiliates, do not exceed $250 million in the aggregate. Based on available data, we find that the number of cable operators serving 685,000 subscribers or less totals approximately 1,450. Although it seems certain that some of these cable system operators are affiliated with entities whose gross annual revenues exceed $250,000,000, we are unable at this time to estimate with greater precision the number of cable system operators that would qualify as small cable operators under the definition in the Communications Act.

178. Direct Broadcast Satellite ("DBS") Service. Because DBS provides subscription services, DBS falls within the SBA-recognized definition of Cable and Other Program Distribution Services. This definition provides that a small entity is one with $12.5 million or less in annual receipts. There are four licensees of DBS services under part 100 of the Commission's rules. Three of those licensees are currently operational. Two of the licensees that are operational have annual revenues that may be in excess of the threshold for a small business. The Commission, however, does not collect annual revenue data for DBS and, therefore, is unable to ascertain the number of small DBS licensees that could be impacted by these proposed rules. DBS service requires a great investment of capital for operation, and we acknowledge, despite the absence of specific data on this point, that there are entrants in this field that may not yet have generated $12.5 million in annual receipts, and therefore may be categorized as a small business, if independently owned and operated.

179. Home Satellite Dish ("HSD") Service. Because HSD provides subscription services, HSD falls within the SBA-recognized definition of Cable and Other Program Distribution Services. This definition provides that a small entity is one with $12.5 million or less in annual receipts. The market for HSD service is difficult to quantify. Indeed, the service itself bears little resemblance to other MVPDs. HSD owners have access to more than 500 channels of programming placed on C-band satellites by programmers for receipt and distribution by MVPDs, of which 150 channels are scrambled and approximately 350 are unscrambled. HSD owners can watch unscrambled channels without paying a subscription fee. To receive scrambled channels, however, an HSD owner must purchase an integrated receiver-decoder from an equipment dealer and pay a subscription fee to an HSD programming package. Thus, HSD users include: (1) Viewers who subscribe to a packaged programming service, which affords them access to most of the same programming provided to subscribers of other MVPDs; (2) viewers who receive only non-subscription programming; and (3) viewers who receive satellite programming services illegally without subscribing. Because scrambled packages of programming are most specifically intended for retail consumers, these are the services most relevant to this discussion.

180. Multipoint Distribution Service ("MDS"), Multichannel Multipoint Distribution Service ("MMDS") Instructional Television Fixed Service ("ITFS") and Local Multipoint Distribution Service ("LMDS"). MMDS systems, often referred to as "wireless cable," transmit video programming to subscribers using the microwave frequencies of the MDS and ITFS. LMDS is a fixed broadband point-to-multipoint microwave service that provides for two-way video telecommunications.

181. In connection with the 1996 MDS auction, the Commission defined small businesses as entities that had annual average gross revenues of less than $40 million in the previous three calendar years. This definition of a small entity in the context of MDS auctions has been approved by the A. The MDS auctions resulted in 67 successful bidders obtaining licensing opportunities for 493 Basic Trading Areas ("BTAs"). Of the 67 auction winners, 61 met the definition of a small business. MDS also includes licensees of stations authorized prior to the auction. As noted, the SBA has developed a definition of small entities for pay television services, which includes all such companies generating $12.5 million or less in annual receipts. This definition includes multipoint distribution services, and thus applies to MDS licensees and wireless cable operators that did not participate in the MDS auction. Information available to us indicates that there are approximately 850 of these licensees and operators that do not generate

revenue in excess of $12.5 million annually. Therefore, for purposes of the FRFA, we find there are approximately 850 small MDS providers as defined by the SBA and the Commission's auction rules.

182. The SBA definition of small entities for Cable and Other Program Distribution Services, which includes such companies generating $12.5 million in annual receipts, seems reasonably applicable to ITFS. There are presently 2,032 ITFS licensees. All but 100 of these licenses are held by educational institutions. Educational institutions are included in the definition of a small business. SBREFA also applies to nonprofit organizations and governmental organizations such as cities, counties, towns, townships, villages, school districts, or special districts, with populations of less than 50,000. 5 U.S.C. 601(5). However, we do not collect annual revenue data for ITFS licensees, and are not able to ascertain how many of the 100 non-educational licensees would be categorized as small under the SBA definition. Thus, we tentatively conclude that at least 1,932 licensees are small businesses.

183. Additionally, the auction of the 1,030 LMDS licenses began on February 18, 1998, and closed on March 25, 1998. The Commission defined "small entity" for LMDS licenses as an entity that has average gross revenues of less than $40 million in the three previous calendar years. An additional classification for "very small business" was added and is defined as an entity that, together with its affiliates, has average gross revenues of not more than $15 million for the preceding calendar years. These regulations defining "small entity" in the context of LMDS auctions have been approved by the SBA. There were 93 winning bidders that qualified as small entities in the LMDS auctions. A total of 93 small and very small business bidders won approximately 277 A Block licenses and 387 B Block licenses. On March 27, 1999, the Commission re-auctioned 161 licenses; there were 40 winning bidders. Based on this information, we conclude that the number of small LMDS licenses will include the 93 winning bidders in the first auction and the 40 winning bidders in the re-auction, for a total of 133 small entity LMDS providers as defined by the SBA and the Commission's auction rules.

184. In sum, there are approximately a total of 2,000 MDS/MMDS/LMDS stations currently licensed. Of the approximate total of 2,000 stations, we estimate that there are 1,595 MDS/MMDS/LMDS providers that are small businesses as deemed by the SBA and the Commission's auction rules.

185. Satellite Master Antenna Television ("SMATV") Systems. The SBA definition of small entities for Cable and Other Program Distribution Services includes SMATV services and, thus, small entities are defined as all such companies generating $12.5 million or less in annual receipts. Currently, there are approximately 250 SMATV operators providing service to approximately 1.2 million residential subscribers. The best available estimates indicate that the largest SMATV operators serve between 15,000 and 55,000 subscribers each. Most SMATV operators serve approximately 3,000–4,000 customers. Because these operators are not rate regulated, they are not required to file financial data with the Commission. Furthermore, we are not aware of any privately published financial information regarding these operators. Based on the estimated number of operators and the estimated number of units served by the largest ten SMATVs, we believe that a substantial number of SMATV operators qualify as small entities.

186. Open Video Systems ("OVS"). Because OVS operators provide subscription services, OVS falls within the SBA-recognized definition of Cable and Other Program Distribution Services. This definition provides that a small entity is one with $ 12.5 million or less in annual receipts. The Commission has certified 25 OVS operators with some now providing service. Affiliates of Residential Communications Network, Inc. ("RCN") received approval to operate OVS systems in New York City, Boston, Washington, DC, and other areas. RCN has sufficient revenues to assure us that they do not qualify as small business entities. Little financial information is available for the other entities authorized to provide OVS that are not yet operational. Given that other entities have been authorized to provide OVS service but have not yet begun to generate revenues, we conclude that at least some of the OVS operators qualify as small entities.

187. Electronics Equipment Manufacturers. Rules adopted in this proceeding could affect manufacturers of DTV receiving equipment and other types of consumer electronics equipment. The SBA has developed definitions of small entity for manufacturers of audio and video equipment as well as radio and television broadcasting and wireless communications equipment. These categories both include all such companies employing 750 or fewer employees. The Commission has not developed a definition of small entities applicable to manufacturers of electronic equipment used by consumers, as compared to industrial use by television licensees and related businesses. Therefore, we will utilize the SBA definitions applicable to manufacturers of audio and visual equipment and radio and television broadcasting and wireless communications equipment, since these are the two closest NAICS Codes applicable to the consumer electronics equipment manufacturing industry. However, these NAICS categories are broad and specific figures are not available as to how many of these establishments manufacture consumer equipment. According to the SBA's regulations, an audio and visual equipment manufacturer must have 750 or fewer employees in order to qualify as a small business concern. Census Bureau data indicates that there are 554 U.S. establishments that manufacture audio and visual equipment, and that 542 of these establishments have fewer than 500 employees and would be classified as small entities. Economics and Statistics Administration, Bureau of Census, U.S. Department of Commerce, 1997 Economic Census, Industry Series—Manufacturing, Audio and Video Equipment Manufacturing, Table 4 at 9 (1999). The amount of 500 employees was used to estimate the number of small business firms because the relevant Census categories stopped at 499 employees and began at 500 employees. No category for 750 employees existed. Thus, the number is as accurate as it is possible to calculate with the available information. The remaining 12 establishments have 500 or more employees; however, we are unable to determine how many of those have fewer than 750 employees and therefore, also qualify as small entities under the SBA definition. Under the SBA's regulations, a radio and television broadcasting and wireless communications equipment manufacturer must also have 750 or fewer employees in order to qualify as a small business concern. Census Bureau data indicates that there 1,215 U.S. establishments that manufacture radio and television broadcasting and wireless communications equipment, and that 1,150 of these establishments have fewer than 500 employees and would be classified as small entities. Economics and Statistics Administration, Bureau of Census, U.S. Department of Commerce, 1997 Economic Census, Industry Series—Manufacturing, Radio and Television

Broadcasting and Wireless Communications Equipment Manufacturing, Table 4 at 9 (1999). The amount of 500 employees was used to estimate the number of small business firms because the relevant Census categories stopped at 499 employees and began at 500 employees. No category for 750 employees existed. Thus, the number is as accurate as it is possible to calculate with the available information. The remaining 65 establishments have 500 or more employees; however, we are unable to determine how many of those have fewer than 750 employees and therefore, also qualify as small entities under the SBA definition. We therefore conclude that there are no more than 542 small manufacturers of audio and visual electronics equipment and no more than 1,150 small manufacturers of radio and television broadcasting and wireless communications equipment for consumer/household use.

188. Electronic Computer Manufacturers. The Commission has not developed a definition of small entities applicable to computer manufacturers.. Therefore, we will utilize the SBA definition of electronic computers manufacturing. According to SBA regulations, a computer manufacturer must have 1,000 or fewer employees in order to qualify as a small entity. Census Bureau data indicates that there are 563 firms that manufacture electronic computers and of those, 544 have fewer than 1,000 employees and qualify as small entities. The remaining 19 firms have 1,000 or more employees. We conclude that there are approximately 544 small computer manufacturers.

189. Description of Projected Reporting, Recordkeeping and other Compliance Requirements. The Report and Order requires all full power commercial and noncommercial television broadcast licensees and permittees to file a pre-election certification form by November 2004. In addition, full power licensees and permittees choosing to participate in the channel election process will file channel election forms in one or more of the three election rounds, and may file conflict decision forms based on the outcome of their election. The purpose of these filings is to permit stations to inform the Commission of their preference for a final DTV channel. Without these election forms, stations could not inform the Commission of their preferred channel for post-transition DTV operation. The decision as to which channel to elect for post-transition operation may be a difficult and time-consuming one for some broadcasters. However, channel election and the development of a new DTV Table of Allotments are steps integral to the digital transition. Factors that could make the channel election decision time consuming are not likely to be related to whether the entity is small or large. Licensees may elect not to participate in the channel election process and not file these forms and instead have the FCC assign them a post-transition channel at the end of the election process.

190. Steps Taken to Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered. The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.

191. In a number of instances, while adopting a given rule for larger entities, the Report and Order considers and adopts alternative requirements for small or smaller market entities to assist these entities in completing the digital conversion. For example, the Report and Order adopts the following interference protection deadlines for DTV channels within the core spectrum: July 1, 2005, for affiliates of the top-four networks (*i.e.*, ABC, CBS, Fox, and NBC) in markets 1–100; and July 1, 2006, for all other commercial DTV licensees as well as noncommercial DTV licensees. Thus, smaller stations and stations in smaller markets are given more time to meet the interference protection deadline. In addition, smaller stations planning to move to another channel post-transition are given lesser requirements than larger stations. For top four affiliates in the top 100 markets, if they will remain on their digital channel assignments after the transition, they must fully replicate and maximize by July 1, 2005. If they will move to another channel post-transition, they must be serving by July 1, 2005 100% of the number of viewers served by the 1997 facility on which their replication was based. The second deadline, July 1, 2006, applies to all other stations. If they will remain on their current digital channel after the transition, they must fully replicate and maximize by this date. If they will move to another channel post-transition, they must be serving by July 2006 at least 80% of the number of viewers served by the 1997 facility on which their replication was based. Failure to replicate or maximize by these deadlines will result in loss of interference protection to the unserved areas. If they have met these deadlines, the item would allow stations that are going to move to a different channel after the transition to carry-over their authorized maximized area to their new channels.

192. While the Commission considered applying the same deadline and replication and maximization requirements to all stations, it concluded that a later deadline and reduced requirement for smaller and smaller market stations is warranted. In addition, to assist stations facing severe financial constraints or obstacles beyond a station's control that are specific to the DTV transition process, the item permits these stations to apply for a six-month waiver of the interference protection deadline.

193. In some instances, a rule was adopted applicable to large and small entities in the same way conferring the same benefits upon both. In furtherance of the significant public interest in rapid band-clearing and to address the potential for stranded investment in facilities outside of core channels, the Report and Order permits certain stations with an in-core NTSC channel paired with an out-of-core DTV channel, stations with two out-of-core channels, and single-channel DTV stations out-of-the-core, to surrender their out-of-core DTV channel before the end of the transition and operate in analog on their in-core channel. Upon approval from the Commission, these stations will "flash-cut" to digital operations on their in-core channel no later than the end of the transition in the station's market. This "flash-cut" policy will assist both smaller and larger stations with an out-of-core DTV channel that are concerned about the cost of constructing DTV facilities outside the core that cannot be operated after the transition. These entities will be permitted to surrender early their out-of-core channel and operate only in analog on their in-core channel until they flash-cut to digital-only operation on that channel no later than the end of the transition. The Commission considered not permitting these stations to flash-cut, but finally concluded that permitting this flash-cut option would best advance the transition and the clearing of the out-of-core spectrum.

194. In addition, the Report and Order permits satellite stations to surrender one of their paired channels and flash

cut from analog to digital transmissions by the end of the transition period. This flash-cut option should provide significant financial relief for satellite stations, many of which are small and all of which serve communities unable to support a full-service station.

195. The Report and Order also adopts another waiver that will most likely benefit smaller stations as opposed to larger stations. The Report and Order requires television licensees that have not yet been granted an initial DTV CP to construct, within a year from the adoption date of this Report and Order, a "checklist" facility that conforms with the parameters of the DTV Table of Allotments and other key processing requirements. The Commission will consider requests for waiver of the one year construction deadline, on a case-by-case basis, using the criteria for extension of DTV construction deadlines. Grounds for an extension must relate to the checklist facility, not the pending non-checklist application. This waiver procedure permits stations facing financial hardship as well as other obstacles to construction of digital facilities to make a showing why waiver of the construction deadline would serve the public interest. The waiver is available to all stations regardless of size or income, but it likely to benefit smaller stations more as these stations are more likely to encounter financial hardships in constructing DTV checklist facilities.

196. The Report and Order declines to postpone the existing phased-in minimum operating hours for smaller and smaller-market digital television stations. However, these phased-in dates permit these stations to step up gradually the number of hours of digital programming they offer. In contrast, top-four network affiliates in the top 30 television markets are required to operate their DTV station at any time that the analog station is operating.

197. Federal Rules Which Duplicate, Overlap, or Conflict with the Commission's Proposals. None.

198. Report to Congress. The Commission will send a copy of the Report and Order, including this FRFA, in a report to be sent to Congress pursuant to the Congressional Review Act. In addition, the Commission will send a copy of the Report and Order, including this FRFA, to the Chief Counsel for Advocacy of the SBA. A copy of the Report and Order and FRFA (or summaries thereof) will also be published in the **Federal Register**.

Ordering Clauses

199. *It is ordered* that pursuant to the authority contained in sections 1, 4(i) and (j), 5(c)(1), 7, 301, 302, 303(f), 303(r), 303(u), 303(w), 303(x), 307, 308, 309, 316, 319, 324, 336(c), 336(f), 337, 330(b), 330(c), 332(c) of the Communications Act of 1934, 47 U.S.C 151, 154(i) and (j), 155(c)(1), 157, 301, 302, 303(f), 303(r), 303(u), 303(w), 303(x), 307, 308, 309, 316, 319, 324, 336(c), 336(f), 337, 330(b), 330(c), 332(c) that this Report and Order *is adopted* and the Commission's rules *are hereby amended* as set forth in Appendix B, and shall become effective November 3, 2004 except for § 73.1201 which contains information collection requirements under the PRA is not effective until approved by OMB. The FCC will publish a document in the **Federal Register** announcing the effective date for this section.

200. *It is further ordered* that, pursuant to 47 U.S.C. 155(c), the Chief, Media Bureau, is *granted delegated authority* to implement the electronic Channel Election Forms and the specific dates adopted in this Order.

201. *It is further ordered* that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *shall send* a copy of this Report and Order, including the Final Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

202. *It is further ordered* that the Commission *shall 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

47 CFR Part 15

Communications equipment, Computer technology, Incorporation by reference, Labeling, Radio, Reporting and recordkeeping requirements, Security measures, Telephone, Wiretapping and electronic surveillance.

47 CFR Part 27

Communications common carriers, Radio.

47 CFR Part 73

Civil defense, Communications equipment, Defense communications, Education, Equal employment opportunity, Foreign relations, Incorporation by reference, Mexico, Political candidates, Radio, Reporting and recordkeeping requirements, Television.

47 CFR Part 90

Administrative practice and procedure, Business and industry, Civil defense, Common carriers, Communications equipment, Emergency medical services, Individuals with disabilities, Radio, Reporting and recordkeeping requirements.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

■ For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR parts 15, 27, 73 and 90 as follows:

PART 15—RADIO FREQUENCY DEVICES

■ 1. The authority for part 15 continues to read as follows:

Authority: 47 U.S.C. 154, 302, 303, 304, 307, 336, and 544A.

■ 2. Section 15.38 is amended by adding paragraph (b)(13) to read as follows:

§ 15.38 Incorporations by reference.

* * * * *

(b) * * *

(13) CEA–766–A: "U.S. and Canadian Region Rating Tables (RRT) and Content Advisory Descriptors for Transport of Content Advisory Information using ATSC A/65–A Program and System Information Protocol (PSIP)," April 2001, IBR approved for § 15.120.

* * * * *

■ 3. Section 15.120 is amended by revising paragraphs (c)(2) and (d)(2) to read as follows:

§ 15.120 Program blocking technology requirements for television receivers.

* * * * *

(c) * * *

(2) Digital television program rating information shall be transmitted in digital television signals in accordance with § 73.682(d) of this chapter.

(d) * * *

(2) Digital television receivers shall react in a similar manner as analog televisions when programmed to block specific rating categories. Effective March 15, 2006, digital television receivers will receive program rating descriptors transmitted pursuant to industry standard EIA/CEA–766–A "U.S. and Canadian Region Rating Tables (RRT) and Content Advisory Descriptors for Transport of Content Advisory Information using ATSC A/65–A Program and System Information Protocol (PSIP)," 2001 (incorporated by reference, *see* § 15.38). Blocking of programs shall occur when a program rating is received that meets the pre-determined user requirements. Digital television receivers shall be able to respond to changes in the content advisory rating system.

* * * * *

PART 27—MISCELLANEOUS WIRELESS COMMUNICATIONS SERVICES

■ 4. The authority citation for part 27 continues to read as follows:

Authority: 47 U.S.C. 154, 301, 302, 303, 307, 309, 332, 336, and 337 unless otherwise noted.

■ 5. Section 27.60 is amended by revising paragraph (b)(1)(iii) to read as follows:

§ 27.60 TV/DTV interference protection criteria.

* * * * *

(b) * * *

(1) * * *

(iii) Submit an engineering study justifying the proposed separations based on the parameters of the land mobile station and the parameters, including authorized and/or applied for facilities, of the TV/DTV station(s) it is trying to protect; or,

* * * * *

PART 73—RADIO BROADCAST SERVICES

■ 6. The authority for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334 and 336.

■ 7. Section 73.624 is amended by revising paragraphs (b) introductory text, (b)(1), and paragraph (f) to read as follows:

§ 73.624 Digital television broadcast stations.

* * * * *

(b) DTV broadcast station permittees or licensees must transmit at least one over-the-air video program signal at no direct charge to viewers on the DTV channel. Until such time as a DTV station permittee or licensee ceases analog transmissions and returns that spectrum to the Commission, and except as provided in paragraph (b)(1) of this section, at any time that a DTV broadcast station permittee or licensee transmits a video program signal on its analog television channel, it must also transmit at least one over-the-air video program signal on the DTV channel. The DTV service that is provided pursuant to this paragraph must be at least comparable in resolution to the analog television station programming transmitted to viewers on the analog channel.

(1) DTV broadcast station permittees and licensees required to construct and operate a DTV station by May 1, 2002, or May 1, 2003, pursuant to paragraph (d) of this section must, at a minimum, beginning on the date on which the DTV station is required to be constructed, provide a digital video program signal, of the quality described in paragraph (b) of this section, during prime time hours as defined in § 79.3(a)(6) of this chapter. These licensees and permittees must also comply with the minimum operating hours requirements in paragraph (f) of this section.

* * * * *

(f)(1) Commencing on April 1, 2003, DTV television licensees and permittees required to construct and operate a DTV station by May 1, 2002, or May 1, 2003, must transmit at least one over-the-air video program signal at no direct charge to viewers on their DTV channel at least 50 percent of the time they are transmitting a video program signal on their analog channel.

(2) Commencing on April 1, 2004, DTV licensees and permittees described in paragraph (f)(1) of this section must transmit a video program signal as described in paragraph (f)(1) of this section on the DTV channel at least 75 percent of the time they are transmitting a video program signal on the analog channel.

(3) Commencing on April 1, 2005, DTV licensees and permittees described in paragraph (f)(1) of this section must transmit a video program signal as described in paragraph (f)(1) of this section on the DTV channel at least 100 percent of the time they are transmitting a video program signal on the analog channel.

(4) The minimum operating hours requirements imposed in paragraphs (f)(1) through (3) of this section will terminate when the analog channel terminates operation and a 6 MHz channel is returned by the DTV licensee or permittee to the Commission.

* * * * *

■ 8. Section 73.682 is amended by revising paragraph (d) to read as follows:

§ 73.682 TV transmission standards.

* * * * *

(d) Digital broadcast television transmission standard. Effective February 1, 2005, transmission of digital broadcast television (DTV) signals shall comply with the standards for such transmissions set forth in ATSC A/52: "ATSC Standard Digital Audio Compression (AC–3)" (incorporated by reference, *see* § 73.8000), ATSC Doc. A/53B, Revision B with Amendment 1 and Amendment 2: "ATSC Digital Television Standard," except for Section 5.1.2 ("Compression format constraints") of Annex A ("Video Systems Characteristics") and the phrase "*see* Table 3" in Section 5.1.1. Table 2 and Section 5.1.2 Table 4 (incorporated by reference, *see* § 73.8000), and ATSC A/65B: "ATSC Program and System Information Protocol for Terrestrial Broadcast and Cable," (Revision B) 2003 (incorporated by reference, *see* § 73.8000). Although not incorporated by reference, licensees may also consult ATSC Doc. A/54, Guide to Use of the ATSC Digital Television Standard, (October 4, 1995), and ATSC Doc. A/69, Recommended Practice PSIP Implementation Guidelines for Broadcasters (June 25, 2002) (Secs. 4, 5, 303, 48 Stat., as amended, 1066, 1068, 1082 (47 U.S.C. 154, 155, 303)).

■ 9. Section 73.1201 is amended by revising paragraphs (b)(1) and (c)(1) to read as follows:

§ 73.1201 Station identification.

* * * * *

(b) *Content.* (1) Official station identification shall consist of the station's call letters immediately followed by the community or communities specified in its license as the station's location; *Provided,* That the name of the licensee, the station's frequency, the station's channel number, as stated on the station's license, and/or the station's network affiliation may be inserted between the call letters and station location. DTV stations choosing to include the station's channel number in the station identification must use the station's major channel number and may distinguish multicast program streams. For example, a station with major channel number 26 may use 26.1 to identify an HDTV program service and 26.2 to identify an SDTV program service. No other insertion between the station's call letters and the community or communities specified in its license is permissible.

* * * * *

(c) *Channel*—(1) *General.* Except as otherwise provided in this paragraph, in making the identification announcement the call letters shall be given only on the channel, or channels in the case of a broadcaster that is multicasting more than a single channel, identified thereby.

* * * * *

■ 10. Section 73.8000 is amended by revising paragraphs (b)(2) and (b)(3) to read as follows:

§ 73.8000 Incorporation by reference.

* * * * *

(b) * * *

(2) ATSC A/53B: "ATSC Digital Television Standard," dated August 7, 2001, Revision B, with Amendment 1 dated May 23, 2002 and Amendment 2

dated May 19, 2003, IBR approved for § 73.682, except for section 5.1.2 of Annex A, and the phrase "*see* Table 3" in section 5.1.1. Table 2 and section 5.1.2 Table 4.

(3) ATSC A/65B: "ATSC Program and System Information Protocol for Terrestrial Broadcast and Cable," (Revision B) March 18, 2003, and IBR approved for § 73.682, IBR approved for §§ 73.9000–73.9001.

* * * * *

PART 90—PRIVATE LAND MOBILE RADIO SERVICES

■ 11. The authority citation for part 90 continues to read as follows:

Authority: Sections 4(i), 11, 303(g), 303(r), and 332(c)(7) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 161, 303(g), 303(r), 332(c)(7).

■ 12. Section 90.545 is amended by revising paragraph (c)(1)(ii) to read as follows:

§ 90.545 TV/DTV interference protection criteria.

* * * * *

(c) * * *

(1) * * *

(ii) Submit an engineering study justifying the proposed separations based on the parameters of the land mobile station and the parameters, including authorized and/or applied for facilities, of the TV/DTV station(s) it is trying to protect; or,

* * * * *

[FR Doc. 04–22189 Filed 10–1–04; 8:45 am]

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Monday,
October 4, 2004

Part VI

The President

Proclamation 7822—National Hunting and Fishing Day, 2004; republication with corrections

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Vol. 69, No. 191
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Presidential Documents

Title 3—

The President

Proclamation 7822 of September 24, 2004

National Hunting and Fishing Day, 2004

By the President of the United States of America

A Proclamation

[**Editorial Note:** Proclamation 7822, originally published on pages 58249–58250 in the **Federal Register** of Wednesday, September 29, 2004, is being reprinted with White House corrections.]

America is a land of majestic beauty, and we take pride in our wildlife, forests, mountains, lakes, rivers, and coastlines. Outdoor recreation is an important part of our Nation's heritage. On National Hunting and Fishing Day, we celebrate the remarkable progress we have made in conserving our environment and recognize those who have worked to conserve our natural resources.

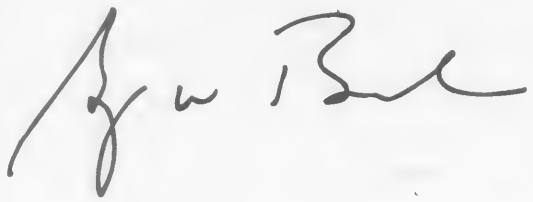
America's hunters and anglers represent the great spirit of our country and are among our Nation's foremost conservationists. These citizens have worked to protect habitat and restore fish and wildlife populations. They volunteer their time, talents, and energy to countless conservation projects, because they recognize the importance of maintaining the natural abundance of our country for future generations.

My Administration is committed to achieving a cleaner, safer, and healthier environment for all Americans, including our hunters and anglers. My Administration has expanded opportunities to hunt and fish at national wildlife refuges and improved habitat on public and private lands. We have cut phosphorus releases into our rivers and streams, and I signed the Healthy Forests Restoration Act to help protect our forests from the risk of wildfires.

Americans are blessed to live amid many wonders of nature, and we have a responsibility to be good stewards of the land. I commend all who advance conservation and help our citizens enjoy the benefits of our environment. These efforts ensure that our national heritage remains a source of pride for our citizens, our communities, and our Nation.

NOW, THEREFORE, I, GEORGE W. BUSH, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim September 25, 2004, as National Hunting and Fishing Day. I call upon the people of the United States to join me in recognizing the contributions of America's hunters and anglers, and all those who work to conserve our Nation's fish and wildlife resources.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-fourth day of September, in the year of our Lord two thousand four, and of the Independence of the United States of America the two hundred and twenty-ninth.



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To provide for the conveyance of the real property located at 1081 West Main Street in Ravenna, Ohio. (Sept. 24, 2004; 118 Stat. 1130)

H.R. 5008/P.L. 108–306

To provide an additional temporary extension of programs under the Small Business Act and the Small Business Investment Act of 1958 through September 30, 2004, and for other purposes. (Sept. 24, 2004; 118 Stat. 1131)

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1–199	(869–052–00099–0)	64.00	Apr. 1, 2004
200–End	(869–052–00100–7)	21.00	Apr. 1, 2004
28 Parts:			
0–42	(869–052–00101–5)	61.00	July 1, 2004
43–End	(869–050–00101–2)	58.00	July 1, 2003
29 Parts:			
0–99	(869–052–00103–1)	50.00	July 1, 2004
100–499	(869–052–00104–0)	23.00	July 1, 2004
500–899	(869–052–00105–8)	61.00	July 1, 2004
900–1899	(869–052–00106–6)	36.00	July 1, 2004
1900–1910 (§§ 1900 to 1910.999)	(869–052–00107–4)	61.00	July 1, 2004
1910 (§§ 1910.1000 to end)	(869–052–00108–2)	46.00	[8]July 1, 2004
*1911–1925	(869–052–00109–1)	30.00	July 1, 2004
1926	(869–052–00110–4)	50.00	July 1, 2004
1927–End	(869–052–00111–2)	62.00	July 1, 2004
30 Parts:			
1–199	(869–052–00112–1)	57.00	July 1, 2004
200–699	(869–052–00113–9)	50.00	July 1, 2004
700–End	(869–052–00114–7)	58.00	July 1, 2004
31 Parts:			
0–199	(869–050–00114–4)	40.00	July 1, 2003
200–End	(869–052–00116–3)	65.00	July 1, 2004
32 Parts:			
1–39, Vol. I		15.00	[2]July 1, 1984
1–39, Vol. II		19.00	[2]July 1, 1984
1–39, Vol. III		18.00	[2]July 1, 1984
1–190	(869–050–00116–1)	60.00	July 1, 2003
191–399	(869–052–00118–0)	63.00	July 1, 2004
400–629	(869–052–00119–8)	50.00	[8]July 1, 2004
630–699	(869–052–00120–1)	37.00	[7]July 1, 2004
700–799	(869–052–00121–0)	46.00	July 1, 2004
800–End	(869–052–00122–8)	47.00	July 1, 2004
33 Parts:			
1–124	(869–050–00122–5)	55.00	July 1, 2003
125–199	(869–050–00123–3)	61.00	July 1, 2003
*200–End	(869–052–00125–2)	57.00	July 1, 2004
34 Parts:			
1–299	(869–050–00125–0)	49.00	July 1, 2003
*300–399	(869–052–00127–9)	40.00	July 1, 2004
*400–End	(869–052–00128–7)	61.00	July 1, 2004
35	(869–052–00129–5)	10.00	[6]July 1, 2004
36 Parts			
1–199	(869–052–00130–9)	37.00	July 1, 2004
*200–299	(869–052–00131–7)	37.00	July 1, 2004
300–End	(869–050–00131–4)	61.00	July 1, 2003
37	(869–050–00132–2)	50.00	July 1, 2003
38 Parts:			
0–17	(869–052–00134–1)	60.00	July 1, 2004
18–End	(869–050–00134–9)	62.00	July 1, 2003
39	(869–050–00135–7)	41.00	July 1, 2003
40 Parts:			
1–49	(869–050–00136–5)	60.00	July 1, 2003
50–51	(869–052–00138–4)	45.00	July 1, 2004
52 (52.01–52.1018)	(869–050–00138–1)	58.00	July 1, 2003
52 (52.1019–End)	(869–050–00139–0)	61.00	July 1, 2003
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60 (60.1–End)	(869–050–00141–1)	58.00	July 1, 2003
60 (Apps)	(869–050–00142–0)	51.00	[8]July 1, 2003
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63 (63.600–63.1199)	(869–052–00146–5)	50.00	July 1, 2004
63 (63.1200–63.1439)	(869–050–00146–2)	50.00	July 1, 2003
63 (63.1440–End)	(869–050–00147–1)	64.00	July 1, 2003
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*81–85	(869–052–00152–0)	60.00	July 1, 2004
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86 (86.600–1–End)	(869–050–00152–7)	50.00	July 1, 2003
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*260–265	(869–052–00160–1)	50.00	July 1, 2004
266–299	(869–050–00159–4)	50.00	July 1. 2003
300–399	(869–050–00160–8)	42.00	July 1, 2003
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*700–789	(869–052–00165–1)	61.00	July 1, 2004
790–End	(869–050–00164–1)	58.00	July 1, 2003
41 Chapters:			
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45 Parts:			
1–199	(869–050–00175–6)	60.00	Oct. 1, 2003
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46 Parts:			
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47 Parts:			
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49 Parts:			
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[1] Because Title 3 is an annual compilation, this volume and all previous volumes should be retained as a permanent reference source.

[2] The July 1, 1985 edition of 32 CFR Parts 1–189 contains a note only for Parts 1–39 inclusive. For the full text of the Defense Acquisition Regulations in Parts 1–39, consult the three CFR volumes issued as of July 1, 1984, containing those parts.

[3] The July 1, 1985 edition of 41 CFR Chapters 1–100 contains a note only for Chapters 1 to 49 inclusive. For the full text of procurement regulations in Chapters 1 to 49, consult the eleven CFR volumes issued as of July 1, 1984 containing those chapters.

[4] No amendments to this volume were promulgated during the period January 1, 2003, through January 1, 2004. The CFR volume issued as of January 1, 2002 should be retained.

[5] No amendments to this volume were promulgated during the period April 1, 2000, through April 1, 2004. The CFR volume issued as of April 1, 2000 should be retained.

[6] No amendments to this volume were promulgated during the period July 1, 2000, through July 1, 2004. The CFR volume issued as of July 1, 2000 should be retained.

[7] No amendments to this volume were promulgated during the period July 1, 2002, through July 1, 2004. The CFR volume issued as of July 1, 2002 should be retained.

[8] No amendments to this volume were promulgated during the period July 1, 2003, through July 1, 2004. The CFR volume issued as of July 1, 2003 should be retained.

[9] No amendments to this volume were promulgated during the period October 1, 2001, through October 1, 2003. The CFR volume issued as of October 1, 2001 should be retained.

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